UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

In the matter of	)	**DEA Docket No. 1362**
	)	Hearing Docket No. 26-96
Schedules of Controlled Substances: Proposed Rescheduling of Marijuana	)	
	)	DEREK C. JULIUS
	)	CHIEF ADMINISTRATIVE LAW JUDGE

GOVERNMENT'S POST-HEARING BRIEF

Respectfully Submitted,

Dated: August 17, 2026

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GOVERNMENT'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

The United States Department of Justice (DOJ), Drug Enforcement Administration (DEA or Government), by and through its undersigned attorneys, hereby submits the following post-hearing brief, to include an Introduction, Statement of the Issue, Background, Proposed Findings of Fact, and Proposed Conclusions of Law[1].

I. INTRODUCTION

The Government comes before this Tribunal in support of its position that marijuana as defined in 21 U.S.C. §802(16)(A) should be transferred from its current placement in Schedule I of the Controlled Substances Act (CSA) to Schedule III on the basis that marijuana no longer fits two of the three statutory requirements to remain in Schedule I. The Government presents to this Tribunal the 2023 recommendation from the Department of Health and Human Services (HHS) that marijuana be moved from Schedule I to Schedule III, fact and expert testimony, and legal arguments.

HHS conducted an extensive ten-month study on the scientific and medical properties of marijuana. As a result of the study, HHS issued a recommendation in 2023 (HHS recommendation) that marijuana be transferred from Schedule I to Schedule III after determining that marijuana has medical benefits for three distinct medical conditions: chronic pain, treatment of anorexia related to a medical condition (anorexia), and nausea and vomiting in conjunction with chemotherapy (nausea and vomiting). Because marijuana has at least one currently accepted medical use, marijuana can no longer remain a Schedule I controlled substance. HHS's assessment, to which DEA must provide significant deference, finds that marijuana's abuse and

[1] This Honorable Court separately requested briefing on the binding effect of the Office of Legal Counsel (OLC) Opinion concerning HHS' use of a new, two-part test to establish marijuana's currently accepted medical use (CAMU) and the acceptance and weight of expert witness testimony presented at the hearing. The OLC and expert witness arguments are contained within the Conclusions of Law section.

dependence profiles better align with Schedule III controlled substances than those contained within Schedule I or II.

HHS' recommendation also described the current landscape of the use of marijuana for treatment by medical professionals. Currently there are over 30,000 practitioners treating more than six million patients in 43 U.S. jurisdictions. Such practices demonstrate that there is no longer a lack of accepted safety for use of marijuana under medical supervision, and as such, marijuana does not fulfill the requirements of being a Schedule I substance. Lastly, during the administrative hearing in the present matter, the Government presented substantial evidence sufficient to show that marijuana's abuse and dependency profiles better align with Schedule III substances than Schedule II.

The parties opposed to marijuana rescheduling (Opposed Parties) [2] argue that marijuana does not have CAMU, which this Tribunal must find to transfer marijuana from Schedule I. They argue that HHS and DEA's traditional five-part test is the suitable CAMU test for marijuana and therefore HHS' new two-part test, which takes into consideration therapeutic marijuana use in state-sanctioned programs, cannot establish marijuana's CAMU. The Opposed Parties also argue that medical use of marijuana will undermine transportation laws and criminal enforcement while impacting employers' ability to manage their operations.

The Opposed Parties' arguments have no merit. OLC issued an opinion binding upon DEA that the traditional five-part test was insufficient to determine marijuana's CAMU because it fails to consider marijuana's state-sanctioned medical use. OLC also determined that while not binding upon DEA, HHS' two-part CAMU test is legally sufficient to establish CAMU. As a

[2] National Drug and Alcohol Screening Association (NDASA); Tennessee Bureau of Investigation (TBI); Smart Approaches to Marijuana (S.A.M.); States of Nebraska, Idaho, and Indiana (Opposed States); DUID Victim Voices (DUID); Dr. Kenneth Finn (Finn); and Dr. Philip Drum (Drum)

result, the Opposed Parties' process argument on the viability of HHS' two-part CAMU test fails.

Further, the Opposed Parties have not offered sufficient fact or expert testimony to rebut HHS' findings that marijuana has CAMU. In fact, two of the experts from the Opposed Parties supported the therapeutic use of marijuana in certain instances. The proffered testimony from the Opposed Parties did not contradict HHS' 2023 findings about the large number of practitioners who are authorized to prescribe marijuana in over 43 U.S. jurisdictions or its medical use in those jurisdictions. In contrast, the Opposition Parties presented evidence establishing that marijuana should be controlled because transportation, criminal enforcement, and employer operations are undermined if the substance is legalized. The Government agrees: marijuana should remain a controlled substance but should be transferred from Schedule I to Schedule III.

The evidence proffered by the Opposed Parties boils down simply to the fact that Schedule III marijuana poses employment and enforcement difficulties, the same as any other controlled substance in Schedules II – V. The evidence did not rebut the Government's *prima facie* case that marijuana has CAMU and thus, no longer fits the statutory requirements to remain in Schedule I and better fits the statutory requirements for Schedule III. As such, the Government respectfully requests that this Tribunal expeditiously recommend that marijuana, as defined in 21 U.S.C. § 802(16)(A), be transferred from Schedule I to Schedule III.

II. STATEMENT OF THE ISSUE

Whether the controlled substance marijuana as defined in 21 U.S.C. § 802(16)(A) should be transferred from Schedule I to Schedule III of the CSA.

III. BACKGROUND

In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236. Title II of that enactment, known as the CSA, regulates the importation, manufacture, distribution, possession, and improper use of substances that have a detrimental effect on public health and welfare. *See* 21 U.S.C. § 801. The CSA establishes five schedules of controlled substances, which includes a list of substances initially placed on each schedule, and contemplates the periodic reevaluation of the initial lists and the addition of other substances to the schedules. *See* 21 U.S.C. § 812.

21 U.S.C. § 811(a) grants the Attorney General authority to transfer substances between the schedules of controlled substances through a rulemaking on the record pursuant to provisions of the Administrative Procedure Act, 5 U.S.C. §§ 553(c), 556, 557. Before initiating a rulemaking for the (re)scheduling of a controlled substance, the Attorney General is required to receive the recommendation of the Secretary of HHS 21 U.S.C. § 811(b). The Attorney General and the Secretary of HHS must consider eight factors set forth in 21 U.S.C. § 811(c) prior to making a determination as to whether a substance is listed as a controlled substance.

21 U.S.C. § 811(c) requires:

> In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:
>
> (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.

The scientific and medical assessment of the eight factors in 21 U.S.C. § 811(c) is referred to herein as the "8FA."

If HHS finds that a substance shall be controlled, it will recommend the placement for that substance using a statutory analysis set out in 21 U.S.C. § 812. The statutory analysis relies on information reviewed in the 8FA to make the ultimate recommendation on placement. Specifically, 21 U.S.C. § 812(b) requires that:

> [A] drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:
>
> (1) Schedule I.
>
> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
>
> (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.
>
> (3) Schedule III.
>
> (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.

21 U.S.C. § 812(b)(1), (3).

On October 6, 2022, President Joseph R. Biden requested the Attorney General and the Secretary of HHS to "initiate the administrative process to review expeditiously how marijuana is scheduled under federal law." Gov't. Exh. 1 at 4. Thereafter, HHS undertook a scientific and medical evaluation of marijuana in accordance with President Biden's request. *Id.*

On August 29, 2023, DEA received HHS' recommendation entitled "Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act." ALJ Exh. 1. HHS, through an evaluation conducted by the Food and Drug Administration (FDA), considered the eight factors determinative of control of a substance under 21 U.S.C. 811(c) the CSA. ALJ Exh. 1 at 1, 5-62. FDA used the scientific and medical information relative to the eight factors to make three findings about marijuana: 1) its relative abuse potential compared to other drugs, 2) whether it has CAMU[3] in treatment in the United States (or a currently accepted medical use with severe restrictions (21 U.S.C. § 812(b)(2)(B), (3)(B)), and 3) its relative safety or ability to produce physical dependence compared to other drugs, as provided under 21 U.S.C. § 812(b). *Id.* at 2-3. HHS ultimately concluded that marijuana met the three findings for control in schedule III set forth in 21 U.S.C. 812(b)(3). *Id* at 1. The National Institute on Drug Abuse reviewed the findings and concurred with HHS' recommendation. *Id.*

The Attorney General then sought the legal advice of OLC on questions relevant to the potential rescheduling of marijuana, namely whether the new two-part HHS test to determine CAMU is legally sufficient. Gov't Exh. 4 at 3. On April 11, 2024, OLC concluded that while not binding upon DEA, HHS' two-part CAMU test is sufficient to establish that marijuana[4] has a

[3] HHS formulated a two-part inquiry to conduct this assessment because neither FDA approval nor DEA's five-part test examine[d] whether health care practitioners are actually using a drug to treat a condition or whether the entities regulating those practitioners allow the drug to be so used. FDA determined that ignoring widespread clinical experience with a drug that is sanctioned by state medical regulators when evaluating whether a drug has CAMU is at odds with the plain meaning of section 812(b). Gov't Exh. 4 at 13-14.

[4] The OLC opinion was not limited to this marijuana rescheduling assessment. The two-part CAMU test has been utilized for other rescheduling matters since its inception. Chiapperino, Tr. 54:11-13.

CAMU. OLC also concluded that satisfying HHS' two-part inquiry is sufficient to establish that a drug has CAMU even if the drug has not been approved by FDA and would not satisfy DEA's five-part test. *Id*. at 4. Further, the prior five-part CAMU test was impermissibly narrow because it did not take into consideration whether health care practitioners recommend marijuana for the treatment of a qualifying condition or whether entities regulating those practitioners allow marijuana to be so used. Gov't Exh. 4 at 13. "Limiting the CAMU analysis to whether a drug has been approved by FDA or meets DEA's five-part test also conflicts with the text of section 812(b) by erroneously equating identification of an 'accepted' medical use under the CSA with the 'approval,' or potential approvability, of a drug" under the Federal Food, Drug, and Cosmetic Act. Gov't Exh. 4 at 14.

OLC further held that while HHS' two-part test is legally sufficient to establish CAMU, DEA is not required to accept HHS' CAMU recommendation. A recommendation by HHS that a drug has, or lacks, CAMU does not bind DEA. However, the scientific and medical determinations that underlie HHS' CAMU recommendation are binding on DEA until the formal rulemaking begins. Once DEA initiates formal rulemaking, DEA must treat the scientific and medical determinations with significant deference. Gov't. Exh. 4 at 4. In addition, OLC held that the plain text of section 812 mandates that when these circumstances [a substance is recommended for medical use by a large number of medical practitioners] exist, and there is available scientific evidence supporting the medical use by those practitioners, it should be considered when determining whether a drug has CAMU. *Id.* at 16-18.

On May 21, 2024, on behalf of Attorney General Merrick Garland, the *Federal Register* published a Notice of Proposed Rulemaking (NPRM) titled "Schedules of Controlled Substances: Rescheduling of Marijuana." In the NPRM, the Attorney General proposed to transfer marijuana and any drug containing a substance within the CSA's definition of marijuana

from Schedule I of the CSA to Schedule III as it was consistent with HHS' analysis. ALJ Exh. 2 at 1, 24. In response to the NPRM, DEA received numerous comments and requests for hearing from interested persons. DEA originally scheduled a hearing pursuant to the NPRM and published a notice to that effect in the *Federal Register* on August 24, 2024. *See Schedules of Controlled Substances: Rescheduling of Marijuana,* 89 FR 70148 (Aug. 29, 2024). On April 28, 2026, the DOJ withdrew the notice of hearing and terminated all proceedings related to the August 29, 2024 Notice. *Schedules of Controlled Substances: Rescheduling of Marijuana; Withdrawal,* 91 Fed. Reg. 22,777, 22,778 (Apr. 28, 2026).

On April 28, 2026, then-Acting Attorney General Todd Blanche issued a notice rescheduling the hearing with respect to rescheduling of marijuana into Schedule III of the CSA. *Id.* at 22,777. On June 29 – July 15, 2026, the Government and Opposed Parties presented testimony supporting their positions in front of the Administrative Law Judge Derek C. Julius.

IV. PROPOSED FINDINGS OF FACT

Background

1. HHS performed an 8FA pursuant to 21 U.S.C. § 811(c) to assess whether marijuana should remain a scheduled substance under the CSA. An 8FA is performed regardless of whether the substance is newly scheduled or transferred from a different schedule. 21 U.S.C. §§ 811, 812.
2. HHS determined that marijuana should remain scheduled but recommended marijuana be transferred from Schedule I to Schedule III, based on its assessment of marijuana's abuse potential, CAMU, and dependance profile pursuant to 21 U.S.C. § 812(b).

Factor One: Marijuana's actual or relative potential for abuse.

3. Under this factor, DEA must consider marijuana's potential for abuse, but the CSA does not define "abuse." ALJ Exh. 1 at 7. Using CSA's legislative history, DEA reviews the following information to determine marijuana's abuse potential: 1) whether people are taking the

substance in sufficient amounts to create a hazard to their health or to the safety of others or their community, 2) whether there is significant diversion of the substance from legitimate drug channels, 3) if individuals are taking the substance on their own initiative or after medical advice from a provider licensed by law to administer such drugs in the course of their professional practice, and 4) whether the substance is related to another drug that is already listed as having a potential for abuse such that it is likely that the "new" substance will have the same potential for abuse. *Id.*

4. Abuse is a complex assessment which considers the effects of the drug, the toxicities associated with the drug, and the use patterns. Chiapperino, Tr. 74:6-14. Abuse cannot be determined by a single test or assessment. *Id.*; ALJ Exh. 1 at 7.

Hazard to health or to the safety of others or community

5. There is evidence of some individuals taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals, but several comparator drugs present greater hazards to the health of the consumer and the safety of others. ALJ Exh. 1 at 7-9.
6. The vast majority of individuals who use marijuana do so in a manner that does not result in dangers to themselves or to their communities. ALJ Exh. 1 at 7. Consistently across databases, across drugs and over time, marijuana has shown fewer adverse outcomes than heroin and alcohol and has been ranked consistently last when compared to other substances for overdose causing death. *Id.* at 8.
7. Risks to public health are lower for marijuana than other comparator substances like heroin, cocaine, and oxycodone based on review of emergency room visits, hospitalizations, unintended exposures, and overdose deaths. ALJ Exh 1 at 9. The public health risks for

heroin, benzodiazepines and cocaine are typically ranked highest with marijuana ranked lower, particularly when the drug utilization rate is used. *Id.*

Diversion from legitimate drug channels

8. There is a lack of data indicating diversion occurring from research and other registered manufacturers of marijuana. ALJ Exh. 1 at 9. The FDA had no evidence of significant diversion from these legitimate channels. *Id.*; Chiapperino, Tr. 205:8-19. However, there are significant additional sources of marijuana in the United States, both from illicit cultivation and productions, illicit importation from other countries, and from State programs that permit dispensing of marijuana for medical use and, in some States, recreational adult use. *Id.*

Marijuana use without medical advice from licensed practitioner

9. Individuals are using botanical marijuana state-sanctioned programs under the guidance of medical practitioners. ALJ Exh. 1 at 9. Individuals are also using marijuana without the guidance or recommendation of medical professionals. *Id.*
10. Marijuana has been a Schedule I substance under the CSA since it was enacted in 1970. ALJ Exh. 1 at 10. The primary compound in marijuana responsible for its abuse potential is delta 9 (Δ9) tetrahydrocannabinol (THC). *Id.*
11. FDA has approved two drug products containing dronabinol (a synthetic form of THC). Burchman, Tr. 64:18-20; *see also* ALJ Exh. 1 at 10. Both substances (brand names Marinol and Syndros) underwent a systematic evaluation of their abuse potential based on animal and human behavioral studies, which showed that dronabinol has abuse potential. ALJ Exh. 1 at 10.
12. HHS' findings regarding abuse potential also suggest that marijuana will continue to be used nonmedically, diverted from legitimate channels, and trafficked as a continued source of nonmedical use. ALJ Exh. 1 at 10.

Abuse comparison to other substances

13. Relative abuse potential of marijuana includes multiple considerations, including consideration of its chemistry, receptor binding, behavioral effects indicating that the substance is rewarding or is similar to other substance controlled by the CSA. ALJ Exh. 1 at 7.

14. FDA examined other substances already controlled by the CSA that would be helpful as comparators and assessed the profile of the use pattern, the tendency for that abuse and non-medical use to produce harms and considered the differences among the test drug [marijuana] versus the comparators. Chiapperino, Tr. 73:15-21.

15. When comparing marijuana to numerous comparator substances, like heroin, oxycodone, hydrocodone, fentanyl, cocaine, benzodiazepines, tramadol, and alcohol, marijuana typically does not produce the highest frequency of adverse events or severity of the substance use disorder. ALJ Exh. 1 at 10.

Factor Two: Scientific evidence of marijuana's pharmacological effects, if known.

16. HHS's analysis of Factor Two includes the assessment of scientific evidence of the pharmacological effects of marijuana based on the effects of Δ9-THC, specifically evaluating the neurochemistry, receptor pharmacology, animal abuse-related behavioral effects, and human behavioral and physiological effects of marijuana. ALJ Exh. 1 at 10-19.

17. Cannabis is the genus of a plant that contains numerous natural constituents, including cannabinoids. ALJ Exh. 1 at 11. The two most abundant cannabinoids present in marijuana are Δ9-THC and cannabidiols (CBD). ALJ Exh. 1 at 11. Δ9-THC is the primary constituent in the cannabis plant. Chiapperino, Tr. 46:19-21.

18. Δ9-THC is the major psychoactive intoxicating cannabinoid in marijuana and is the component of marijuana that is primarily responsible for its abuse potential. ALJ Exh. 1 at 11. In contrast, CBD has negligible abuse potential. *Id.*

19. There are two cannabinoid receptors: CB_1 and CB_2. ALJ Exh. 1 at 11. Δ9-THC and CBD have varying affinity and effects at the cannabinoid receptors. *Id.* at 12. Δ9-THC is a partial agonist at both CB_1 and CB_2 receptors. *Id.* However, CB_1 receptors are the main pharmacological site of action for Δ9-THC, making CB_1 receptors the site that is responsible for the abuse potential of marijuana. *Id.*

20. Cannabinoid receptors are located in the area of the cerebral cortex and spinal cord that relate to pain control and modulation. Burchman, Tr. 569:19-25. When marijuana molecules latch onto cannabinoid receptors, pain control can occur. Burchman, Tr. 570:1-3.

21. During the last 30 years, the potency of marijuana, with regard to Δ9-THC, has increased significantly. ALJ Exh. 1 at 12.

22. Epidemiology data demonstrates that humans self-administer Δ9-THC for its ability to produce positive responses ALJ Exh. 1 at 16.

23. Clinical studies for FDA-approved drugs (Marinol and dronabinol) investigated the effects of Δ9-THC and identified several common responses, including positive responses of euphoria and happiness; along with sedation, anxiety and negative responses of agitation and paranoia. ALJ Exh. 1 at 16-18. The studies also found perception, psychiatric, social, and cognitive changes, along with physiological responses. *Id.*

24. The positive changes that occur following use of marijuana are pleasurable to many humans and are associated with drug-seeking and drug-taking. ALJ Exh. 1 at 16-18. These effects are typically dose-dependent, with higher doses and routes of administration that produce faster

onset and more intense responses and the likelihood of more negative subjective effects. *Id.* at 18.

25. The rewarding responses are consistent with the prevalence of marijuana's non-medical use, which includes abuse that can lead to other negative consequences. ALJ Exh. 1 at 19.

Factor Three: The state of current scientific knowledge regarding marijuana.

26. Cannabis is a genus of annual flowering plant with digitate leaves in the family Cannabaceae Martinov and is generally treated as a single, highly polymorphic species known as Cannabis sativa L. ALJ Exh. 1 at 19.

27. The Cannabis sativa plant naturally contains many different compounds and more than 550 have been identified, such as: cannabinoids, terpenoids, flavonoids, stilbenoids, steroids, polysaccharides, benzoquinone, phenanthrenes, spiroindans, lignans, fatty acids, sugars, hydrocarbons, amino acids, and proteins. ALJ Exh. 1 at 20.

28. Cannabinoids are mainly found in living Cannabis sativa plants in their non-psychoactive carboxylated forms (i.e., acid form), which require drying, heating, combustion, or aging to decarboxylate to their neutral forms and are primarily composed of C21 terpenophenolic compounds. *Id.* The most abundant neutral form cannabinoids are Δ9-THC and CBD, but nearly 200 have been identified in the plant and are divided into subclasses: cannabigerols (CBGs), cannabichromenes (CBCs), CBDs, Δ9-THCs, (-)-Δ8-trans-tetrahydrocannabinols (Δ8-THCs), cannabicyclols (CBLs), cannabielsoins (CBEs), cannabinols (CBNs), cannabinodiols (CBNDs), cannabitriols (CBTs), and the miscellaneous cannabinoids. *Id.*

29. Although both Δ9-THC and Δ8-THC produce marijuana's psychoactive effects, Δ9-THC is significantly more abundant. ALJ Exh. 1 at 21. Thus, marijuana's psychoactive effects are attributed to Δ9-THC. *Id.* Only small quantities of Δ8-THC have been found in plants. *Id.*

30. Marijuana is not a single chemical with a consistent and reproducible chemical profile or predictable and consistent clinical effects. ALJ Exh. 1 at 22. Differences in harvest location, growing conditions, the season of harvest, and the manner in which marijuana is processed, handled, transported and tested may result in differences in the quality in the product. *Id.* at 20-22.

31. Due to the variation of the chemical composition in marijuana strains, marijuana is not a single chemical and does not have a consistent and reproducible chemical profile with predictable or consistent clinical effects. Akinfiresoye, Tr. 1364:14-19. Further, marijuana is not a substance as it is not a singular molecular entity. *Id*. at 1365:17-22.

32. Like any other botanical substance, marijuana plants are heterogeneous in nature and contain a complex chemical profile. ALJ Exh. 1 at 20; *see also* Chiapperino, Tr. 210:25, 211:1-3. Moreover, variable organic plant material, as well as manufactured preparations, result in a variety of product forms that dictate different routes of administration, associated risks, and differences in quality of the product used, which may also influence risk for users. ALJ Exh. 1 at 20. The potential for high variability of marijuana and marijuana-derived products, both in product composition and impurity profile, are major considerations for the potential variability of drug effects and safety. *Id.*

33. Because of the different sources of marijuana in state-approved programs, there are no unified controls on the cultivation and manufacturing of marijuana products, which raise concerns regarding the products' safety, quality, and consistency. ALJ Exh. 1 at 22.

34. Marijuana or derived products can generally be categorized as one of four types: (1) flowers, (2) concentrates, (3) edibles, and (4) topicals. ALJ Exh. 1 at 21-22.

35. Generally, inhalation of a drug is the route that produces the fastest rate of drug absorption. ALJ Exh. 1 at 23. Once marijuana is inhaled, Δ9-THC is absorbed through the lungs in the

form of an aerosol within seconds. *Id.* Psychoactive effects begin immediately following absorption. *Id.* An individual's experience and technique with smoking marijuana determines the dose absorbed. *Id.*

36. When marijuana or Δ9-THC is administered orally (such as by eating marijuana-infused foods), the effects start within 30 to 90 minutes. ALJ Exh. 1 at 23.

37. Although there are differences in absorption of Δ9-THC depending on route of administration, the distribution, metabolism, and excretion of Δ9-THC is similar regardless of how the drug is administered. ALJ Exh. 1 at 24.

38. To ascertain whether marijuana had a CAMU, HHS assessed the current widespread use of marijuana under the supervision of licensed Health Care Providers (HCP) under state-authorized programs. ALJ Exh. 1 at 25. In doing so, HHS, through the actions of the Office of the Assistant Secretary for Health (OASH) found there were over 30,000 HCPs authorized to recommend the use of marijuana for more than six million patients at the time of HHS' review. *Id.* Although state programs differ, HHS found several programs that have been in place for multiple years that actively monitor marijuana's medical use and the product quality characteristics of the marijuana dispensed. *Id.*

39. One of the states which implemented marijuana state programs is New Hampshire. Marijuana became available for patient treatment in 2016. Burchman, Tr. 579:18-21; New Hampshire State Code: Revised Statutes Ann. (RSA) 126-X. New Hampshire created a Therapeutic Cannabis Medical Oversight Board, under the New Hampshire Department of Health and Human Services, consisting of multiple board members who are medical providers, including Dr. Corey Burchman (Burchman). Burchman, Tr. 542:14-16. New Hampshire has established a list of conditions and associated, qualifying symptoms, that must be attested to by a medical professional prior to a patient's access to marijuana for

medicinal use. The marijuana products dispensed in the four New Hampshire state dispensaries are tested by certified labs and warning materials are provided to the patient consumer by the dispensary regarding product safety concerns and driving warnings. Burchman, Tr. 618-620.

40. In New Hampshire, a physician may recommend marijuana to a patient that suffers from a qualifying condition and qualifying symptom (New Hampshire Therapeutic Cannabis Program, RSA 126-X)). Burchman, Tr. 608-609. The physician then attests to the condition and symptom and the patient applies for a medical marijuana card. When/if they receive it, the patient seeks marijuana from one of four regulated dispensaries in New Hampshire. Burchman, Tr. 610:9-22.

41. The counter staff at the New Hampshire dispensaries cannot provide medical advice to customers. Burchman, Tr. 611. The recommending provider should advise the patient on the benefits and risks associated with marijuana for their medical condition, any interactions with their other medicines, the type of product and dose to seek, and how to titrate until they decrease their pain sensation. Burchman, Tr. 611-614.

42. Based on state law and regulations, the marijuana products purchased at dispensaries may contain QR codes to identify the product strain and concentration, certificates of analyses from a certified lab to address the contents of the marijuana product and the concentration of THC and CBD therein, and warning labels to remind patients that they should not consume marijuana and drive a motor vehicle and may cause certain side effects. Burchman, Tr. 618-620.

43. HHS found at least 15 medical conditions included in state programs wherein licensed HCPs operating in accordance with implemented state programs could recommend marijuana for the treatment of those conditions. ALJ Exh. 1 at 26, n.9. FDA added another condition

(anxiety) to HHS' list of 15 based on state-level marijuana usage data but ultimately did not find sufficient scientific support for CAMU for anxiety. ALJ Exh. 1 at 26, ns. 9 and 11.

44. FDA then reviewed the science for seven conditions, which included the six identified by HHS plus anxiety, and found sufficient scientific support to demonstrate CAMU for marijuana for the purposes of rescheduling for 1) pain, 2) anorexia with a medical condition, and 3) nausea and vomiting, usually in the context of chemotherapy (CAMU conditions). ALJ Exh. 1 at 25-29; Chiapperino, Tr. 50:9-17, 59:9-16, 61:18-24.

Pain

45. Pain is the indication for which there were the most available studies that examine the use of marijuana for treatment purposes. The FDA considered 39 randomized clinical trials and eight observational studies. Most of the observational studies were excluded on the basis of bias as evaluated under the systematic review process for determining bias. When the data was considered, there was a small margin of benefit. However, in a narrower category of neuropathic pain, the studies were more supportive of a therapeutic benefit. There was at least one study with moderate quality of evidence showing benefit. Chiapperino, Tr 62:4-63:1. *see also* Chiapperino, Tr. 499:12-14; ALJ Exh. 1 at 26-29, 160-177, 180-185.

46. The University of Florida identified data that supported the effectiveness of marijuana for the treatment of pain, although the results were inconclusive or mixed. ALJ Exh. 1 at 27.

47. The National Academies of Sciences & Medicine, 2017, concluded in their review that there was "substantial evidence" that marijuana provided a therapeutic benefit for the treatment of pain. ALJ Exh. 1 at 27, 182.

48. The Agency for Healthcare Research and Quality's living systematic review showed evidence of benefits to pain patients, but the effects were small. ALJ Exh. 1 at 182-3; Chiapperino, Tr. 63:19-23.

49. A Harvard study authored by Staci Gruber found that marijuana was effective for pain. Burchman, Tr. 583:24-25, 584:6. Specifically, the study found that "relative to baseline, following 3 and 6 months of treatment, medical cannabis patients exhibited improvements in pain which were accompanied by improved sleep, mood, anxiety, and quality of life, and stable conventional medication use. Reduced pain was associated with improvements in aspects of mood and anxiety. The results generally suggest increased THC exposure was related to pain-related improvement, while increased CBD exposure was related to improved mood.". *See* Finn Exh. 125, slide 7.

50. FDA reviewed results from 37 state medical marijuana programs and obtained access to surveys of patients from Minnesota and Maryland using marijuana. ALJ Exh. 1 at 28. Data from those two states found that most patients did not report any side effects from marijuana and if they did, the side effects were mild. *Id*. Given the response method, FDA noted that the survey results may overestimate the positive experiences. *Id*. However, data from the Minnesota program revealed that pain was one of the common conditions for which individuals sought marijuana for medical treatment. Chiapperino, Tr. 71:12-22.

51. Over the course of several years, Dr. Burchman found that marijuana use by chronic pain patients provided a therapeutic benefit, including patients who suffer from neuropathic pain. Burchman, Tr. 579-581, 587:4-25, 590-593.

52. Dr. Burchman treated chronic pain patients that were able to titrate their opioids down after starting a marijuana treatment, including some patients that were able to stop taking opioids entirely. Burchman, Tr. 793-4.

53. Dr. Burchman, a pain management physician who has treated thousands of chronic pain patients, found botanical marijuana superior for pain control than synthetic THC because botanical marijuana contains multiple cannabinoids in addition to THC that also confer

analgesic effects that are lacking in the FDA-approved synthetic THC. Burchman, Tr. 582: 21-25, 583:1-5.

54. Dr. Bertha Madras (Madras), the addiction expert presented by SAM, testified that there is scientific evidence of marijuana's efficacy for neuropathic pain patients, although she believes that the science is weak. Madras, Tr. 1230:18-24. Dr. Kenneth Finn, also a pain management physician, admitted that he previously recommended marijuana for his pain patients and currently believes that there is likely a therapeutic benefit to marijuana. His concern is mainly with the dosing and quality controls for the substance. Finn, Tr. 1617:24-25, 1618:1-4, 1620:12-20, 1629:9-10, 1670:15-22.

Nausea and Vomiting

55. FDA's analysis found credible scientific support that marijuana has CAMU when treating nausea and vomiting in conjunction to chemotherapy. Chiapperino, Tr. 61:18-24.

56. FDA's analysis examined available studies and in some of those studies, the information showed that benefit [for treating nausea and vomiting] was identified with a moderate quality of evidence. Chiapperino, Tr. 61:23-25, 62:1-3.

57. Data from the Minnesota state program for marijuana use revealed that nausea and vomiting were one of the common conditions for which individuals sought marijuana for medical treatment. Chiapperino, Tr. 71.

58. There are two FDA-approved synthetic cannabinoids (dronabinol and nabilone) that are approved to treat chemotherapy-induced nausea and vomiting. ALJ Exh. 1 at 157. Given the efficacy shown by these products in their clinical trials for FDA approval, marijuana was assessed to determine if it had similar effects. *Id.*

59. The University of Florida identified two randomized controlled trials that used whole plant cannabis of THC-CBD extract and found a benefit of marijuana over the placebo with a

moderate-quality of evidence. ALJ Exh. 1 at 160. The results from these studies support a positive effect of cannabis on chemotherapy-induced nausea and vomiting. *Id.*

Anorexia

60. FDA's analysis found credible scientific support for the use of marijuana for treatment of anorexia. A moderate quality of evidence in these systematic reviews means that the true effect of marijuana is probably similar to the observed result or reported effort. Chiapperino, Tr. 61:7-17.

61. A study reviewed by the FDA found moderate-quality evidence that participants with HIV anorexia-cachexia increased their caloric intake with marijuana cigarettes although there was low-quality evidence that the cannabis increased the participants' body weight. ALJ Exh. 1 at 145; Chiapperino, Tr. 61:7-17.

62. Dr. Madras also noted that clinical marijuana trials showed that marijuana had positive effects for cachexia/wasting syndrome. S.A.M. Exh. 47, slide 13.

63. Data on the botanically derived marijuana is more limited than data on synthetic marijuana, like dronabinol, that has been FDA-approved to treat anorexia associated with HIV. ALJ Exh. 1 at 189. However, a Mucke 2018 study found participants on botanical marijuana and dronabinol gained weight with no serious adverse events and another review of three studies using botanical extracts and synthetic THC showed a trend toward increased appetite when compared to a placebo. *Id.*

Safety Review for CAMU Conditions

64. Data from state programs support the lack of serious adverse events from a result of marijuana use. Data from Maryland's state program demonstrated that, for people using marijuana for medical conditions, there were very low incidences of safety concerns and reported adverse effects. Chiapperino, Tr. 69:12-21.

65. Similarly, data from Minnesota's state program showed that the individuals using marijuana for therapeutic conditions did not report any significant adverse effects. Chiapperino, Tr. 70:18-24.

Factor Four: Marijuana's history and current pattern of abuse.

66. HHS' factor four assessment reviews the federal and state level history of marijuana control, marijuana sources for nonmedical and medical use, marijuana use since the passage of the CSA, and current patterns of abuse. This assessment also includes the use of comparator substances. ALJ Exh. 1 at 29.

67. Marijuana (as "an alcoholic extract of the dried tops of *Cannabis sativa*") was described in the United States Pharmacopoeia as early as 1850. ALJ Exh. 1 at 29. In 1942, marijuana was removed from the United States Pharmacopeia. *Id.*

68. Regulations and legal restrictions over the consumption of marijuana began with the passage of the Pure Food and Drug Act in 1906, marijuana began to be characterized by the federal government as "addictive" and/or "dangerous." ALJ Exh. 1 at 29-30. In 1931, the importation of marijuana into the United States began to be restricted under regulations under the Pure Food and Drug Act, except for medicinal purposes. ALJ Exh. 1 at 30. Subsequently, the Marihuana Tax Act of 1937, Public Law 75–238, 50 Stat. 551, imposed taxes that effectively prohibited marijuana use for medical, nonmedical, scientific, or industrial purposes. *Id.* In 1970, Congress passed the CSA, which effectively repealed all previous federal drug laws and placed marijuana in schedule I. *Id.*

69. Changes in state-level marijuana law began in 1996 with the passage of California's Proposition 215, the Compassionate Use Act. ALJ Exh. 1 at 31. This law legalized the use, possession, and cultivation of marijuana for treatment of numerous illnesses, including chronic pain and anorexia, as long as they had a recommendation from their physician. *Id.*

At the time of HHS' review, 38 states, and a territory had approved marijuana for medicinal use, and 23 states and a territory approved marijuana for nonmedical use. ALJ Exh. 1 at 32.

70. Since the passage of the CSA, marijuana use has vacillated over time. ALJ Exh. 1 at 32. From 2007 to 2017, there were steady year-over-year increases in general population past-month use, although HHS found no clear explanation for the increased use rates. *Id.*

71. Based on National Survey on Drug Use and Health (NDSUH), from 2015 to 2019 the past-year use of marijuana for any reason (nonmedical and medical) among people ages 12 years and older increased from 14 to 18%. ALJ Exh. 1 at 33. This is in contrast to past-year use (nonmedical and medical) of comparator drugs that have FDA-approved therapeutic indications. Use of the comparator drugs declined or remained relatively stable over the same timeframe, including hydrocodone (22 to 16%), benzodiazepines (12 to 11%, 2017 to 2019 only), oxycodone (11 to 9%), tramadol (7 to 6%), zolpidem (4 to 3%), and ketamine (less than 1%). ALJ Exh. 1 at 33-34.

72. NDSUH survey suggests that most individuals who used marijuana did not do so based on a recommendation from an HCP but marijuana use was more frequent among users with an HCP recommendation. ALJ Exh. 1 at 34-35. By contrast, nonmedical and medical use of comparator drugs (hydrocodone, benzodiazepine, oxycodone, tramadol, zolpidem, and ketamine) generally remained stable or decreased. ALJ Exh. 1 at 33-34. Most people who reported the nonmedical use of marijuana did not report nonmedical use of the comparator drugs. ALJ Exh. 1 at 34. The prevalence of alcohol use during this time also increased and far exceeded marijuana use in this study. *Id.*

73. A National Center for Disease Control and Prevention (CDC) survey, the Behavioral Risk Factor Surveillance System, found that adults were more likely to use marijuana medicinally

and participants who used marijuana medicinally were more likely to use it daily or nearly daily. ALJ Exh. 1 at 35.

74. Two other national surveys, Monitoring the Future and Youth Risk Behavior Surveillance System (YRBSS), found that older high school students used alcohol more frequently than marijuana. ALJ Exh. 1 at 36-37. Marijuana/hashish was the most commonly used illicit drug. *Id.* at 36.

75. Data from International Cannabis Policy Survey, a national survey, supported the premise that the interest in use of marijuana to treat medical conditions is genuine, as people are still seeking practitioner's advice in states where they have access to marijuana with or without that advice. Chiapperino, Tr. 68:1-6

76. HHS concluded that medical and nonmedical use of marijuana is extensive, but less than alcohol and more than other scheduled comparator drugs. ALJ Exh. 1 at 38.

Factor Five: The scope, duration, and significance of abuse of marijuana

77. To perform this assessment, HHS analyzed the consequences of marijuana use to comparator substances based on a variety of national data sources, including the United States Poison Centers National Poison Data System (NPDS), NSDUH, Treatment Episode Data Set (TEDS), National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO), National Emergency Department Sample (NEDS), National Inpatient Sample (NIS), and National Forensic Laboratory Information System (NFLIS). ALJ Exh. 1 at 38.

78. The number of poison center abuse cases analyzed from 2015-2021 found that marijuana was consistently ranked fourth, under alcohol, heroin, and benzodiazepines. ALJ Exh. 1 at 39. The alcohol poison control cases are approximately 2.5x the number of marijuana poison control cases. *Id.*

79. When assessed based on annual utilization, which divides the number of poison control abuse cases by the prevalence of use based on persons 12 and older from 2015 to 2019, heroin had the highest rate at 7,201 cases per million [people] with marijuana significantly lower at 70 to 75 cases per million people. ALJ Exh. 1 at 40.

80. An analysis of medical outcomes, related to exposure based on severity, timing, and assessment of clinical effects, for all single-substance poison control abuse cases involving marijuana or comparator drugs show that serious medical outcomes were greatest with illicit fentanyl (81%) and heroin (79%), followed by oxycodone (70%), ketamine (64%), tramadol (62%), cocaine (59%), hydrocodone (44%), marijuana (41%), benzodiazepines (32%), alcohol (31%), and zolpidem (27%). ALJ Exh. 1 at 40. Marijuana had a death rate of less than 1%, although death rates may be underreported. *Id.*

81. NSDUH provided national survey data on the prevalence of substance use disorder (SUD) in 2021 for persons 12 years old and older who used nonmedical marijuana, heroin, cocaine and alcohol. ALJ Exh. 1 at 41. SUD is classified as mild, moderate and severe. *Id.* Of the individuals who used marijuana in the prior year, 24% met the criteria for SUD who used marijuana only and 30% met that criteria if they used marijuana and another illicit substance. *Id.* More than half of each marijuana group met the criteria for mild SUD. *Id.* By comparison, 81% of the individuals who took heroin met the criteria for SUD, 30% for cocaine, and 17% for alcohol. ALJ Exh. 1 at 41. The mild, moderate, severe SUD percentages were not available for heroin, but less than half of the participants with SUD who consumed cocaine met the definition for mild SUD and more than half with SUD who consumed alcohol met the definition of mild SUD, like the marijuana SUD findings. *Id.*

82. TEDS collects information from admissions from state-approved facilities that are required by the state to provide this data. ALJ Exh. 1 at 41-42. Out of 1.4 million admissions

documented, marijuana was listed on 10% of the admissions as the primary drug. *Id.* at 42. Alcohol scored the highest at 31%, followed by heroin at 21%. *Id.* In 2015, marijuana was the primary drug in 14% of admissions, representing a drop in marijuana-as-primary admissions. *Id.* Marijuana and cocaine were more likely to be reported as the secondary or tertiary drug. *Id.*

83. The NAVIPPRO surveillance system found that marijuana was the most frequently cited drug used in the prior month by adults who sought SUD treatment at a participating facility from 2020 to 2021, followed by alcohol and heroin. ALJ Exh. 1 at 42. The sample size for this review was 76,249 facility assessments. *Id.*

84. In a NEDS assessment of approximately 28 million emergency room visits wherein the patient was noted as having a marijuana, alcohol or cocaine-related disorder, although drug use did not need to be the reason for the visit, alcohol scored the highest number of visits, followed by marijuana and then cocaine. ALJ Exh. 1 at 43. Marijuana-related disorders accounted for a third of the alcohol-related visits. *Id.* at 44.

85. HHS compared hospitalizations of marijuana, alcohol and cocaine presented in the NIS, which collected 7 million inpatient stays from more than 45 states and the District of Columbia. ALJ Exh. 1 at 44. Like the NEDS, the NIS found alcohol-related disorders had the highest estimated hospitalizations from 2016 to 2020. *Id*. The estimated annual hospitalizations for marijuana were approximately half that of alcohol, of which less than half were for single substance marijuana-related disorder. Estimated annual cocaine hospitalizations were approximately half those from marijuana, but not after the hospital stays are adjusted for utilization. *Id.* When adjusted for utilization, cocaine hospitalizations were between approximately 7,000 to 8,000 per 100,000 individuals. Marijuana stays resulted in approximately 2,000 stays and alcohol resulted in 1,000 stays per 100,000. *Id*.

86. The NFLIS is a program of the Diversion Control Division of DEA and helps monitor drug encounters with law enforcement nationally. ALJ Exh. 1 at 44. Because not all drugs encountered by law enforcement are tested, the data is limited. The number of cannabis reports from this system have decreased yearly. *Id.* at 45.

87. Of the comparator substances, alcohol, heroin, and cocaine were routinely found to have greater adverse outcomes compared to marijuana, including death, where marijuana was in the lowest ranking group. Although marijuana produces clear evidence of harmful consequences, those consequences were relatively less harmful than other comparator drugs. ALJ Exh. 1 at 46.

Factor Six: What, if any, risk there is to the public health

88. In assessing the sixth factor, HHS looked to many of the same studies reviewed in factors two, four, and five along with other data on the risks to youth, driving while marijuana-impaired, and adverse events reported to various information systems. ALJ Exh. 1 at 47.

89. The NSDUH data from 2021 for nonmedical marijuana users show that the prevalence of substance use disorder is highest for persons between 12-17 years old and it decreases with age and is higher for individuals who use marijuana nonmedically with other substances. ALJ Exh. 1 at 47.

90. The Toxicology Investigators Consortium Core Registry (ToxIC) comprises of over 50 locations in the United States and several international locations. ALJ Exh. 1 at 49. Of 829 cases where patients are seen by a medical toxicology physician as part of their medical care based on marijuana ingestion, 342 were for unintentional ingestion, including young children. *Id.* Two cases reported in the ToxIC Core Registry involved marijuana-containing product exposure with a death outcome. *Id.* at 50. Both events involved the inhalation route

of exposure and intentional misuse or abuse. *Id.* A 16-year-old boy had acute exposure and a 21-year-old male had a vaping-induced pulmonary injury. *Id.*

91. NPDS data provides unintentional general exposure data from poison control cases from 2015 to 2021. ALJ Exh. 1 at 50. The highest number of unintentional exposures in total poison control cases are from benzodiazepines, followed by alcohol and then marijuana. *Id.* When adjusted for utilization rate, benzodiazepines remained this highest number, followed by heroin and then marijuana. *Id.* The marijuana cases represented 98 cases per one million people and benzodiazepines represented 148 cases per one million people. *Id.*

92. NPDS data also found that marijuana has the highest percent of unintentional-general exposure as a single substance. ALJ Exh. 1 at 50. Marijuana has a higher unintentional exposure rate for children less than 6 years old that most comparator drugs except alcohol and benzodiazepines. *Id.* at 51. The most frequent documented related clinical effects for children less than 6 years of age are mild/moderate central nervous system depression (82%), vomiting (10%), and tachycardia (10%). *Id.*

93. NSDUH collected data from 2021 on driving under the influence of marijuana, alcohol, cocaine and heroin for persons 16 years old and older. ALJ Exh. 1 at 51. Alcohol scored the highest, followed by marijuana and then cocaine. *Id.* When assessed based on age categories, the 21 to 25 age bracket had the highest level of driving under the influence, with marijuana scoring slightly higher than alcohol. *Id.*

94. A YRBSS study found that high school students 16 years and older in 2017 reported driving under the influence of marijuana 53% of the time at least once in the past month and 21% reported driving under the influence of marijuana at least six times in the past month. ALJ Exh. 1 at 51.

95. FDA received 133 adverse events or quality and labeling complaints involving marijuana-containing products via various databases from January 2012 to October 2022. ALJ Exh. 1 at 52. FDA does not receive reports for every event so the reports submitted cannot be used to calculate the incidence of adverse events. *Id.* Although FDA received 11 reports that had an outcome related to death, upon further review, none of these events were included in the 133 cases because the death reports were miscoded, related to a different product, or contained insufficient information to associate the death to marijuana. *Id.* FDA received 66 case reports, mostly from vape products, in 2019 and the case report number dropped significantly thereafter to between 10 and 20 for 2020, 2021 and most of 2022. *Id.* Most of these reports included serious outcomes, including required medical intervention and hospitalization. *Id.*

96. According to the National Vital Statistics System-Mortality and Drug-Involved Mortality (NVSS-M) information over a 10-year period (2012 to 2021) the total number of overdose deaths involving marijuana was much lower than that of most comparators. ALJ Exh. 1 at 53. Fentanyl had the highest total number of overdose deaths (n=258,785) followed by cocaine (n=119,208), heroin (n=118,992), and benzodiazepines (n=87,581). *Id.* Alcohol had a much lower number of overdose deaths (n=10,484), with marijuana producing the lowest number (n=5,957). *Id.* Polysubstance deaths were common. *Id.*

97. Based on the NVSS-M data, fentanyl remained the highest at 12,843 overdose deaths when evaluating for single substance overdoses, followed by heroin (6,078), cocaine (2,774), alcohol (1,338) and then benzodiazepines (277). ALJ Exh. 1 at 53. In comparison, marijuana had 160 overdose deaths. *Id.* When adjusting for utilization, single substance marijuana overdose deaths account for 0.14 deaths per 100,000 people and heroin and cocaine resulted in the highest overdose deaths at 22.22 and 4.79, respectfully. *Id. See also* Chiapperino, Tr. 88:21-25, 89:1-11.

98. When marijuana is a single entity in an overdose case report, events of death are very rare, usually attributed to a secondary event, like an accident or a fall or self-harm. Chiapperino, Tr. 77:19-22, 78:9-12.

99. In another study on overdose death rates for marijuana and several comparators, the Drug Involved Mortality data from 2017 found single substance overdose deaths for fentanyl were highest at 6,057, followed by heroin (2,660), cocaine (2,987), oxycodone (695), benzodiazepines (512), hydrocodone (275), tramadol (120) and marijuana (12). ALJ Exh. 1 at 53. Heroin is a Schedule I controlled substance; cocaine, fentanyl, oxycodone and hydrocodone are Schedule II controlled substances; and benzodiazepines and tramadol are Schedule IV controlled substances.[5]

100. Overdose deaths from marijuana are much lower compared to overdose deaths from Schedule II opioids. Chiapperino, Tr. 78:6-9. Overdose deaths from marijuana are also much lower than overdose deaths due to heroin. Chiapperino, Tr. 78:20-22.

101. Dr. Burchman testified that while he worked in the emergency department (ED), he treated approximately 200-500 overdose deaths caused by opioids and no overdose deaths caused by marijuana. Burchman, Tr. 594:20-25, 595:1-3. Dr. Burchman stated that a marijuana overdose causing death case would be "so rare" that it would be a "reportable incident" that would like by published by the Morbidity and Mortality Weekly Report by the CDC. Burchman, Tr. 595:3-9.

102. Opioid receptors, referred to as mu receptors, are located through the central nervous system, spinal cord as well as a large concentration in the brainstem, which is "the seat of

[5] 21 U.S.C. 812(c) Schedule I(b)(10); 21 U.S.C. 812(c) Schedule II(a)(4)&(b)(6); 21 CFR 1308.11(c)(11), 21 CFR 1309.12(b)(1)(vi), (b)(1)(xiv), (b)(4),(c)(9), & 21 CFR 1308.14(b)(3), 1308.14(c).

respiratory drive." When opioids affect the receptors in the brainstem, it can stop the patient from breathing and the patient will die of respiratory arrest. Burchman, Tr. 603:3-10.

103. Although there are significantly more cannabinoid receptors than mu receptors in the brain, the brainstem is basically devoid of cannabinoid receptors. As a result, a patient could consume a "huge dose of THC" and it will not affect the patient's breathing. Burchman, Tr. 603:15-23.

104. From April 2016 to June 2022, the greatest number of healthcare encounters *(i.e.*, inpatient, outpatient, ED, or institutional) in the FDA's Sentinel Distributed Database[6] were for benzodiazepine poisonings, followed by heroin, marijuana, alcohol, and cocaine. ALJ Exh. 1 at 55. The marijuana encounters (17,961) were less than a third of the encounters for benzodiazepines (63,074). *Id.* When assessing the patients' diagnoses, chronic pain was the highest listed diagnosis in the 8FA summary for marijuana and benzodiazepines. *Id.* at 55-56.

105. The FDA Sentinel Distributed Database results were consistent with the Centers for Medicare and Medicaid Services (CMS) review of patients who had a medical encounter related to drug poisoning from 2017 to 2021. Over 63 million patient encounters were assessed and benzodiazepine poisonings accounted for about 8x more medical encounters than marijuana poisonings. ALJ Exh. 1 at 57.

106. The risks to public health from marijuana are low when compared to heroin, cocaine, and benzodiazepines based on emergency room and hospital stays and overdose deaths. ALJ Exh. at 58.

[6] FDA's Sentinel System is an active surveillance system for post-marketing medical product safety that uses administrative claims data from three national health insurers (Aetna, Humana Inc., and Optum) and six regional integrated delivery systems (Health Partners, Kaiser Permanente Colorado, Kaiser Permanente Hawaii, Kaiser Permanente Northwest, Kaiser Permanente Washington, and Marshfield) that contribute to the Sentinel Distributed Database (FDA, 2023a, 2023b, 2023c, 2023d).

107. Marijuana is routinely ranked in the lowest among the comparator drugs for overdose deaths. ALJ Exh. 1 at 58.

108. There is consistent evidence across multiple databases referenced in the 8FA that show while marijuana poses a risk to public health, it is lower than that posed by most comparator drugs. ALJ Exh. 1 at 58.

109. There are several FDA-approved products that contain botanical, synthetic, or structurally related forms of CBD and Δ9-THC. ALJ Exh. 1 at 197. These four products – Marinol, Syndros, Cesamet, and Epidiolex – contain dronabinol, the most abundant cannabinoid in the cannabis plant. *Id.*; *see also* Chiapperino, Tr.72:5-12. These FDA approval actions signify safety and efficacy for use of dronabinol in that patient population. Chiapperino, Tr. 72:5-12.

Factor Seven: Marijuana's psychic or physiological dependence liability

110. To assess this factor, HHS looked to the addiction and substance use disorder (SUD) implications for marijuana. SUD may occur in a broad range of severity, from mild to severe. ALJ Exh. 1 at 58.

111. There is ample evidence to suggest that marijuana has abuse potential as noted in previous findings of fact and the HHS' 8FA. ALJ Exh. 1 at 58-62.

112. Substance use disorders are generally defined by an inability to cease drug use despite harmful consequences. ALJ Exh. 1 at 59. In the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), Cannabis Use Disorder (CUD) shares diagnostic criteria common to substance used disorders for other drugs of abuse. *Id.*

113. CUD is estimated at between 10% to 20% in those that regularly use marijuana. ALJ Exh. 1 at 59. The National Comorbidity Study found 9% of lifetime users of cannabis met the definition of dependence in the DSM's Revised Third Edition as did 32% of tobacco users,

23% of opiate users, and 15% of alcohol users. *Id.* The risk was higher for lifetime marijuana users with a history of psychiatric or substance dependence comorbidity. *Id.*

114. Of those that sought substance abuse treatment in 2020, per the TEDS study, 10% sought treatment for marijuana as the primary substance of abuse. ALJ Exh. 1 at 59. Alcohol was three times more likely to be the primary substance of abuse and heroin was twice as likely. *Id.*

115. Marijuana can produce psychological dependence in some individuals, but the likelihood of serious outcomes is low, suggesting that high psychological dependence does not occur in most individuals that use marijuana. ALJ Exh. 1 at 66.

116. When considering mild, moderate, and severe substance use disorder, marijuana skews very heavily toward mild substance use disorder. Chiapperino, Tr. 81:10-13.

117. Physical dependance is associated with a specific withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood levels of the drug, or by administering an antagonist. ALJ Exh. 1 at 60.

118. When marijuana is administered chronically, it leads to tolerance. ALJ Exh. 1 at 60. Abrupt discontinuation of marijuana after prolonged use produces withdrawal symptoms. *Id.* Although research has not been done on withdrawal symptoms for occasional marijuana users, individuals who use marijuana chronically and heavily experience withdrawal symptoms between 24-48 hours after drug discontinuation. *Id.* Those symptoms peak within two to six days and reduce over one to two weeks thereafter. *Id.*

119. The most commonly reported withdrawal symptoms from clinical investigations are sleep difficulties, decreased appetite and weight loss, craving, irritability, anger, anxiety or nervousness, and restlessness. ALJ Exh. 1 at 60. Less commonly reported withdrawal symptoms include depressed mood, sweating, shakiness, physical discomfort, and chills. *Id.*

120. Physical dependence may occur in up to 40-50% of individuals who use marijuana on a regular basis, but the symptoms associated with marijuana withdrawal are relatively mild compared to alcohol, heroin, and opioids. ALJ Exh. 1 at 60; Burchman, Tr. 595-597.

Opioid comparison

121. While opioids provide pain reduction, opioids result in habituation or tolerance wherein the patient must take increased amounts of the opioid to quell the pain until the high doses no longer work. Burchman, Tr. 592-593. Habituation with marijuana occurs as well, but to a far less extent than the habituation experienced by opioid patients. *Id.*

122. Downregulation is when opioid receptors shrink and do not work as well, requiring the patient to consume more opioids. If the patient continues to take more opioids to ease their pain, they will become addicted. If they decrease their dose, they will go through withdrawal. Burchman, Tr. 945-947.

123. Opioid withdrawal is also far more uncomfortable to patients than marijuana withdrawal. While patients suffering marijuana withdrawal suffer sleepiness and anxiety, the symptoms are mild in comparison to opioid withdrawal, which is "horrific," protracted, and may result in death. Burchman, Tr. 595-597.

<u>Factor Eight: Whether the substance is an immediate precursor of a substance already controlled under this subchapter</u>

124. Marijuana is not an immediate precursor of another controlled substance. ALJ Exh. 1 at 62.

V. PROPOSED CONCLUSIONS OF LAW

A. Marijuana has a currently accepted medical use for rescheduling purposes.

i. HHS appropriately utilized the two-part test to determine CAMU for marijuana.

FDA may use any of three avenues to determine whether a substance has CAMU: 1) FDA approval of a new drug application wherein the active ingredient in that drug, if it needs to be controlled; 2) DEA's five-part test; and 3) HHS' Two-Part CAMU test. *See* Chiapperino, Tr. 53:6-25, 54:1-6; Gov't Exh. 4 at 12-18. All three avenues are legitimate methods of assessment; the FDA can consider any of the three tests that lead to a finding of CAMU. Chiapperino, Tr. 414:18-20; Gov't Exh. 4 at 12-18. In the absence of an FDA approval, [FDA] will consider both the relevance of the five-point test and the relevance of the two-part test. *Id.* at Tr. 414:20-22. The five-part test is akin to a new drug application for FDA approval and thus relies on replicated controlled studies of a product that can be easily reproduced to an exacting degree for controlled trial purposes. Gov't Exh. 4 at 12-18. The five-factors of DEA's prior CAMU test are based on the "core FDCA standards for acceptance of drugs for medical use" and four of the five factors were "expressly derived from the FDCA or FDA regulations setting forth requirements that a drug must meet before receiving FDA approval." *Id.* at 9, citing 57 Fed. Reg. at 10,504-05.

1. *The OLC opinion is binding on DEA*

On April 11, 2024, OLC issued a memorandum opinion for the Attorney General titled *Questions Related to the Potential Rescheduling of Marijuana*. The Attorney General has the authority to provide advice and opinion on questions of law to the President and heads of departments. 28 U.S.C. §§ 511-512, 28 CFR 0.5(c). The Attorney General delegated this authority to the Assistant Attorney General OLC pursuant to his authority under 28 U.S.C. §§ 510. 28 CFR 0.25.

OLC memoranda "are binding on the Department of Justice and other Executive Branch agencies and represent the official position of those arms of government." *Tenaska Washington Partners, L.P. v United States*, 34 Fed. Cl. 434, 439; *see also Cherichel v. Holder*, 591 F.3d 1002, 1016 n. 17 (8th Cir. 2010). The *Tenaska* Court noted that the OLC memorandum at issue was extensively researched and reviewed and involved "input from several divisions and other offices, as well as high-ranking offices of the Department of Justice." *Id.* Although the *Tenaska* OLC opinion substantially changed the prior views of the Department, it was binding on the Executive Branch.

While *all* AG memos and OLC opinions may not be binding on the Executive Branch,[7] the OLC opinion on marijuana rescheduling is binding on DEA.[8] The OLC opinion herein, like the one in *Tenaska*, was "thoroughly analyzed the relevant legal issues and offered a reasoned opinion as to the constitutional concerns present in that case." *See City of Seattle v. Trump,* No. 17-497-RAJ, 2017 U.S. Dist. LEXIS 173376, at *12 (W.D. Wash. Oct. 19, 2017); *see also* Tenaska, *34 Fed. Cl. at 439.* Unlike the two pages in the AG memo for the 2017 EO in *Santa Clara* and *Seattle*, the marijuana OLC opinion assessed the CAMU legal framework within the rescheduling context for 36 pages, inclusive of significant legal debate and analysis.

The "head of an executive department may require the opinion of the Attorney General on questions of law arising in the administration of his department." 28 U.S.C. § 512. The

[7] *See, e.g., City of Santa Clara v. Trump*. 275 F. Supp. 3d 1196, 1212 (N.D. Cal. 2017) (holding that it is not conclusively established "that all Attorney General Memoranda are binding on the Executive Branches"); *City of Seattle v. Trump,* No. 17-497-RAJ, 2017 U.S. Dist. LEXIS 173376, *8, 12 (finding the Attorney General memorandum at issue did not offer any "legal interpretations or determinations" and was without sufficient legal analysis to render it a legal opinion).

[8] The *Santa Clara* and *Seattle* cases note that the memo at issue in their matters was an AG memo and that one at issue in *Tenaska* is an Office of Legal Counsel opinion, but they do not address any legal distinctions between the two types of legal memorandums and ultimately find that the AG memo is not a legal opinion and does not bind the executive agencies. For the purposes of this argument, the Government will treat the OLC opinions and AG memos as synonymous.

marijuana OLC opinion was requested by the Attorney General to address the legal distinction between the historic five-part CAMU test and HHS' new two-part CAMU test used for botanical marijuana. Gov't Exh. 4 at 3. OLC opinions are often used to resolve disagreements between federal agencies and thus was appropriate here. This OLC opinion is a reasoned legal opinion, that was thoroughly researched to address a question impacting several federal agencies concerning the legal sufficiency of a newly developed test for drug rescheduling and is binding on DEA. *See Tenaska*, 34 Fed. Cl. 434.[9]

2. *OLC Opinion Findings*

OLC concluded that DEA's current approach to determine whether a drug has CAMU through the application of its five-part test is impermissibly narrow. Further, satisfying HHS's two-part inquiry is sufficient to establish that a drug has a CAMU even if the drug has not been approved by FDA and would not satisfy DEA's five-part test. Gov't Exh. 4 at 4. After the initiation of formal rulemaking, DEA must accord HHS's scientific and medical determinations "significant deference" and may not undertake a *de novo* assessment of HHS's findings at any point in the process. *Id.* DEA may place marijuana in the schedule most aligned with its properties and may create its own test to determine where marijuana best fits. The only tests presented to this Court at the hearing were the two-part CAMU test, which has been OLC-approved, and the five-part test that OLC determined was insufficient for this purpose.

[9] Alternatively, if this Court were to find that it is not legally binding, DEA should treat the OLC opinion as binding as a matter of custom. *See Campaign for Accountability v. Department of Justice*, No.24-5163 (D.C. Cir. 2025); Memorandum from David J. Barron, Acting Assistant Attorney General, to Attorneys of the Office of Legal Counsel 1 (July 16, 2010) (Best Practices Mem.). OLC opinions are "nearly universally regarding as binding on the executive branch." *Article: The Practice of Executive Constitutionalism*, 111 Va. L. Rev. 1530, *1576, (Dec 2025). In 2010, OLC said that its "core function, pursuant to the Attorney General's delegation, is to provide controlling advice to Executive Branch officials on questions of law that are centrally important to the functioning of the Federal Government. *Id.*; 2010 Best Practices Memorandum, *supra* note 79, at 1. This Honorable Court should consider the OLC opinion binding and hold that, as a result, HHS' two-part CAMU test was sufficient to establish CAMU for rescheduling purposes.

Further, OLC opined that any CAMU test the DEA chooses to utilize must contain an evaluation of whether at the present time the medical community widely understands that a drug has a "use in treatment in the US" and consideration of the scientific evidence that supports the relevant use. Gov't Exh. 4 at 14-17. In fact, when these circumstances [the widespread current experience with medical use of a Schedule I drug . . . by licensed health care professionals operating in accordance with implementing state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine] exist, the plain text of section 812 mandates that they be taken into account when determining whether a drug has CAMU." *Id*. at 16. These considerations provide good evidence of whether there is widespread agreement within the medical community that using the drug would be a reasonable treatment option. *Id*. at 18-19.

ii. DEA must provide HHS's scientific and medical determinations "significant deference" and cannot perform a "'*de novo*' assessment of HHS's findings at any point in the process."

Pursuant to the OLC opinion, DEA must afford HHS's scientific and medical determinations *significant* deference. Gov't Exh. 4 at 23-26. "Defer" is defined as yielding to another's judgment. Defer, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/defer (last visited Aug. 13, 2026). While DEA is not prohibited from a thoughtful review of the HHS materials, it may not perform an entirely new (*e.g. de novo*) assessment of HHS' eight-factor findings on marijuana's medical and scientific properties. These findings include routine reference to studies that showed marijuana has CAMU for various conditions. To overturn HHS's findings, DEA must find that contrary medical and scientific findings presented by the Opposed Parties are strong enough to rebut those presented by HHS. *See* Gov't Exh. 4 at 23-26. The Opposed Parties have failed to do so.

iii. Marijuana has CAMU for chronic pain, anorexia/wasting, nausea and vomiting.

The Government's witnesses, along with several opposition party witnesses, testified that marijuana has a medicinal use. This was borne out by the science and practical application in medical practices nationwide. FDA's internal assessment, along with the University of Florida's separate, parallel review, identified medical studies in support of marijuana's use for the treatment of the CAMU conditions.

The Opposed Parties' scientists also testified that marijuana has been shown in studies to provide therapeutic benefits to patients suffering from those conditions. Specifically, Dr. Finn agreed that there are components of marijuana that can be "beneficial in medicine" and that he has recommended the use of marijuana for the treatment of pain. Finn, Tr. 1617:15-21, 1670:15-22. Additionally, Dr. Madras, through her testimony and demonstrative exhibit, noted the benefits of marijuana in specific areas to include, cachexia/wasting syndrome, secondary effects on appetite and pain for cancer patients, neuropathic pain, and in cases of severe nausea. SAM Exh. 47 at 13, 16; Madras Tr. 1230. Lastly, Dr. Deepak D'Souza (D'Souza) testified a scientific study showed a standardized full spectrum extract from cannabis sativa had a beneficial impact on pain, as compared to a placebo. D'Souza Tr. 2255:7-25, 2261:10-13; *see also* Opposed States Exh. 17, 19, (D'Souza studies recognizing positive benefits re: nausea and anorexia). As such, testimony from both Government and Opposed Parties alike support the Government's position that marijuana does, in fact, provide some benefit for patients with the CAMU conditions.

A substance may be contraindicated for a condition for which it is not recommended, but that does not mean the medication is any less beneficial for the recommended therapy.
No party presented any evidence at the hearing that suggested a CAMU finding requires a substance to have no effect on any other condition or ailment. As noted throughout the hearing, other scheduled substances with accepted medical uses are contraindicated for other conditions.

While the Government is sensitive to the contraindications of marijuana, these risks do not rebut a finding of CAMU.

In contravention to the Government's use of an approved test for CAMU, the Opposed Parties improperly relied on DEA and FDA's impermissibly narrow prior five-point test for CAMU, which cannot be used to establish CAMU for marijuana. Specifically, Dr. Madras testified that the studies supporting therapeutic use for the CAMU conditions were not strong enough to pass FDA's new drug application process. Madras, Tr. 1230:18-24. The FDA new drug application process, however, relies on an entirely different standard than the one at issue herein. She admitted in her testimony that there are studies in support of the CAMU conditions, as did Dr. Finn. Tr. 1617: 24-25, 1618:1-4, 1620:12-20, 1629: 9-10, 1670: 15-22.

Drs. Burchman and Finn were the only pain management physicians who testified at the hearing, and both have, at some point in their careers, recommended marijuana to patients for the treatment of chronic pain. Dr. Burchman testified at length about his patients' success using marijuana to transition from chronic opioid use, the significant differences in severity of withdraw from opioids versus marijuana, and hundreds of patients he has lost from opioid overdoses compared to no patients lost to marijuana. Burchman, Tr. 579-581, 595-597, 593-595. Dr. Finn admitted that he recommended marijuana to his chronic pain patients and while he does not currently recommend marijuana for that patient population, his concerns are namely the dosing and control of the product. Finn, Tr. 1610:1-17, 1617:24-25, 1618:1-4, 1620:12-20, 1629:9-10, 1670:15-22.

By considering whether a substantial number of licensed health care providers have gained clinical experience with a drug under state-authorized programs, HHS determined whether there is widespread agreement within the medical community that using the drug would be a reasonable treatment option. *See* Gov't Exh. 4 at 18-19. FDA's assessment of marijuana use

by way of the Minnesota and Maryland state studies, coupled with Dr. Burchman's testimony about New Hampshire's state dispensing practice, bolster the Government's position that marijuana is presently being utilized by health care practitioners to treat certain medical conditions.

B. Marijuana has safely been accepted for use under medical supervision.

Marijuana currently has widespread use as a treatment method for medical conditions. OASH found that more than 30,000 health care practitioners across 43 jurisdictions are authorized to recommend the use of marijuana for more than six million registered patients, constituting widespread clinical experience associated with various medical conditions recognized by a substantial number of jurisdictions across the United States. ALJ Exh. 1 at 25, 119. For some jurisdictions, programs have been in place for several years and include features that actively monitor medical use and product quality characteristics of the marijuana dispensed. *Id.* OASH also discovered that marijuana was being recommended for treatment for at least 15 medical conditions. *Id.* at 79.

Marijuana is also being prescribed safely. This is demonstrated by the fact that several of the jurisdictions that allow marijuana for treatment purposes require additional training by its respective health care practitioners. Ten jurisdictions require specific education on the use of marijuana prior to recommending marijuana for medical conditions. *Id.* at 81. Two states require practitioners to pass an exam for certification to prescribe marijuana. *Id.* HHS specifically examined two state programs – Maryland and Minnesota – where marijuana was recommended for treatment by health care practitioners. In Maryland, for the patients using marijuana for therapeutic indications, the program reported very low incidences of safety concerns and adverse events. Chiapperino, Tr. 69:12-21. In Minnesota, marijuana was used with a reasonable amount of safety. Chiapperino, Tr. 71:4-7.

Witnesses from both the Government and Opposed Parties support the safe use of marijuana under medical supervision. Dr. Burchman safely transitioned multiple chronic pain patients from opioids to marijuana. Burchman, Tr. 579:4, 581:5. Dr. Finn testified that he has recommended marijuana to patients for the treatment of pain.[10] Finn, Tr. 1617:24-25, 1618:1-4, 1670:15-20. HHS' findings about the number of physicians who recommend marijuana across 43 U.S. jurisdictions and real-life experiences of Drs. Burchman and Finn support the Government's position that marijuana has accepted for use under medical supervision.

C. Because marijuana has a currently accepted medical use and has safely been accepted for use under medical supervision, it cannot remain a Schedule I controlled substance.

Marijuana no longer fits the statutory requirements for Schedule I because it has a currently accepted medical use within the United States and it has an accepted safety for its use under medical supervision. 21 U.S.C. § 812(b)(1) mandates that a Schedule I controlled substance has no currently accepted medical use in treatment in the United States and that there is a lack of accepted safety for use of the drug under medical supervision. As discussed above, marijuana has CAMU in treating three therapeutic conditions – pain, anorexia as a medical condition, and nausea and vomiting in conjunction with chemotherapy. Marijuana is being considered for treatment by 30,000 health care practitioners throughout 43 jurisdictions, which demonstrates that it has safely been accepted for use under medical supervision. As such, marijuana no longer satisfies the statutory requirements to remain in Schedule I.

[10] As described below, the Government believes Dr. Finn's testimony should be given no weight due to his disregard for the Tribunal's instructions for sequestered testimony. However, should the Tribunal choose to give any consideration to Dr. Finn's testimony, the Government highlights portions of his testimony where admits to recommending marijuana to his pain patients.

D. FDA's recommendation for placement of marijuana in Schedule III is well supported in the record.

i. Marijuana's potential for abuse is better aligned with Schedule III, than Schedule I.

Marijuana's potential for abuse falls below that of Schedule I controlled substances. Marijuana, including those products with high levels of Δ9-THC, has fewer negative and less serious outcomes compared to drugs in schedules I or II. ALJ Exh. 1 at 62-63. Epidemiological data, like population adjusted rates for emergency department visits and hospitalizations, the likelihood of being diagnosed with a serious substance use disorder, deaths reports to poison control centers, and overdose deaths when used with other drugs or as a single substance, support the position that the use of marijuana has fewer negative outcomes compared to other substances in Schedule I. *Id.*

Overall, the utilization adjusted rate of diverse outcomes involving marijuana like poison control reports, emergency department visits, and overdose deaths was consistently lower than the utilization adjusted rates of adverse outcomes involving comparators Schedule I or II substances like heroin, cocaine, fentanyl, hydrocodone, or oxycodone and even lower than some Schedule III and IV substances like ketamine and benzodiazepines. *Id.* at 8-9, 39-46. In comparison to other Schedule I or II controlled substances, the epidemiological data, like reports from poison control centers and emergency departments, support the position that the abuse of marijuana is less severe than other substances in Schedules I or II, as marijuana is not typically among the substances producing the most frequent or severe incidences of adverse outcomes.

ii. Marijuana's dependance profiles are better aligned with Schedule III than Schedule II.

When comparing marijuana to the comparator substances (heroin, fentanyl, oxycodone, hydrocodone, cocaine, ketamine, benzodiazepines, zolpidem, and tramadol), marijuana skews very heavily toward mild substance use disorder. Chiapperino, Tr. 81:8-12. In contrast, the

comparator substances have a higher proportion of moderate and severe substance use disorder. *Id.* at 81:18-20. While marijuana can produce some psychic dependence in some individuals, the likelihood of serious outcomes is low, suggesting that high psychological dependence does not occur in most individuals who use marijuana. ALJ Exh. 1 at 66. When comparing marijuana to the comparator substances, marijuana is not typically amongst the substances producing the most frequent incidence of adverse outcomes or severity of substance use disorder. *Id*. at 10.

Physical dependence is a state of adaption, manifested by withdrawal symptoms produced by abrupt cessation. ALJ Exh. 1 at 60. The withdrawal symptoms associated with marijuana are relatively mild compared to heroin and opioids. *Id.* Dr. Burchman corroborated this sentiment, noting that opioid withdrawal is far more uncomfortable to patients than marijuana withdrawal. Individuals going through marijuana withdrawal may experience sleep difficulties, decreased appetite and weight loss, craving, irritability, anger, anxiety or nervousness, and restlessness. ALJ Exh. 1 at 60. Uncommon symptoms include depressed mood, sweating, shakiness, physical discomfort, and chills. *Id*. Marijuana withdrawal symptoms are generally not clinical symptoms that would bring somebody to a hospital. Burchman, Tr. 597:6-8. Further, marijuana withdrawal symptoms are mild in comparison to opioid withdrawal, which is "horrific," protracted, and may result in death. Burchman, Tr. 595-597. Thus, abuse of marijuana leads to low to moderate physical dependence. Because marijuana's potential for abuse and dependency profiles align most similarly to other substances in Schedule III, marijuana should be transferred from Schedule I to Schedule III.

E. Although multiple witnesses testified as an expert, several witnesses lacked necessary reliability and credibility and should be afforded no weight.

Pursuant to this Court's June 18, 2026 Preliminary Order, "[a]ll expert determinations will be made following the hearing and objections to expert qualifications should be made in writing." Prelim. Order, at 5. Experts must have expertise and their opinions "must be supported

by substantial and reliable evidence." *Trinity Pharmacy* II, 83 FR 7304, 7324 (2018) (internal citation omitted). The ALJ determines the weight to be accorded the expert's testimony. See *Id. see also* FRE 702; *United States ex rel. Raggio v. Jacintoport Int'l*, LLC, 2015 U.S. Dist. LEXIS 197849, *23-26 (D.D.C. 2015).

i. Dr Burchman testified with reliable expertise and should be accepted as an expert witness.

Government witness Dr. Corey Burchman testified before this Tribunal about his medical training and extensive experience treating pain patients with marijuana and opioids alike. Dr. Burchman's credentials and clinical experience qualify him as a medical expert in the treatment of pain using marijuana and opioids. The Federal Rules of Evidence Rule 702 govern the parameters for testimony by expert witnesses, stating that "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
(b) the testimony is based on sufficient facts or data;
(c) the testimony is the product of reliable principles and methods; and
(d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case."

Dr. Burchman's training, knowledge, and experience fit squarely into the expert witness qualifications contemplated by the Federal Rules of Evidence. As discussed further below, his testimony about his clinical experience is invaluable in assisting the Tribunal in determining whether marijuana has CAMU and should be accorded great weight.

Dr. Burchman is a board-certified physician who held a special designation in pain management and currently holds a designation in anesthesiology. Gov't Exh. 6; Burchman, Tr. 548-550. He graduated medical school from George Washington University, completed several

internships and residencies, and treated acute and chronic pain patients from approximately 1983 until he retired from his Dartmouth-affiliated practice in 2019. Gov't Exh. 6; Burchman, Tr. 514:15-25, 550:22-24, 551-556, 558-560. He was appointed by the Governor of New Hampshire in 2018 to the Therapeutic Medical Cannabis Oversight Board, where he still volunteers and provides medical guidance on the use of marijuana for various conditions and symptoms and routinely reviews the medical science and literature on the therapeutic use of marijuana, particularly in the treatment of pain. Burchman, Tr. 544-546. Multiple state courts have recognized and designated Dr. Burchman as a medical expert at trial. Burchman, Tr. 564:7-16.

Dr. Burchman has treated approximately ten thousand chronic pain patients with opioids, and, after New Hampshire allowed the use of marijuana for the treatment of chronic pain in 2016, he transitioned several hundred patients from opioids to marijuana. Burchman, Tr. 564-565. Dr. Burchman noted that, in his medical opinion, "marijuana is extremely helpful in chronic pain patients as an effective means of analgesia" (*Id.* at Tr. 581:14-23), that marijuana was a "viable and useful tool in the pain practitioner's toolbox, particularly to transition patients from opioids" (*Id.* at Tr. 591:2-15), and that it was specifically beneficial for chronic pain patients. *Id.* at Tr. 591-592. He further opined that botanical marijuana provides a substantially greater benefit than synthetic THC or opioids for chronic pain patients. *Id.*, at Tr. 591-592, 607:16-25.

Dr. Burchman's prior and current board certifications and close to 30 years of direct patient care of pain patients provides the specialized knowledge to assist the trier of fact determine whether marijuana provides a therapeutic benefit to chronic pain patients. *Id.*; *see also* FRE 702; *United States ex rel. Raggio* at *23-26.

Dr. Burchman possesses the requisite qualifications and expertise to testify about his treatment of chronic pain patients with marijuana, the significant benefits it provided to those patients compared to the severe habituation, withdrawal and overdose-causing-death concerns he

observed when his patients took long-term opioids. His testimony will assist the finder of fact in ultimately determining whether marijuana has CAMU and what Schedule it should be placed in. Dr. Burchman's expert designation should be accepted by this Court and his medical opinions afforded significant weight. *See Trinity Pharmacy II*, 83 FR 7304, 7324 (2018).

ii. Witnesses who testified outside the scope of their expertise and whose testimony on those subjects should be afforded no weight by this tribunal.

The Opposed Parties called several witnesses and attempted to designate them as expert witnesses. Many of the so-called expert witnesses do not have the qualifications to be recognized as an expert witness. For the ones who actually possessed the requisite credentials to be recognized as an expert in their respective fields, the Opposed Party solicited testimony that was well beyond the scope of their expertise or asked them to opine on matters that are not relevant to the ultimate issue. The Tribunal should give such testimony little to no weight.

Dr. D'Souza was proffered as an expert in five areas: the pathophysiology of psychotic disorders, conducting clinical trials, peer review process for medical research, uses of marijuana for medical purposes, and effects of marijuana on the human brain and body. D'Souza, Tr. 2224:14-21. The Opposed States, however, solicited testimony from Dr. D'Souza about pain management, which is outside Dr. D'Souza's admitted expertise. D'Souza, Tr. 2225:5-6. Dr. D'Souza himself limited his own expertise to the practice and field of psychiatry. D'Souza, Tr. 2225:5-6. As such, any testimony from Dr. D'Souza outside of his own proffered expertise should be given little to no weight by this Tribunal.

iii. Opposed Parties witnesses proffered testimony irrelevant to the ultimate issue.

Other Opposed Parties called witnesses who offered testimony irrelevant to the ultimate issue: whether marijuana has CAMU and its appropriate scheduling. For example:

- Two witnesses focused their testimony on workplace safety concerns: Patrice Kelly's[11] testimony focused solely on hypothetical, future hurdles that may or may not present themselves in workplace drug testing;[12] and

- Jo McGuire based her opposition to rescheduling marijuana on the hypothetical assumption that testing in the workplace may become difficult, though not impossible.[13]

- DUID Victim's Voices proffered Ed Wood[14] as an expert witness on drugged driving. Mr. Wood testified extensively against the *legalization* of marijuana, not the *regulation* of marijuana.[15] Mr. Wood also provided irrelevant and speculative testimony regarding impacts on marijuana prosecutions and law enforcement impairment testing.

- Laura Stack spoke about the personal and tragic impact of marijuana on her life.[16]

- Special Agent in Charge Erica Stephens provided testimony about her personal experiences working with marijuana from an enforcement and testing perspective and spoke about marijuana's "deregulation" and "legalization."[17]

- Dr. Karen Randall, who was proffered as an expert in the field of emergency medicine with a specialty in pediatric medicine and a certificate in cannabis medicine and science, focused her testimony on the dangers of adolescents consuming marijuana.[18]

- Sheriff William Honsal, who was proffered as an expert[19] in crime associated with marijuana, marijuana diversion, and the effects of marijuana legalization, testified about the issues and impact of marijuana in Humboldt County, California.

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[11] As objected to on the record, NDASA failed to provide any proper or sufficient notice as to her purpose or testimony. *See* NDASA PHS; Tr. 1021. 1-18. Additionally, despite this lack of notice, NDASA attempted to provide Ms. Kelly as a legal expert in federal drug testing. Kelly Tr. 1021:21-25, 1022, 1-2, 1023, 13-21. *See Crow Tribe of Indians v. Racicot*, 87 F.3d 1039, 1045 (9th Cir. 1996)(stating the law is clear that "[e]xpert testimony is not proper for issues of law").

[12] Kelly, Tr. 1028:5-6, 1031:19-21, 1040:1-5, 1041:3-9, 1044:1-5

[13] McGuire, Tr. 120-122, 134:22-25, 135:1-7.

[14] Mr. Wood disregarded the Tribunal's instructions that all witnesses were to be sequestered and not observe testimony until properly excused by the Tribunal. ALJ Preliminary Order at 5. Mr. Wood admitted to reviewing and analyzing the testimony of the Government's witnesses prior to his testimony. Wood, Tr. 1503:9. Such influence was on display throughout Mr. Wood's testimony as he commented on specific phrasing and statements of Government witnesses. Wood, Tr. 1502-1503. This disregard for the Tribunal's instruction led to a fatal bias in testimony that is unable to be cured other than providing little to no weight to the testimony of Wood. Wood, Tr. 1509-1511.

[15] Wood, Tr. 1145:8-25.

[16] The Government acknowledges the personal impact of Ms. Stack's testimony and commends her testimony.

[17] Stephens, Tr. 1808:17-25, 1820:10-25, 1830:21-25, 1837:8-25, 1838:1-5.

[18] Randall, Tr. 2065:18-22.

[19] The Opposed States failed, in any meaningful capacity, to properly notice Sheriff Honsal as an expert at any point prior to his testimony. Honsal, Tr: 2420:21-25, 2421:1-2. As a witness for the Opposed States, Sheriff Honsal admitted he has no meaningful connection to Nebraska, Idaho or Indiana. Honsal, Tr. 2491-2493.

None of these witnesses provided relevant information sufficient to overcome HHS's CAMU determination and recommendation that marijuana should be rescheduled.

iv. Witnesses who disregarded the Tribunal's admonition for sequestration

Mr. Wood[20] and Dr. Finn[21] ignored the Tribunal's instructions for sequestration.[22] Both admitted to reading and reviewing the transcripts of the testimony tendered prior to their appearances on the stand. Their testimony has been irreparably tainted and cannot be cured other than providing it little to no weight.

v. Other Witnesses from the Opposed Parties

Dr. Phillip A. Drum, testifying on his own behalf, tendered himself as an expert in the field of hospital pharmacy practice with vast knowledge in the area of marijuana and impaired driving. Drum, Tr. 1901:19-25, 1902:1-3. Dr. Drum testified that, in his opinion, there is no scientific indication or medical use for a plant-based marijuana product despite agreeing that doctors and pharmacists reviewing such studies may come to different conclusions and opinions. Drum, Tr. 1902:8-15, 1903:7, 12, 1905:3-5, 2000:3-21. Dr. Drum testified that Schedule II "would be potentially more appropriate level for marijuana" because of its rapid absorption." Drum, Tr. 1912:9-15. To this point, Dr. Dum focused portions of his testimony on completely irrelevant product marketing, packaging inserts, and the perceived difficulty for a pharmacist to accurately decipher the appropriate amount to dispense to a patient. Drum, Tr. 1909:1-24, 1910: 1-21, 1917:14-17, 1972: 6-7.[23] Further, Dr. Drum's opinion on marijuana's medical use for specific conditions, primarily cachexia and cancer pain patients, is limited to his personal experience with two patients. Drum, Tr. 1925-1927.

[20] Wood, Tr.1502-1503.
[21] Finn, 1572-1573.
[22] ALJ Preliminary Order at 5; ALJ Standing Order re Parties at 4.
[23] In Dr. Drum's own summary of his testimony, he let the Tribunal know that his focus is on "federal oversight" and stronger testing, reporting, packaging inserts, not the ultimate issue of CAMU. Drum, Tr. 1995-1996.

Dr. Drum testified regarding the effects of marijuana on various demographics to include pregnant women and combat veterans. Drum, Tr. 1910:19, 1953:24-25, 1954:1-22, 1969:24, 1970:1-24. Such testimony was well outside of Dr. Drum's proffered expertise and no proper foundation for such opinion was ever laid for such testimony. Dr. Drum's testimony is also irrelevant to the conditions for which a CAMU determination has been demonstrated by the Government.

VI. CONCLUSION

Marijuana can no longer remain in Schedule I because it no longer satisfies two of the three statutory requirements of 21 U.S.C. § 812(b): whether it has CAMU and whether there is accepted safety its use under medical supervision. As discussed above, this Tribunal need only find that marijuana has CAMU for one medical condition for marijuana to be transferred out of Schedule I. HHS' recommendation found that marijuana had CAMU for not one, but three, therapeutic conditions. In addition, it can no longer be said that there is a lack of accepted safety for use of marijuana under medical supervision as 38 states have established regulatory regimes that have allowed over 30, 000 doctors to treat more than six million patients. None of the testimony from the Opposed Parties contradict these findings.

Marijuana most appropriately belongs in Schedule III because its abuse potential and dependency profile most align with those substances in Schedule III. Marijuana's abuse potential is less than the comparator substances in Schedules I and II. While marijuana can produce psychological dependence, the likelihood of serious adverse outcomes is low when compared to the comparator substances in Schedules I and II. Marijuana has low to moderate physical dependence, as evidenced from its withdrawal symptoms, which are relatively mild compared to heroin and opioids. Once again, none of the testimony from the Opposed Parties contradict these findings.

For these reasons, the Government respectfully request that this Tribunal recommend marijuana be transferred from Schedule I to Schedule III.

Respectfully Submitted,

Dated: August 17, 2026

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Certificate of Service

I hereby certify that on August 17, 2026, I electronically submitted the foregoing Government's Post Hearing Brief to the DEA Office of Administrative Law Judges via the DEA Judicial Mailbox, at ECF-NPRM@dea.gov, and so caused a copy to be delivered to the following recipients:

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