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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Jennifer N. Murphey, individually and on behalf of all others similarly situated, Plaintiff, v. The United States of America; Merrick B. Garland, United States Attorney General, United States Department of Justice; Anne Milgram, Administrator of the United States Drug Enforcement Administration; and Mark Brnovich, Attorney General of the State of Arizona, Defendants.	Case No.: COMPLAINT

Plaintiff brings this action, individually and behalf of all others similarly situated, seeking declaratory and injunctive relief for constitutional and Administrative Procedure Act violations by Defendants with regard to the Controlled Substances Act (CSA), the Arizona Controlled Substances Act (AZCSA), the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances.

The CSA is one of the deadliest laws in American history, contributing to at least one million deaths, and countless societal harms. Americans are now more likely to die

from overdose than motor vehicles accidents. This landmark law, originally touted to combat drug abuse and protect the safety and welfare of Americans, has perpetuated the exact opposite. One of its true purposes, to oppress blacks and those whose beliefs did not align with the government, is no secret and we have the benefit of 52 years of data showing the success of this depraved purpose, yet the CSA persists.[1]

The CSA limits drug treatment for many mental and physical conditions to that created and aggressively marketed by pharmaceutical companies, which, more often than not, causes addiction, dependency, and additional, often worse, medical conditions, thereby keeping Americans dependent on commercial drugs. The CSA enables the misinformation perpetuated by pharmaceutical companies and their continued profitability, all at the expense of individual safety, well-being, and cognitive liberty.

Many Americans have had at least some faith that proper drug evaluations were and are being conducted prior to control through the CSA. Many Americans believed the propaganda created by Defendants which falsified the effects of certain substances, and thereby, unwittingly supported a law that told us plants, like marijuana, are dangerous, but commercial pharmaceutical drugs are not. This trust transferred to the medical community, who is bound by the CSA and who is indoctrinated, as early as medical school, by the misinformation spread by pharmaceutical companies and propaganda. The veil is being

[1] "You want to know what this [war on drugs] was really all about? The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the antiwar left and black people. You understand what I'm saying? We knew we couldn't make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did." John Ehrlichman, Assistant to the President for Domestic Affairs under President Richard Nixon

lifted and that trust is broken.

What we are permitted and limited to placing in our own bodies for our own well-being is far too important of a subject matter to place in the hands of a law enforcement agency, especially one whose primary objective is allegedly to control drug trafficking, assumptively to have its hands in a lucrative industry and control the free thinking of Americans. It is also far too important of a subject matter to be handled in the arbitrary, bias, careless, misleading, and harmful way in which it has been handled thus far.

The CSA, as the driving force behind mass addiction, incarceration, deaths, and drug prohibition-related crime has affected virtually every American family. Thousands, if not millions, of good people now walk around believing they are bad, weak, and worthless because of an addiction, which most often starts with a prescription, or because they have been branded with a disorder or as a criminal. They carry massive amounts of shame and guilt. Many of our loved ones are mere shells of their former selves. We have failed our fellow humans, our brothers and sisters, by allowing this to persist, especially in light of 52 years of ongoing data showing the CSA's destruction. I am tired of seeing my loved ones, and strangers alike, truly believing they are worthless. These are good people from whom society as a whole would benefit with their well-being and success.

There are ones who will keep us sleeping and there are ones who will bring the dawn. I pray the Court will be the latter and, with the power invested in it, liberate the American people from one of the most harmful and deadliest laws in our history. To do otherwise is to say Americans cannot be trusted with our personal thoughts, intentions, and decisions pertaining to our own minds, bodies and spirits. There is nothing in law supporting such an egregious conclusion.

JURISDICTION AND VENUE

1. This action arises under the Constitution, laws and treaties of the United States, 42 U.S.C. § 1983, and the Constitution and laws of the State of Arizona.

2. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1367 and 5 U.S.C. § 702. This Court also has jurisdiction under 28 U.S.C. § 1343(a)(3) to redress deprivations "under color of any State law, statute, [or] ordinance . . . of any right, privilege or immunity secured by the Constitution of the United States," and under 28 U.S.C. § 1346 (United States as a defendant). As explained in more detail below, there is a present and actual controversy between the parties that is ripe for judicial review.

3. Pursuant to 28 U.S.C. § 2201-2202 and 5 U.S.C. § 706, this Court has the authority to grant declaratory relief and to issue preliminary and permanent injunctions.

4. This Court has personal jurisdiction over Defendants and their officials because Defendants are officials of agencies of the federal government operating within the United States.

5. Venue is proper in this district under 28 U.S.C. § 1391(b) & (e).

PARTIES

6. Plaintiff, Jennifer N. Murphey, is a resident of and an attorney licensed to practice law in the State of Arizona. She is subject to the provisions and criminal penalties of the CSA, AZCSA, and the relevant international treaties.

7. Defendant the United States of America is a party to the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances and is responsible for carrying out its obligations thereunder.

8. Defendant Merrick B. Garland is the Attorney General of the United States,

the principal officer of the Department of Justice, and is responsible for the execution and enforcement of the CSA.

9. Defendant Anne Milgram is the Administrator of the United States Drug Enforcement Agency (DEA). Under delegated authority, the DEA implements the CSA.

10. Defendant Mark Brnovich is the Attorney General of the State of Arizona and is responsible for the execution and enforcement of the AZCSA.

INTRODUCTION

11. When it comes to personal choice, wellbeing and the substances Americans are permitted to place or prohibited from placing in their own bodies, it cannot be understated the criticality of full-disclosure, accuracy, thorough unbiased analysis, transparency, prompt consideration of all new, evolving, and relevant information, and the freedom of meaningful choice with regard to our minds, bodies, and spirits. The CSA and its execution satisfy none of these critical elements in any meaningful manner.

12. The Attorney General and DEA, through the CSA, are responsible for ensuring the health and general welfare of all Americans. They have abused their discretion and consistently failed this responsibility, perpetuating the opposite, by ignoring the known dangers of currently prescribed medications and spreading misinformation to the general public and the medical community. This failure, along with haphazard, arbitrary and bias decision making, and prohibition of safe alternatives to prescribed medications, has ultimately led to the harm and cognitive control and suppression of millions of people.

FACTUAL ALLEGATIONS

I. CONTROLLED SUBSTANCES ACT FRAMEWORK

13. The CSA, 21 U.S.C. § 801 *et seq*., provides the primary framework

governing the scheduling, manufacture, distribution, and dispensing of controlled substances.

14. The CSA places substances, natural, synthetic or otherwise, into one of five schedules allegedly based on their potential for abuse or dependence, their accepted medical use, and their accepted safety for use under medical supervision.

15. Controlled substances are assigned to schedules based on the following findings:

(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.

(2) Schedule II. -
(A) The drug or other substance has a high potential for abuse.
(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(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.

(4) Schedule IV. -
(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
(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 limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V. -

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(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 limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

21 U.S.C. § 812.

16. The United States Attorney General is charged with making the findings required for any scheduling decisions, including adding substances to the schedules and re- or descheduling substances, by considering the following the following eight factors for each substance it proposes to control or remove 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.

Id. § 811.

17. Prior to controlling a substance, the Secretary of Health and Human Services (HHS) must evaluate the substance and make a scheduling recommendation based on the eight factors above and submit to the DEA, who is then bound by the Secretary's recommendations with regard to scientific and medical matters. The Secretary delegates the substance evaluation process to the Food and Drug Administration (FDA).

II. THE EXECUTION AND EFFECTS OF THE CSA VIOLATE ITS PURPOSE

18. The CSA was promulgated in part for the "prevention of drug abuse and drug

dependence" and "to provide for treatment and rehabilitation of drug abusers and drug dependent persons" (84 Stat. 1236 (1970) (preamble)), and to ensure the health and general welfare of the American people. 21 U.S.C § 801(1). However, the CSA and Defendants' careless execution thereof, perpetuate the exact opposite of the CSA's purpose, causing it to be one of the deadliest and most harmful laws in U.S history, with no demonstrated benefits to our Country.

19. One of the main aspects of the CSA is its criminal penalties, including those for simple possession. However, all data shows that drug-related arrests do not improve drug abuse or dependency rates, drug-related deaths or crime, recidivism, nor do they benefit the health, safety, economy, or welfare of the American people.

20. For example, from 2009 to 2019 only 1 in 13 people who were arrested and had a drug dependency received treatment while in jail or prison. Drug- and alcohol-related mortality rates increase fivefold in prisons and threefold in jails.[2] Overdose deaths in the U.S. have tripled since 1990, with close to 100,000 deaths each year. Drug deaths rose 8,370% in some U.S. counties from 1980 to 2014.[3] Most of these deaths are caused by prescription drugs.[4] Opioids are a factor in 72% of overdose deaths[5] and are now the fifth leading cause of death in the U.S.[6] Fentanyl is now the leading cause of death in the United

[2] https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/02/drug-arrests-stayed-high-even-as-imprisonment-fell-from-2009-to-2019

[3] https://www.cnn.com/2018/03/13/health/drug-deaths-increase-study/index.html

[4] https://www.ncsl.org/research/health/drug-overdose-death-rate-postcard.aspx

[5] https://www.cdc.gov/drugoverdose/deaths/index.html

[6] Schiller, E. Y., Goyal, A., & Mechanic, O. J. (2022). Opioid Overdose. In StatPearls. StatPearls Publishing.

States among adults aged 18-45.[7] In January 2021, drug overdose deaths exceeded homicides by 306.7% and outnumber deaths from motor vehicle accidents and suicides combined.[8]

21. Drug dependency rates have continually risen since the enactment of the CSA. The majority of drugs being abused are prescription drugs. Of those who began abusing opioids in the 2000s, 75% reported that their first opioid was a prescription drug.[9]

22. There are many additional societal consequences of Defendants' failure to carry out the intended purpose of the CSA. For example, in 2017, the rate of children entering foster care due to parental drug abuse rose for the sixth consecutive year to 131 per 100,000 children nationally – a 53% increase since 2007.[10] Around 26% of homeless adults[11] and 71% of homeless youth have a substance use disorder.[12]

III. LACK OF DEFINITIONS AND MEANINGFUL PROCEDURES LEAD TO ARBITRARY AND BIAS SCHEDULING DECISIONS

23. All controlled substances are supposed to scheduled into one of five schedules based on their accepted medical uses, their potential for abuse, and their psychological and physical effects on the body. However, this is not what actually occurs.

24. Although the Attorney General is authorized to promulgate rules, regulations

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[7] https://www.wral.com/fentanyl-overdose-becomes-leading-cause-of-death-for-adults-age-18-to-45/20200135/

[8] https://drugabusestatistics.org/drug-overdose-deaths/

[9] https://nida.nih.gov/publications/research-reports/prescription-opioids-heroin/prescription-opioid-use-risk-factor-heroin-use

[10] https://www.floridarehab.com/news/parental-drug-abuse-causing-increase-in-foster-care/

[11] https://www.nationalhomeless.org/factsheets/addiction.pdf

[12] Gomez, R., Thompson, S. J., & Barczyk, A. N. (2010). Factors associated with substance use among homeless young adults. Substance abuse, 31(1), 24–34. https://doi.org/10.1080/08897070903442566

and procedures to effectively execute his functions under the CSA, he has failed to do so, which leaves the scheduling factors undefined, applied in an inconsistent and bias manner, and without a meaningful nexus to the findings required for each schedule. This has resulted in a series of arbitrary and dangerous scheduling decisions.

25. Further, there is an absence of any rules or guidance as to what medical, scientific, or other evidence must be considered in scheduling decisions to ensure impartiality. Currently, corporate-funded information is consistently favored over independent studies. This has led to a bias selection of evidence, with an apparent motive to promote highly profitable and addictive commercial drugs, while keeping safer substances that might help eliminate addiction, treat multiple diagnoses, expand consciousness, but are not relatively profitable, out of the hands of the public.

26. Abuse potential is given substantial weight in scheduling decisions, yet "abuse" and "potential for abuse" are not defined. Additionally, the DEA does not address what would constitute a "low potential for abuse" versus a "high potential for abuse."

27. Instead, while still avoiding defining "abuse", the DEA has set forth four prongs which it alleges it uses to determine whether a substance or drug has a "potential for abuse".[13] These four prongs are problematic for multiple reasons, such as: (1) three of the four prongs often do not apply or are not relevant; (2) there is no express or implied nexus between the prongs and "potential for abuse"; (3) the DEA and HHS consistently either ignore three of the four prongs when making their respective conclusions or fail

[13] *See* e.g. Docket: DEA-2022-0025, Supporting and Related Materials: DEA Eight Factor Analysis, Doc. ID: DEA-2022-0025-0003 (Jan. 2022); HHS Basis for Recommendation, Doc. ID: DEA-2022-0025-0002 (Dec. 2021).

altogether to give any weight to or tie the prongs to their conclusions; (4) the prongs are applied inconsistently among various substances and drugs in scheduling evaluations and decisions; (5) the prongs favor pharmaceuticals over natural substances; and (6) are primarily tailored towards assessing whether a substance or drug is likely to be diverted from legal channels, i.e. focusing on the money trail, rather than safety, health, and welfare.

28. Also problematic is that HHS has defined "drug abuse" in a manner unrelated to the four prongs set forth by the DEA to assess the same.[14] Therefore, when HHS considers the eight factors during a scheduling assessment, it does so using a definition not shared by the DEA. Yet the DEA will rely on and cite HHS's assessment without differentiating between the two definitions.

29. As is apparent from past scheduling decisions, including in the example evaluations discussed below, when a substance or drug has not been previously marketed, which is essentially all drugs or substances going through the scheduling process, the DEA and HHS will base their evaluations and subsequent recommendations, in substantial part, on substances or drugs that they deem are similar to the substance or drug proposed to be scheduled. Meaning, if a pharmaceutical company develops a new drug needing to be scheduled, if it's similar to a currently scheduled drug, then the DEA and HHS will conclude the new drug should be scheduled the same without giving any meaningful weight to the safety and benefits of the actual drug under consideration. This careless tactic is highly dangerous and violative of any individual receiving prescribed medications.

[14] *Assessment of Abuse Potential of Drugs, Guidance for Industry*. U.S. Department of Health and Human Services, (Jan. 2017).

A. Examples of Arbitrary and Bias Scheduling Decisions

30. Although there are multiple instances of the careless, inconsistent and bias application of the undefined factors and arbitrary selection of supportive evidence used in scheduling decisions, a comparison of daridorexant (proposed to be placed on Schedule IV) and five tryptamine substances (proposed to be placed on Schedule I), both the subject of recent rulemaking proceedings, will be discussed below as examples of such instances.

i. Daridorexant

31. On April 7, 2022, the DEA published an Interim Final Rule (IFR)[15] placing daridorexant on Schedule IV of the CSA.

32. Daridorexant is a new commercial drug and is considered a hypnotic. In its evaluation and IFR, the DEA stated it is similar to the Schedule IV hypnotics, zolpidem (Ambien), suvorexant (Belsomra), and lemborexant (Dayvigo), with regard to its abuse potential, pharmacological effects, scope, duration, significance and pattern of abuse, risk to public health and dependence, and thus, should be scheduled accordingly.

33. Multiple studies indicate that hypnotics cause substantially elevated hazards of deaths (especially overdose deaths, quiet deaths at night, and suicides), significantly elevated incidents of cancer, infections, depression, automobile crashes, falls, other accidents, and hypnotic-withdrawal insomnia and offer little to no health benefit.[16] Neither the DEA nor HHS cited this information in their evaluations.[17]

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[15] Schedules of Controlled Substances: Placement of Daridorexant in Schedule IV, 87 Fed. Reg. 20313 (Apr. 7, 2022) (to be codified at 21 C.F.R. pt. 1308).

[16] Kripke D. F. (2016). Hypnotic drug risks of mortality, infection, depression, and cancer: but lack of benefit. F1000Research, 5, 918. https://doi.org/10.12688/f1000research.8729.3

[17] *See supra* fn. 13.

34. Individuals who take Ambien could be more than five times likely to die within two and a half years than someone who does not take a sleep aid, and Ambien and similar drugs may have been associated with over 500,000 excess deaths in the U.S. in 2010 alone.[18] Neither the DEA nor HHS cited this information in their evaluations.

35. The FDA has found at least 66 reported examples of patients who took these drugs and engaged in dangerous activities, such as sleepwalking or driving while not fully awake, including twenty deaths linked to carbon monoxide poisoning, drowning, fatal falls, hypothermia, car crashes and apparent suicide.[19] Neither the DEA nor HHS cited this information in their evaluations.

36. The prescribing information for daridorexant includes warnings and precautions, such as: caution against next-day driving and other activities requiring complete mental alertness, sleep paralysis, hypnagogic/hypnopompic hallucinations, cataplexy, sleepdriving, and engaging in other activities while not fully awake. Ambien prescribing information states that "visual and auditory hallucinations have been reported as well as behavioral changes such as bizarre behavior, agitation and depersonalization." Neither the DEA nor HHS cited this information in their evaluations.

37. Ambien and similar drugs can cause physical dependence and dangerous withdrawal symptoms including seizures.[20] Neither the DEA nor HHS cited this

[18] Kripke D.F., Langer RD, Kline L.E. (2012) Hypnotics' association with mortality or cancer: a matched cohort study BMJ Open 2012;2:e000850. doi: 10.1136/bmjopen-2012-000850; https://bmjopen.bmj.com/content/2/1/e000850.citation-tools

[19] https://www.washingtonpost.com/national/health-science/fda-issues-warning-about-risks-of-ambien-other-sleeping-aids/2019/05/03/ccda8560-6ced-11e9-be3a-33217240a539_story.html

[20] *See supra* fn. 16.

information in their evaluations.

38. One of the three findings required before placing a drug in Schedule IV is that the substance has a "currently accepted medical use in treatment." In its evaluation, HHS admitted that daridorexant does not have a currently accepted medical use for treatment, but stated that "[i]f daridorexant is approved, there will be a currently accepted medical use."

39. Despite the above available information, in considering the risk to public health posed by daridorexant, HHS stated "[t]hese data show that in healthy individuals, daridorexant produces rewarding and depressant effects, as would be expected from a DORA," and the DEA concluded in their respective evaluations that daridorexant met the findings required for placement in Schedule IV.

ii. 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT

40. On April 11, 2022, the DEA published a Notice of Proposed Rulemaking (NPR)[21] to place five tryptamine substances on Schedule I of the CSA. The DEA stated the substances are similar to the Schedule I substances DMT, 5-MeO-DiPT, psilocybin, and LSD with regard to their abuse potential, pharmacological effects, scope, duration, significance and pattern of abuse, risk to public health and dependence, and thus, should be scheduled accordingly.

41. Multiple studies have been published about the relative safety, lack of

[21] Schedules of Controlled Substances: Placement of 4-hydroxy-*N,N*diisopropyltryptamine (4-OH-DiPT), 5-methoxy-*alpha*-methyltryptamine (5-MeO-AMT), 5-methoxy-*N*-methyl-*N*isopropyltryptamine(5-MeO-MiPT), 5-methoxy-*N,N*-diethyltryptamine (5-MeO-DET), and *N,N*diisopropyltryptamine (DiPT) in Schedule I, 87 Fed. Reg. (proposed Jan. 14, 2022) (to be codified at 21 C.F.R. pt. 1308).

dependence or addiction, non-toxicity, profound health and therapeutic benefits for multiple conditions, including the ability to treat substance abuse disorders and addiction with use of tryptamines.[22] None of these studies and related information were considered by the DEA and HHS in their evaluations.[23]

42. In the NPR and associated evaluations, the DEA and HHS assume, without supporting evidence, that tryptamines are being used primarily for their hallucinogenic effects, and state "consumption of these five tryptamines due to their hallucinogenic properties poses a safety hazard to the public health."

43. Contrary to that assumption, in a survey about what influenced users to try tryptamines like psilocybin mushrooms, "hallucinations" was not listed as one of the top factors.[24] And despite the name hallucinogens, "most hallucinogens do not consistently cause hallucinations."[25] However, the DEA and HHS ignored this information from studies, surveys and medical professionals, and instead focused on and misrepresented ten-

[22] Frecska, E., Bokor, P., & Winkelman, M. (2016). The Therapeutic Potentials of Ayahuasca: Possible Effects against Various Diseases of Civilization. Frontiers in Pharmacology, 7, 35. https://doi.org/10.3389/fphar.2016.00035.

Winkelman, Michael (2014). Psychedelics as Medicines for Substance Abuse Rehabilitation: Evaluating Treatments with LSD, Peyote, Ibogaine and Ayahuasca. Current Drug Abuse Reviews 7, 101-116.

[23] Docket: DEA-2022-0001, Supporting and Related Materials: DEA Eight Factor Analysis, Doc. ID: DEA-2022-0001-0005 (Aug. 2021); HHS Basis for Recommendation, Doc. IDs: DEA-2022-0001-0002, 03, 04, 06 & 07 (Mar. & May 2012).

[24] Hallock RM, Dean A, Knecht ZA, et al.: A survey of hallucinogenic mushroom use, factors related to usage, and perceptions of use among college students. Drug Alcohol Depend. 2012;130(1–3):245–8 10.1016/j.drugalcdep.2012.11.010.

[25] Forrest, Jeffrey S. MD; Chief Editor: Glen L Xiong, MD: Hallucinogen Use https://emedicine.medscape.com/article/293752-overview?reg=1#showall (last updated Sept. 28, 2020).

year old online anecdotal accounts by tryptamine users.[26] The DEA and HHS failed to consider anecdotal accounts from users of Ambien and other hypnotics from the same website consulted for the tryptamines, which, using the same analysis, would have produced a similar conclusion about use of Ambien and similar Schedule IV substances for their hallucinogenic effects.[27]

44. Moreover, the DEA and HHS failed to put forth a valid basis as to why the potential side effect of "hallucinations" poses a safety hazard to public health warranting Schedule I placement for tryptamines, but warranting Schedule IV placement for daridorexant and similar substances which also can cause hallucinations and which have contributed to far more emergency room visits and deaths.

45. Numerous studies and anecdotal accounts dating at least from the 1940's to present confirm that tryptamines and similar substances have been used and studied for their profound therapeutic and personal benefits, including the expansion of consciousness, making it reasonable to assume that a significant motivating factor for using these substances is therapeutic rather than simply to experience hallucinations. In fact, as is well-known, our own federal government historically used tryptamines and similar substances to aid in intelligence operations for reasons far beyond any incidental hallucinations.

46. For example, LSD was marketed and successfully used in the 1940's by psychiatrists in psychotherapy.[28] Numerous studies show that psilocybin, DMT, other tryptamines, and LSD have been proven to robustly promote neurogenesis and positively

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[26] *See*, HHS Basis for Recommendation, Doc. IDs: DEA-2022-0001-0002, 03, 04, 06 & 07 (Mar. & May 2012).

[27] https://erowid.org/experiences/exp.cgi?S1=143&S2=-1&C1=-1&Str=

[28] *See supra,* Forrest at fn. 25.

affect salivary cortisol response, among many other clinical benefits, and can treat individuals with depression, opioid and other addictions, PTSD, anxiety, mood disorders, inflammation, cluster headaches, and many other physical and psychological conditions.[29] No information or related studies about these substantial therapeutic benefits were cited by the DEA and HHS in their evaluations.

47. Studies have also shown that tryptamines and related substances "are one of the safest known classes of CNS drugs", "are generally considered physiologically safe and do not lead to dependence or addiction" as "serotonergic hallucinogens do not have direct effects on brain dopaminergic systems, a pharmacology that appears essential for nearly all drugs that can engender dependence."[30] The DEA admitted in the NPR that hallucinogens are not usually associated with physical dependence. However, it concluded that psychological dependence exists "as evidenced by the continued use of these substances despite knowledge of the potential toxic and adverse effects." There is no rational, supporting or scientific basis for this conclusion. Moreover, this groundless

[29] *See, e.g.*: Ly, C., et al. (2018). Psychedelics Promote Structural and Functional Neural Plasticity. Cell reports, 23(11), 3170–3182. https://doi.org/10.1016/j.celrep.2018.05.022.

Uthaug, M. V., Lancelotta, R., Szabo, A., Davis, A. K., Riba, J., & Ramaekers, J. G. (2020). Prospective examination of synthetic 5-methoxy-N,N-dimethyltryptamine inhalation: effects on salivary IL-6, cortisol levels, affect, and non-judgment. Psychopharmacology, 237(3), 773–785. https://doi.org/10.1007/s00213-019-05414-w

Galvão, A., de Almeida, R. N., Silva, E., Freire, F., Palhano-Fontes, F., Onias, H., Arcoverde, E., Maia-de-Oliveira, J. P., de Araújo, D. B., Lobão-Soares, B., & Galvão-Coelho, N. L. (2018). Cortisol Modulation by Ayahuasca in Patients with Treatment Resistant Depression and Healthy Controls. Frontiers in psychiatry, 9, 185. https://doi.org/10.3389/fpsyt.2018.00185

McAllister, Peter MD (2018), Headache Horizons: Tuning in to Psychedelics for Treatment of Suicide Headaches, Practical Neurology, https://practicalneurology.com/articles/2018-oct/headache-horizons-tuning-in-to-psychedelics-for-treatment-of-suicide-headaches

[30] Nichols, David E. "Psychedelics." Pharmacological reviews vol. 68,2 (2016): 264-355. doi:10.1124/pr.115.011478 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4813425/

statement could apply to all controlled drugs with adverse side effects, including toxic and dangerous drugs such as Schedule IV hypnotics and benzodiazepines.

48. The DEA and HHS both admitted that there has been only one death associated with the five tryptamines recommended for placement on Schedule I, and that it is unclear whether the use of the tryptamine played any role in that death as the decedent also used the antidepressant, bupropion, and alcohol at the time of death.

49. In the NPR, the DEA cited law enforcement encounters of tryptamines as indicative of their potential for abuse and hazard to public health, without setting forth a rational and non-prejudicial nexus connecting law enforcement encounters to those indicators. Moreover, law enforcement encounters and seizures of the Schedule IV substances to which daridorexant is compared have been numerous and, on information and belief, substantially outnumber law enforcement seizures of tryptamines.[31] Yet, neither the DEA nor HHS considered law enforcement encounters with substances similar to daridorexant when recommending its placement on Schedule IV, but instead reserved that factor for tryptamines.

50. As a final example of the numerous inconsistencies in the application of the scheduling factors, although the DEA and HHS stated in the respective evaluations for daridorexant and the five tryptamines that there is no currently accepted medical use for treatment for either, they ignored this finding for daridorexant, but used this finding as

[31] https://www.cbp.gov/newsroom/local-media-release/prescription-medication-seized-cbp-indianapolis#:~:text=INDIANAPOLIS%E2%80%94%20U.S.%20Customs%20and%20Border,under%20the%20Controlled%20Substance%20Act

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/april-6-2018-new-hampshire-residents-sentenced-participating-scheme-distribute-misbranded-drugs

determinative for placing these five tryptamines on Schedule I.

51. If the factors were defined, tied to the ultimate recommendations, and applied consistently, in a non-arbitrary and non-bias manner, and all available information was given due consideration and equal weight, the schedules would look vastly different than they do currently.

IV. SCHEDULING ACTIONS AND OMISSIONS VIOLATE THE CSA

52. Healthcare is one of the most rapidly evolving fields, with thousands of studies occurring at any given time producing new developments and uncovering new information with regard to controlled and uncontrolled substances. Therefore, with a law, such as the CSA, that effectively controls and criminalizes freedom of choice with regard to personal healthcare and wellbeing, it is critical that new information is given constant, consistent, and fair consideration so that individuals may have access to beneficial and potentially life-saving substances, without facing criminal charges, and prompt transparent information about any uncovered dangers of controlled drugs available by prescription.

53. The CSA contemplates such evolution and requires substances to be scheduled according to currently available information. *See* §§ 801(1), 811(a) & (c), and 812(a) & (b). However, despite the fast-growing and continuous research on various substances and drugs, Defendants ignore this information, consistently fail to update the schedules and propose re- or descheduling of drugs or substances to reflect current information, thereby, violating the currentness requirements of the CSA and unlawfully enforcing the CSA.

54. Moreover, the Attorney General has failed to establish, by rule or otherwise, procedures to ensure a uniform periodic system of review to evaluate new or newly

discovered information to schedule, re- or deschedule, or to assess the appropriateness of the current schedules as required by the provisions of the CSA.

55. One is left to wonder why this happens and has persisted for decades. Apparent reasons are to fuel the substantial amount of profits received by the government through drugs produced and marketed by pharmaceutical companies, to keep the nation sick, addicted to, and dependent on these drugs, to keep certain natural remedies that are not profitable out of the hands of the public, and to suppress the evolution of individual consciousness that would be gained through the legalization of substances such as psychedelics and which would threaten government control over the American people.

56. As previously described herein, when a substance or drug has not been previously marketed or scheduled, the DEA and HHS will base their evaluations and subsequent recommendations, in substantial part, on currently scheduled substances or drugs that they deem are similar to the substance or drug proposed to be scheduled. Therefore, each time the DEA makes a scheduling recommendation based on a comparison to other controlled substances, it constructively affirms the currentness of each finding required under § 812 for each comparator substance or drug. However, the DEA fails to evaluate those comparator substances or drugs to ensure those substances satisfy the required findings at the time of the actual comparison.

57. For example, when the DEA and HHS used Ambien, Belsomra, and Dayvigo as comparators on which to base the scheduling decision for daridorexant, they did not consider recent studies or other information to ensure the finding requirements were met for those comparator substances at the time of the comparison.

58. Moreover, although the DEA and HHS admitted there is no currently

accepted medical use for daridorexant, they recommended placement of that drug on Schedule IV which requires a finding of "currently accepted medical use."

59. As another example, the DEA based its 2022 scheduling recommendation for the tryptamines, discussed above, on an HHS evaluation completed ten years prior, in 2012, and failed to consider numerous studies since that time that could have led to findings contrary to a Schedule I placement.

60. When the CSA was enacted in 1970, multiple substances, including DMT, Ibogaine, LSD, psilocyn, were unlawfully placed on Schedule I with a finding that these did not have any currently accepted medical use, despite the actual medical use, and numerous scientific research studies about the health benefits and low dependency rates of those substances, occurring at that time.

61. Further, the DEA recently denied a petition to reschedule marijuana from Schedule I to Schedule II, stating there is no currently accepted medical use, despite the numerous states who have legalized medical marijuana and despite the numerous studies indicating accepted medical use, and the actual medical use currently occurring.

62. One of the three findings required for a Schedule IV or V drug is that the potential for abuse and dependence for that drug is lower than that of the drugs listed in the schedule above it; i.e. Schedule IV drugs must have a lower potential for abuse and a lower risk of physical or psychological dependence than Schedule III drugs. However, the DEA consistently fails to make this finding as required or ensure this finding stays accurate and current during the time a specific drug remains scheduled.

63. For example, when proposing to schedule daridorexant as a Schedule IV drug based on its similarities to other hypnotics, the DEA failed to assess the abuse potential

and dependence of those comparator hypnotics in relation to Schedule III drugs as required. Had it done so, it would have determined that daridorexant, in fact, does not have a lower potential for abuse or a lower risk of physical or psychological dependence relative to some Schedule III drugs such as, for example, ketamine.

64. Moreover, even in the absence of the proposed scheduling of daridorexant, should the DEA ensure on an ongoing basis that all currently scheduled drugs remained scheduled as appropriate to the required findings, drugs such as benzodiazepines and hypnotics would be required to be rescheduled, as these have a higher potential for abuse and dependence than many Schedule III drugs as evidenced by numerous studies generated since the time of their initial scheduling.

65. The required finding that a substance has a "currently accepted medical use for treatment" is automatic when a drug when it is the subject of a new drug application (NDA), despite the fact a drug has never actually been used for medical treatment in the U.S. In the absence of an NDA, the DEA and HHS will evaluate a whether a drug meets this finding by applying a five-part test set forth in *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

66. However, this five-part test suffers from defects, such as setting higher standards for substances without an associated NDA versus those with one. It is also selectively and arbitrarily applied as it is not being applied to scheduled drugs when those drugs are being used as comparators to other drugs, or when new information about currently scheduled drugs is discovered.

67. One element of the five-part test requires "a consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety

and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. ***A material conflict of opinion among experts precludes a finding of consensus***."[32] Meaning, if just one expert among the national community of experts holds a conflicting opinion about the safety or effectiveness of a substance without an NDA, then a finding that the substance has a "currently accepted medical use for treatment" cannot be had.

68. To the contrary, a drug with an accompanying NDA, and thereby not subject to the five-part test, need only complete the NDA approval process for the "currently accepted medical use" finding to be made. The decision of whether an NDA is approved is made by only one person, a senior FDA official, after considering recommendations by a review team, rather than through a consensus of the national community of experts.

69. Should this five-part test be applied consistently to all drugs or substances, including those with an NDA; those without an NDA but which are currently scheduled and used as comparators for a drug or substance proposed to be scheduled, re- or descheduled; and periodically to all currently scheduled drugs to ensure those continually meet the findings after their initial scheduling, then several Schedule II-V drugs would be rescheduled to Schedule I as those drugs would fail the test for current medical acceptance. For example, there is a lack of consensus by medical experts about the safety of various benzodiazepines, such as Xanax, and hypnotics, such as Ambien (schedule IV drugs), which are responsible for numerous deaths, yet these remain on Schedule IV.[33]

[32] Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53767 (Aug. 12, 2016). (emphasis added).

[33] Donovan T. Maust, et al., Benzodiazepine Use and Misuse Among Adults in the United States, Psychiatric Services 2019 70:2, 97-106 (citing decades of evidence

70. Moreover, based on one of the elements of the five-part test and the requirements for an NDA, before a drug or substance can be found to have a "currently accepted medical use" its chemistry must be known and reproducible. Meaning it must have the ability to be commercialized and marketed. This standard keeps some substances, such as certain natural remedies which are highly beneficial for individual health and well-being, non-addictive and much safer than many Schedule II-V substances, from placement outside Schedule I.

V. THE PROVISIONS OF THE CSA ARE FACIALLY DEFECTIVE

71. The CSA contains several provisions which are contradictory and do not allow for a proper execution of the CSA. Many provisions of the CSA do not permit proper assessment of the universe of substances or drugs so that the very purpose of the CSA can be carried out.

72. Once a substance has been placed on Schedule I, it faces multiple barriers, many of which are insurmountable, preventing or severely limiting re- or descheduling potential where appropriate. This prevents legal access to and a fair assessment of many substances that are highly beneficial, relatively safe, and potentially life-saving, while fast-tracking the approval or maintaining the Schedule II-V status of dangerous, but highly profitable, commercial drugs.

73. Because substances in Schedule I have no accepted medical use under the

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regarding safety concerns);

Gerlach, Lauren, D.O., M.Sc., et al., 1 in 4 older adults prescribed a benzodiazepine goes on to risky long-term use, study finds, University of Michigan, Sept. 10, 2018, https://ihpi.umich.edu/news/1-4-older-adults-prescribed-benzodiazepine-goes-risky-long-term-use-study-finds

CSA, they are not legally permitted to be used for medical purposes. However, in order to be rescheduled, a Schedule I substance must meet the following criteria: (1) current acceptance for medical use; (2) safety for use under medical supervision; and (3) individuals are taking the substance on the basis of medical advice, rather than on their own initiative. As explained above, these criteria are impossible, or near impossible, for Schedule I substances to meet. This means that when a substance is scheduled arbitrarily to Schedule I, it will likely stay there indefinitely, despite evolving and substantial evidence of its safety and benefits. In fact, in the history of the CSA, there has never been a re- or descheduling of any non-commercial Schedule I substance.

74. Rescheduling a substance or drug requires it to have scientific evidence supporting its use. However, a substance's Schedule I status limits researchers' ability to conduct clinical research involving the substances and patients' ability to access the substance for medical purposes. Research studies of Schedule I substances must be government approved, approval of which has essentially been halted in light of the appropriations bill for FY2021, providing that no appropriated funds may be used "for any activity that promotes the legalization of any drug or other substance included in schedule I" of the CSA, except "when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or . . . federally sponsored clinical trials are being conducted to determine therapeutic advantage."

75. Dr. Nora Volkow, Director of the National Institute on Drug Abuse (NIDA) has recently stated that a Schedule I drug's designation "detracts researchers who want to investigate it, because it's just much more cumbersome than doing studies with other substances." Dr. Volkow even said herself that she hesitates to study Schedule I substances

because of the hurdles caused by the CSA. These legal impediments delay research into potentially life-changing and life-saving substances.

76. Additionally, anything placed on Schedules II-V must be approved by the FDA. However, the FDA will only approve substances or drugs for which the potency can be controlled. Under the framework, this limits the potential for medicinal use of certain natural remedies. The current protocol for the FDA provides that a natural plant must be cultivated, controlled, and dosed in such a way that can be controlled, which leaves natural healing in the hands of pharmaceutical companies so that they can generate profits, thereby profiting the government.

77. The Schedule I required finding that a drug have "no currently accepted medical use for treatment" essentially forecloses the rescheduling of highly dangerous and deadly Schedule II-V commercial drugs from being placed on Schedule I as these drugs are currently used medically for treatment. This provision has tied the hands of the DEA to reschedule drugs, such as Oxycontin, resulting in billions of dollars spent unsuccessfully on research and development of ways to increase control of this drug and curb the current opioid epidemic. Meanwhile, pharmaceutical companies can sit back knowing their Schedule II-V drugs are virtually untouchable and continue indefinitely to generate billions of dollars.

VI. THE CSA'S BROAD CRIMINAL PROVISIONS EXCEED DEFENDANTS' AUTHORITY UNDER THE COMMERCE CLAUSE AND VIOLATE THE NECESSARY AND PROPER CLAUSE

78. The CSA's broad criminal provisions governing personal cultivation, possession and use of controlled substances exceeds the bounds of the Commerce and Necessary and Proper Clauses of the United States Constitution.

79. The Commerce Clause does not give uninhibited authority to Congress to violate the personal activities of individuals with regard to their own home and person. To the contrary, Congress may reach purely local activities only where those activities have a substantial affect in interstate commerce or there is a rational basis for so concluding. A rational basis must be one based on logic, and when available, actual data – not pure imagination. Fortunately, we do not have to imagine or rely on 52-year-old congressional findings to form a rational basis today. We now have decades of actual data, that cannot be ignored, with regard to the criminal provisions of the CSA and its actual effect on interstate commerce, including the illicit drug market.

80. In previous court cases involving the CSA and the Commerce Clause, Defendants argued that they have the ability to regulate illegal markets, in addition to those that are legal. While this may be true if executed within the parameters of the Constitution, there is absolutely no basis in law giving Congress the authority to ensure the continued supply and demand of an illegal interstate drug market by prohibiting personal at-home cultivation, possession, and use of certain substances. This concept is akin to an argument that Congress has authority to ensure individuals participate in an illicit interstate drug market and ensure drug traffickers stay profitable and in business.

81. Moreover, it defies logic to state that personal at-home cultivation, possession, or use of certain substances affects the interstate market in a way that undercuts the regulatory scheme of the CSA. One main purpose of the CSA is to allegedly reduce the illicit drug market. There is nothing in the scheme of the CSA that purports a purpose to maintain an illicit drug market or support drug traffickers. It is completely irrational, and unsupported by any evidence, to conclude that when individuals are permitted to cultivate

and consume certain substances, such as marijuana for example, for their personal use that this would undercut the CSA's overall scheme.

82. Defendants and federal courts have also previously pointed to a 52-year-old congressional finding stating "[c]ontrolled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate" as a basis for Defendant's authority under the Commerce Clause to outlaw personal at-home cultivation, possession, and use of certain substances. However, both Defendants and the courts have failed to dig even one layer under the surface of this finding to question how it is at all relevant to the Defendant's regulation of interstate markets. Cultivation location is not an element required for the prosecution of the crimes of possession or trafficking.

83. Also, 52 years of data show that the criminal provision of the CSA related to personal at-home cultivation, possession and use are not necessary and proper for the beneficial execution of Defendants' authority to regulate interstate commerce. Data shows that arrests for personal at-home cultivation, possession or use of controlled substances have no correlation to the reduction of drug trafficking – one of the main purported purposes of the CSA. The data also shows that the overall execution of the CSA has no positive correlation to the reduction of the illicit interstate drug market. Defendants can't rationally argue both, i.e. claim illicit drug trafficking threatens the safety, health and welfare of the American people, yet argue in favor of maintaining the supply and demand of the illicit drug market.

VII. THE SINGLE CONVENTION ON NARCOTIC DRUGS AND THE CONVENTION ON PSYCHOTROPIC SUBSTANCES SUFFER FROM THE SAME, AND ADDITIONAL, DEFECTS AS THE CSA

84. The United States is a party to the 1961 United Nations Single Convention on Narcotic Drugs ("Single Convention") and the 1971 United Nations Convention on Psychotropic Substances ("Psychotropic Convention"), both of which are international treaties requiring placement of certain substances into one of four schedules and set forth minimum controls for each schedule and other related procedures. As a party to these Conventions, the U.S. is required to fulfill certain obligations such as scheduling and placing specific controls on certain substances.

85. Under Article 3 of the Single Convention and Article 2 of the Psychotropic Convention, if a party has information about a substance which, in its opinion may justify an amendment to the schedules, the party shall provide such information to the Secretary-General of the United Nations, who then forwards only the information he deems relevant to the World Health Organization (WHO) for assessment, to other parties and the Commission on Narcotic Drugs (Commission).

86. Under the Psychotropic Convention, if WHO makes the following findings, it is required to submit an assessment to the Commission with a recommendation: (1) a substance has the capacity to produce dependency and central nervous system stimulation or depression or similar abuse and similar ill effects as an already scheduled substance; and (2) there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting international control. The assessment WHO provides to the commission must include the following: (1) extent or likelihood of abuse; (2) the degree of seriousness of the public health and social problem;

and (3) the degree of usefulness of the substance in medical therapy.

87. Under the Psychotropic Convention, the Commission is bound by WHO's assessment as to scientific and medical matters. The Commission then makes a scheduling decision, bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, by which all parties to the Convention are bound. Should a party disagree with the decision about a substance, that party is still obligated, at a minimum, to apply to the controlled substance the controls of the schedule above it.

88. WHO's assessment standard under the Single Convention is much lower than that under the Psychotropic Convention, requiring WHO only to consider whether a substance is "liable to abuse" and whether is produces "similar ill effects" as currently scheduled substances. Similar to the Psychotropic Convention, WHO submits its recommendation to the Commission, who makes the ultimate decision with regard to amending the schedules. However, under the Single Convention, the Commission's decision is not governed by any standards or requirements – only that it make a decision in accordance with WHO's recommendation.

89. The Conventions and their mandates upon the U.S. suffer from many of the same, and some additional, defects as those described above with regard to the CSA, such as a lack of definitions, meaningful procedures, and highly subjective scheduling decisions.

90. First, despite all the information a party might submit to the Secretary-General, he has discretion to forward only what information he deems is relevant to the other parties, the Commission and WHO. Meaning, information a party may feel is relevant and important might never be seen by anyone other than the Secretary-General, or considered by WHO in its assessment.

91. Next, the Conventions provide no procedures, standards, or definitions governing the elements listed above in WHO's assessment, or governing the Commission's ultimate decision. As an example, similar to the CSA, "abuse" is not defined and can be interpreted by WHO in whichever way it deems appropriate for a specific substance. WHO and the Commission are also not required to consider any specific information with regard to the assessment, recommendation or ultimate decision. Rather, they both are given full discretion to select what information they will or will not consider.

92. Although the Commission's decisions are subject to review, upon a party's request only, by the International Narcotics Control Board for decisions under the Single Convention and by the Economic and Social Council of the United Nations for decisions under the Psychotropic Convention, neither of the Conventions set forth any standards of review by which either of these entities must abide.

93. The Conventions also lack any mechanisms to ensure the schedules continually reflect current information. This is problematic when WHO looks to currently-scheduled substances, many of which were placed in the schedules over 50 years ago, to make a comparison during its assessment as described above. This is also problematic as the only occasion by which a currently-scheduled substance is reviewed is through the non-mandatory subjective process described above, i.e. when a party, WHO, or the Commission has information they feel justifies a change. The U.S. has failed to set forth any procedures by which or to whom a person or entity may submit information they believe may justify a change to the schedules. This means that when a U.S. citizen submits a petition to DEA to request a schedule change within the CSA, even where the substance involved is scheduled by one of the Conventions, under both the CSA and the Conventions the U.S. is

not required to submit that information to the Secretary-General for review. This also means that should the multiple U.S. research institutions[34] who have extensive information about the benefits of certain Schedule I substances, such as psilocybin mushrooms and other psychedelics, wish to submit information to the U.S. to amend the schedules of the Conventions, there are no procedures by which to do this nor is there anything mandating or governing a review by the U.S. government of this information.

94. One of the most troubling aspects of the Conventions is the complete absence of anything defining either of the Convention's four schedules. The only element differentiating the schedules are the various controls required for each schedule. The Conventions are devoid of any required findings, descriptions, standards, or anything else that would provide guidance as to or justify which schedule a substance should be or was placed, thereby providing the Commission, or reviewing entities, full discretion with no accountability.

95. The CSA also fails to ensure objectivity or set forth standards and procedures in its processes involving the Conventions. *See* § 811(d). When the U.S. receives notice from the Secretary-General that a substance is being considered for scheduling, re- or descheduling, or that a scheduling decision has been made by the Commission pursuant to the Psychotropic Convention, HHS has full discretion, without any governing procedures,

[34] *See e.g.*, John Hopkins Center for Psychedelic and Consciousness Research https://hopkinspsychedelic.org/;
Multidisciplinary Association for Psychedelic Research (MAPS) https://maps.org/; Yale School of Medicine https://medicine.yale.edu/psychiatry/research/programs/clinical_people/psychedelic/research/;
Stanford Psychedelic Science Group https://med.stanford.edu/spsg.html.

to determine what information it will consider and what is appropriate to present to the Secretary-General for discussion about the proposed change, and to determine whether it agrees with any scheduling decision by the Commission. Depending on the situation, the information selected by the HHS will be used to represent the US's position with regard to the substance under consideration.

96. Decisions made by the Commission pursuant to the Single Convention fare worse under the CSA, than the Psychotropic Convention, as the DEA has authority under § 811(d)(1) to control substances under the Single Convention without making any findings required by §§ 811(a) or 812(b), without following the rulemaking procedures under §811(a) and without securing an evaluation and recommendation from HHS.

97. We have over 50 years of data, evidence and evolving research that justifies amendment to the schedules, yet neither Convention sets forth any mandates requiring consideration thereof. And despite any position, opinion, or belief held by the American people, its medical community, HHS, or the U.S., and regardless of the existence of substantial evidence in support thereof, we are bound by all scheduling decisions made by the Commission, no matter how arbitrary and bias that decision is.

98. As mentioned earlier herein, when it comes to something so important and fundamental as our personal wellbeing, healthcare, consciousness, minds and bodies, and what we are legally permitted or not permitted to use for the benefit thereof, it is absolutely critical that procedures and terms are defined so as to strictly promote credibility, accountability, and transparency. The lack of procedures and the amount of unfettered discretion given to a handful of people to make decisions on behalf of all Americans is deeply troubling.

99. The Conventions also set forth penal provisions which exceed the bounds of the Commerce and Necessary and Proper Clauses of the United States Constitution in a similar manner as the CSA. Therefore, paragraphs 78-83 are incorporated herein and apply with equal force and relevance to the Conventions.

VIII. AN ORCHESTRATED SYSTEM OF COGNITIVE CONTROL AND PERPETUATION OF MISINFORMATION AND HARM

100. The CSA exerts control over a large portion of American healthcare, thereby placing the health and well-being of Americans and individual choice with regard to healthcare and well-being primarily in the hands of a law-enforcement agency. Medications are involved in 80% of all treatment plans and affect almost every aspect of a patient's life. Prescriptions dispensed in the U.S. have increased by 1 billion over just ten years.[35] Drugs controlled through the CSA, which largely consist of Central Nervous System (CNS) drugs are among the top prescribed drugs.[36] Over 12% of adults have a prescription for benzodiazepines[37] and over 10% for pain medications.[38]

101. The CSA is a closed regulatory system which makes it criminal to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. This means that all licensed medical professionals and all health insurance companies are bound by the CSA. This is disturbing as the DEA dictates what certain healthcare treatments are available to us through decision making which does not

[35] https://www.pcpcc.org/sites/default/files/event-attachments/CMM%20Brief.pdf

[36] https://clincalc.com/DrugStats/Top300Drugs.aspx

[37] https://nida.nih.gov/news-events/science-highlight/research-suggests-benzodiazepine-use-high-while-use-disorder-rates-are-low

[38] https://www.cdc.gov/nchs/products/databriefs/db369.htm#:~:text=In%202015%E2%80%932018%2C%2010.7%25,one%20or%20more%20prescription%20opioids.

adequately and fairly consider all or current information about safety, health risks, dependency, and benefits of drugs and substances. Currently, only addictive CNS drugs are legal to prescribe; all non-addictive CNS substances are Schedule I drugs, making them completely illegal.

102. Americans are at the mercy of the DEA's decisions with regard to each controlled prescription drug that enters their bodies. There exists a certain level of trust by people when going to their provider and receiving treatment that controlled drugs have been thoroughly analyzed for both their safety and benefits and that they are receiving accurate and transparent information. This trust is extensively violated and exploited each time the DEA makes a scheduling decision or fails to make a scheduling change based on accurate and current information.

103. Further, the informed consent doctrine is essentially null with regard to controlled substances when patients are deprived of complete and transparent information about newly discovered dangers of Schedule II-V drugs and of their options for safer and more effective remedies that may be arbitrarily placed or kept on Schedule I. The DEA continuously spreads and perpetuates the spread of misinformation through its execution of the CSA and effectively through the entire medical profession.

104. The CSA also perpetuates a healthcare system designed to keep Americans continuously addicted to or dependent on commercial prescription drugs, thereby controlling healthcare consumerism and perpetuating the mass numbing and emotional suppression of the population.

105. As an example, benzodiazepines (benzos) and are among the most prescribed

drugs, with 27% of doctor visits resulting in a benzo prescription.[39] Yet benzodiazepines do not cure or treat the root cause of the conditions for which they are prescribed resulting in long-term use, can cause dependency within a matter of days, emotional numbness, dangerous and sometimes fatal withdrawal symptoms and require tapering to reduce those withdrawal symptoms.[40] Benzos have been reported as one of the top five drugs to quit.[41] Many users report a fear of withdrawals, which can be dangerous and fatal, as a top reason to stay on these prescribed medications, which is frightening as benzos caused over 11,000 deaths in 2017.[42] Benzo use is also strongly linked to the development of diseases which often require more commercial drugs to treat, including Alzheimer's disease.[43]

106. As another example, for those with opioid use disorder, the vast majority of whom started opioid use with a prescription,[44] treatment of withdrawal symptoms primarily consists of replacing the opioid of abuse with the commercial synthetic opioids, suboxone and buprenorphine. As synthetic opioids, both of these alleged treatments are themselves addictive, cause physical and psychological dependence which can persist long-term after quitting the drugs, cause dangerous and sometimes fatal withdrawal symptoms and require tapering to reduce those withdrawal symptoms.[45]

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[39] https://www.newscientist.com/article/2230379-benzodiazepine-prescriptions-reach-disturbing-levels-in-the-us/

[40] *Id.*

[41] https://americanaddictioncenters.org/adult-addiction-treatment-programs/hardest-quit

[42] https://www.newscientist.com/article/2230379-benzodiazepine-prescriptions-reach-disturbing-levels-in-the-us/

[43] https://drugabuse.com/blog/5-things-doctors-dont-tell-you-about-benzos/

[44] https://nida.nih.gov/publications/research-reports/prescription-opioids-heroin/prescription-opioid-use-risk-factor-heroin-use#ref

[45] https://americanaddictioncenters.org/withdrawal-timelines-treatments/methadone; https://americanaddictioncenters.org/suboxone/withdrawal.

107. On the other hand, many Schedule I substances, such as naturally occurring plants and fungi, such as iboga, psilocybin, and ayahuasca have all been found to have profound therapeutic benefits for numerous conditions such as anxiety, depression, drug addiction, alcoholism, they do not require extended use and are often effective with a single dose at treating the aforementioned conditions, do not cause dependence, addiction, or withdrawal symptoms, are much safer than Schedule II-V addictive drugs, it is near impossible to overdose on these and deaths are extremely rare.[46] Moreover, these address the root causes of numerous conditions due, in part, to their neurogenesis, anti-inflammatory, and cortisol regulation capabilities, and due in part to the reflective mental state they induce that allows users to identify and confront and address the psychological roots of their addictions, psychological conditions, or hindering belief systems. Numerous studies show how effective these substances, along with other psychedelics can be in treating addiction, which is largely caused by prescription drugs. Yet these substances, which could help with the opioid epidemic among many other harms perpetuated by the CSA, are kept illegal by the DEA, meaning individuals must depend on dangerous commercial drugs.

108. Moreover, the CSA is structured in such a way that personal choice to use such natural treatments in their naturally occurring form, without synthesis and commercialization, cannot become legal because rescheduling requires a finding of "currently accepted medical use". As discussed above, this finding can only be satisfied through either the existence of an NDA or satisfaction of the five-part test, both of which

[46] *See supra* fns. 22 & 29.

require that a substance's chemistry be known and reproducible, i.e. it must be marketable. This means that naturally occurring remedies must go through the hands of pharmaceutical companies before becoming legally available for personal use.

109. Further, when comparing Schedule II-V substances, such as benzodiazepines, opioids, and prescription amphetamines with Schedule I substances, such as ayahuasca, psilocybin mushrooms, iboga, LSD, and MDMA, the orchestration of control over individual liberties, such as mental cognition and consciousness, becomes appallingly evident. The former often causes emotional blunting, meaning the user emotions and conscious are dulled. While the latter profoundly expands consciousness, of which Defendants are fully aware.

110. Of particular concern is that all scheduling decisions include a large element of considering personal intention or motivation for using a drug or substance, thereby attempting to ascertain individual cognition and further exert control over cognitive liberty and mental autonomy. HHS defines "drug abuse" as "the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect."[47] An individual's underlying intention for using a substance or drug is something so personal and intimate such that it cannot be understood or ascertained by another, much less a government entity, nor should it be of any concern to the Defendants. There is no rational nexus between personal intention and the furtherance of the alleged purposes of the CSA. Moreover, HHS does not define what is considered "non-therapeutic use." Using the Merriam-Webster definition of "therapeutic" ("of or relating to the

[47] *See supra* fn. 14.

treatment of disease or disorders by remedial agents or methods having a beneficial effect in the body or mind; producing a useful or favorable result or effect"), it is difficult to imagine use of a drug or substance for non-therapeutic purposes and irrational to conclude as such based on pure imagination on behalf of Defendants. Although Defendants refuse to define "drug abuse", the CSA essentially criminalizes drug abuse. Criminalizing drug abuse is criminalizing the intention or personal thought processes behind personal drug use. Therefore, criminalizing drug abuse is criminalizing minds.

IX. DEPRIVATION OF FUNDAMENTAL RIGHTS OF PLAINTIFF AND ALL OTHERS SIMILARLY SITUATED

111. "[W]e have regularly observed that the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, 'deeply rooted in this Nation's history and tradition'."[48] "There is a general tradition of self-sovereignty, and as teaching that the liberty protected by the Due Process Clause includes 'basic and intimate exercises of personal autonomy'."[49] "It is a promise of the Constitution that there is a realm of personal liberty which the government may not enter."[50] "Because our notions of liberty are inextricably entwined with our idea of physical freedom and self-determination, the Court has often deemed state incursions into the body repugnant to the interests protected by the Due Process Clause."[51] "[T]he constitutional protection for the human body is surely inseparable from concern for the mind and spirit that dwell therein."[52]

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[48] *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (internal quotations omitted).

[49] *Id*. at 724.

[50] *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 847 (1992).

[51] *Cruzan ex rel. Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 287 (1990).

[52] *Id*. at 343.

112. Personal consciousness, emotions, psyche, and cognition are the most intimate aspects of our own human existence. How we choose interact with, expand, or access those are paramount to personal and mental autonomy, self-sovereignty and self-determination; as is a meaningful choice of what we consume for our own physical and mental well-being.

113. Throughout my life, I have experienced alcoholism, drug addiction, depression, anxiety, panic attacks, migraine headaches, chronic fatigue, digestive issues, and other conditions, and have been prescribed benzodiazepines, anti-anxiety medications, and other harmful or ineffective commercial drugs, as a result. I came to a point in my life recently where I wanted to truly address and overcome these conditions, but did not want to be prescribed harmful pharmaceutical drugs, as I had before, and was fearful of becoming emotionally and cognitively suppressed by or dependent on these drugs, as I had before. After some research, I learned about the incredible benefits and safety of natural remedies including ayahuasca, iboga, marijuana, coca leaves, and psilocybin mushrooms, as described earlier herein. However, all of these remedies are illegal to purchase, cultivate, or possess, due to the unconstitutional scheduling processes and related criminal provisions, as discussed herein. In the recent past, I have been traveling out of the country for extended periods of time so that I can legally access and use these profound remedies for my personal healing and enlightenment. The positive physical and mental transformation I have experienced as a result is nothing short of incredible.

114. I have a constitutionally protected liberty interest in exercising my personal and mental autonomy by determining and choosing what is best for my own mind, body and spirit. I also have a protected liberty interest to interact with and expand my own

consciousness. I also have a liberty interest in growing plants or fungi of my choosing for personal use in the sanctity of my own home and choosing to consume those substances. The CSA unlawfully treads into those sacred and intimate realms of my human existence by criminalizing my private life choices to continue using the natural remedies described above for my personal healing, rather than pharmaceutical drugs.

115. I also have a constitutionally protected liberty interest in informed consent with regard to treatment. Yet, that right is null when I cannot be informed about all treatment options from the medical community as a result of the CSA, including certain natural alternatives to pharmaceutical commercial drugs, and information about dangers of pharmaceutical drugs is omitted or not considered during the scheduling process. "'The root premise' of informed consent 'is the concept, fundamental in American jurisprudence, that '[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.'"[53] This includes "a right to evaluate the potential benefit of treatment and its possible consequences according to one's own values and to make a personal decision whether to subject oneself to the intrusion."[54]

116. Most importantly, I have a constitutionally protected liberty interest in meaningful choice with regard to my own healthcare and wellbeing. Yet Defendants, through the CSA and international treaties, control what is or is not available for my personal healthcare through unconstitutional processes that ignore scientific research, mislead the public and the medical community, schedule substances in an arbitrary, bias,

[53] *Id.* at 306 n.5 (quoting *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129-130 (1914) (Cardozo, J.)).

[54] *Id.* at 309.

non-transparent and inconsistent manner, and by failing to update the schedules, thereby depriving me, along with all Americans, of our right to meaningfully choose our own treatment for our own well-being.

117. I fully intend to continue exercising the above protected liberty interests by forgoing pharmaceutical treatment and cultivating, possessing, and/or using personal amounts of psilocybin mushrooms, ayahuasca, iboga, marijuana, coca leaves, and any other substance I choose, in my own home, to the extent I feel is necessary for my own well-being, consciousness, and mental and physical health. However, my exercise of these liberty interests is deterred by and in direct conflict with the provisions and execution of the CSA, AZCSA and relevant international treaties. Further, due to the continued enforcement by Defendants of the criminal provisions thereof, I genuinely fear and face a credible threat of prosecution for such exercise.

118. Defendants' ongoing violations of my constitutional rights, without due process of law and in violation of the Commerce and Necessary and Proper clauses, have and will continue to cause me irreparable harm, for which I have no plain, speedy, or adequate remedy, and which will be redressed by the relief requested.

X. ARIZONA'S CONTROLLED SUBSTANCES ACT

119. Arizona's Controlled Substances Act (AZCSA), A.R.S. § 36-2501 *et seq*., provides that the controlled substance schedules provided in the CSA shall be adopted by rule and such rules shall be amended, as necessary, to reflect any changes to the CSA schedules. The AZCSA provides no additional or state-specific procedures for reviewing or amending its schedules.

120. Arizona's criminal provisions with regard to controlled substances, A.R.S. §

13-3401 *et seq*., also substantially mirror those provided in the CSA.

121. The harm caused by the AZCSA is substantially similar to that of the CSA, such as mass overdose deaths, addiction, and imprisonment without treatment.[55]

122. Therefore, paragraphs 1-118 are incorporated herein by reference and apply with equal force and relevance to the AZCSA.

CLAIMS FOR RELIEF

COUNT I
Violation of Plaintiff's Due Process Rights under the Fifth Amendment (42 U.S.C. § 1983)

123. Plaintiff realleges and incorporates by reference Paragraphs 1 through 122 as if set forth fully herein.

124. The Fifth Amendment to the U.S. Constitution provides that "No person shall be . . . deprived of life, liberty, or property, without due process of law . . .."

125. The federal Defendants have deprived Plaintiff of multiple liberty rights without substantive and procedural due process of law.

COUNT II
Violation of Plaintiff's Due Process Rights under the Fourteenth Amendment of the U.S. Constitution and under Article 2 of the Arizona State Constitution (42 U.S.C. § 1983)

126. Plaintiff realleges and incorporates by reference Paragraphs 1 through 122 as

[55] *See e.g*., https://directorsblog.health.azdhs.gov/tag/substance-abuse/ (providing that over 11,000 Arizonans have died from opioid overdose from 2017 to 2021); https://www.azmirror.com/2020/01/03/sentencing-reform-debate-shines-light-on-lack-of-substance-abuse-treatment-in-prisons/ (providing that although 78% of inmates have a history of substance abuse, less than 4% receive treatment while incarcerated); https://wallethub.com/edu/drug-use-by-state/35150 (Arizona ranks number 18 for states with worst drug problem and number 5 for the percentage of adults with unmet treatment needs).

if set forth fully herein.

127. The Fourteenth Amendment to the U.S. Constitution provides that no State shall deprive "any person of life, liberty, or property, without due process of law".

128. Article 2, Section 4 of the Arizona State Constitution provides that "No person shall be deprived of life, liberty, or property without due process of law."

129. The State Defendant has deprived Plaintiff of multiple liberty rights without substantive and procedural due process of law.

COUNT III
Violation of the Commerce and Necessary and Proper Clauses
(42 U.S.C. § 1983)

130. Plaintiff realleges and incorporates by reference Paragraphs 1 through 122 as if set forth fully herein.

131. Article I, Section 8 of the U.S. Constitution provides that Congress shall have power to regulate commerce among the several states and to make all laws which shall be necessary and proper for carrying its powers into execution.

132. The Conventions' penal provisions and the CSA's criminal provisions violate the Commerce and Necessary and Proper clauses.

COUNT IV
Violation of the Administrative Procedure Act (APA)

133. Plaintiff realleges and incorporates by reference Paragraphs 1 through 125 as if set forth fully herein.

134. Under the APA, 5 U.S.C. § 706, a reviewing court has authority to:

> Hold unlawful and set aside agency action, findings, and conclusions found to be:
>
> A. arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

B. contrary to constitutional right, power, privilege, or immunity;

C. in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

D. without observance of procedure required by law;

E. unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

F. unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

135. Defendants' execution of the CSA violates the APA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court grant the following relief:

1. Declare that:

a. The CSA and Defendants' execution and enforcement thereof violates the substantive and procedural due process guarantees of the Fifth Amendment of the U.S. Constitution.

b. The 1961 Single Convention on Narcotic Drugs violates the due process guarantees of the Fifth Amendment of the U.S. Constitution.

c. The 1971 Convention on Psychotropic Substances violates the due process guarantees of the Fifth Amendment of the U.S. Constitution.

d. The AZCSA and the State Defendant's execution and enforcement thereof violate the substantive and procedural due process guarantees of the Fourteenth Amendment of the U.S. Constitution.

e. The AZCSA and the State Defendant's execution thereof violate the due process guarantees of Article 2, Section 4 of the Arizona State Constitution.

f. The CSA and the Conventions violate the Commerce and Necessary and Proper clauses of the U.S. Constitution.

g. The U.S. Attorney General and DEA Defendants' execution of the CSA violates the APA.

2. Preliminary and permanently enjoin Defendants from enforcing the criminal provisions of the CSA and AZCSA with respect to the following:

(1) Simple possession of any controlled substance;

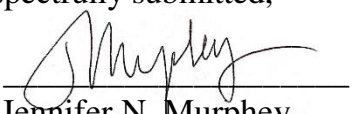
(2) Manufacture and use of personal amounts of any plant or fungi substances currently controlled under the CSA.

3. Award Plaintiff reasonable attorney's fees and costs.

4. Order such other and further relief as the Court deems just and proper.

Dated this 21st day of July, 2022.

Respectfully submitted,

By: 

Jennifer N. Murphey
pro se