UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of	
Schedules of Controlled Substances:	**DEA Docket No. 1362**
Proposed Rescheduling of Marijuana	**Hearing Docket No. 26-96**

CONCLUSION STATEMENT OF DR. PHILLIP DRUM

Introduction

Thank you for the opportunity to discuss marijuana harms, as seen from the perspective of a clinical drug-expert pharmacist and an emergency medicine/pediatric physician. We would like to reiterate that marijuana, with its 300+ "active" ingredients as claimed by the marijuana industry, is not a medicine (fraudulent statement #1).

Traditional pharmacologic standards and practices are being ignored, as stated by multiple witnesses. The States are simply not regulating and protecting the public with their current practices in place. Dosages for various formulations are unknown. Currently, marijuana is the active ingredient in: tampons, condoms, intravaginal suppositories, inhalers, topical creams or ointments, rectal suppositories, sublingual applications, lip balms, oral gummies, chips, candies, cereals, sodas or alcohol-infused products, and smoked versions including: dabs, waxes, joints or bong hits. What is the dose for each of these products as defined by pharmacologic standards and practices? None have been identified by the FDA or HHS for any of the three indications that are claimed. The marijuana industry claims that "regulatory" activities will

provide patient safety, dosing consistency or product reliability (fraudulent statement #2). State testing requirements have frequently been found to be fraudulent and completely insufficient as displayed by Dr Drum. Product recalls have been late and hap-hazardous, if they occur at all. The bottom line is - there has been no FDA approval for any indication so it must remain a CS I.

Finally, the harms are paramount, and are being minimized and use has been normalized by the media and popular vote making marijuana out to be as both a recreational drug and a "medicine", thus making it seem safer to the public at large. True medicine must display benefits greater than the risks. Let there be no question that our children are using marijuana in record numbers, exceeding alcohol use now.

The marijuana industry refers to the youth-use studies to claim marijuana use is not going up in children (fraudulent statement #3). As explained by Dr. Randall, school truancy rates have increased since marijuana legalization, and these are the children most likely to be using marijuana. If the children are NOT in school, they are no longer being counted by the studies.

We will take you through multiple key points in response to the following activities, fraudulent statements by the marijuana industry, and related topics:

- Diversion activities,
- DEA mission to prevent diversion,
- Children's use,
- Adolescent use increasing use,
- Entourage Effects — false claims of the need for the entire plant,
- Images on the internet have not been proven to be AI generated,
- Cartoons that are focused towards youth,
- The medical community is in agreement that marijuana is not medicine,

- False claims that marijuana prevents opiate deaths,
- CS III status is the wrong choice,
- HHS misrepresentation of generalized anorexia in place of anorexia associated with AIDS,
- State regulations are failing to protect the public, and
- Marijuana is a known carcinogen and mutagen.

We discourage rescheduling marijuana from a CS I to a CS III substance at this time without full FDA approval, including the package insert.

Diversion

During Dr. Randall's testimony the DEA lawyers on cross examination implied that the significant cause of childhood ingestions and use of cannabis was secondary to diversion of products on the part of the parents (fraudulent statement #4). This is completely inaccurate. While diversion from parents to children/toddlers may be true for some cases, the majority of children and adolescent cases involve marijuana products from sources outside the home. Dr. Randall did discuss many ways in which adolescents can obtain marijuana products. Additionally, those who turn 18 during their high school year can easily receive a medical marijuana recommendation and bring products to school to sell. Children are also finding ways to acquire marijuana via Snap Chat, deliveries by Uber or Lyft, prepaid VISA cards, direct online sales, selling out the front and back doors of legal marijuana dispensaries, from their peers, as well as, many other social methods. Parental diversion, as suggested during cross-examination, is only a very small fraction of the methods children are using to obtain marijuana products. Clearly, at this point in time, diversion is happening on a large scale, and Dr. Randall's recommendation is to first control the amount of diversion - on multiple fronts, including law enforcement

techniques - before changing the controlled substance status, which will enhance sales due to the Federal government approving marijuana as medicine.

DEA Mission – to prevent Diversion

The DEA mission statement is to enforce the controlled substances laws and regulations within the United States and bring cases of inappropriate use to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing into or destined for illicit traffic in the United States. The states are Claiming to have regulatory oversight of product strength and consistency (fraudulent statement #5). The state of California allows a very potent hallucinogen to possess 200 times the maximum FDA-approved THC/dronabinol dose in a legal medical product (2000 mg of THC in a medical product in California as mentioned/displayed by Dr Drum). Marijuana was made more available when marijuana was moved from a "medical" product to recreational use and the trafficking of marijuana to children increased as is evident by the increasing poison control calls and visit to the Emergency Rooms across America. Lowering the scheduling class will only enable this trend to continue and likely worsen, as the public perception of marijuana products will be that the products are safe, have real medical indications, and are FDA-approved despite the lack of defined dosing schedules and required precautions/warnings on the labels and child proofing containers.

Further, to claim that it is debatable that the federal government conversion from CS I to CS III is similar to claim that medical marijuana in a state would not impact hospitalizations (fraudulent statement #6). In a study from 2015 in Drug and Alcohol Dependence entitled *The impacts of marijuana dispensary density and neighborhood ecology on marijuana abuse and*

dependence by C Mair, et al

(https://pmc.ncbi.nlm.nih.gov/articles/PMC4536157/pdf/nihms705271.pdf), the researchers investigated associations between marijuana abuse/dependence hospitalizations and community demographics and environmental conditions from 2001 to 2012 in California. They showed for **every one additional dispensary** per square mile in a ZIP code was cross-sectionally **associated with a 6.8% increase in the number of marijuana hospitalizations** with a marijuana abuse/dependence ICD-10 code. This is clear evidence that when marijuana use is liberalized, abuse/dependence increases. Parents who may be reluctant to allowing children to use marijuana because the Federal Government has NOT approved marijuana as medicine (because it remains a CS I substance) will no longer feel that reluctance, if made a CS III.

Children's use

From the paper by Bertino et al - Ex # 68 of Dr Randall's testimony and slide number 63, exposures of children 6-12 years old in 2009 was 21 exposures and increased to 2894 in 2024. This is an increase in poison control cases/exposures of **13,781%**. This increase in exposures comes at a time when the potency of marijuana has dramatically increased. That same scientific article displays, that for children **under the age of 6 years old,** exposures **increased 6,386%** (in 2009 – 132 reports and in 2024 – 8,430 reports). There can be no debate that the numbers of exposures are increasing. (see page 2121:14). This paper proved the US Government interactions with marijuana laws DO have an effect on subsequent under aged marijuana child use. There were 3 examples cited in the scientific paper – the 2009 Ogden Memo, the 2013 Cole Memo and the 2018 US Farm Bill. Dr Randall explained that the marijuana industry's claims that child use is not increasing (fraudulent statement #3) has resulted in increasing truancy rates in school due to drug use. If the child using drugs is no longer going to school, then the rate of

active use reported in these school studies is NOT reflected – because they are no longer IN school to take the survey. There are multiple studies that show childhood and adolescent use leads more readily to addiction in this age group. Having to hold children in the emergency department for weeks or longer precipitates withdrawal symptoms that often need to be managed with anti-psychotic medication which, they themselves, have devastating adverse effects.

Adolescent Use

The marijuana industry also claim that adolescent use is not increasing (fraudulent statement #3). Each and every day in the United States more children try marijuana and a portion of those will become addicted. They are trying marijuana at a time when their brains are vulnerable to addiction and neurodevelopmental changes that may be permanent, leading to a life-long problems with addiction. Once these children become addicted or suffer the serious consequences of marijuana, getting treatment is exceptionally difficult. Treatment beds for adolescent addiction and psychosis are at a premium, especially in marijuana legal states. Many of these children sit in Emergency Rooms in hospitals for days, weeks, or even months across the country waiting for a pediatric psychic bed to become available. The court heard of multiple cases of suicides being committed by these youth who were addicted to marijuana.

Entourage effects is false

As mentioned during the presentation, the marijuana industry and the second Government witness claim the entourage effect (the need for 100+ cannabinoids + 200 + terpines + flavinoids) is needed for the product to become medicine (fraudulent statement #7). Dr Drum discussed this in slide #25. Also, ZD Cooper, SD Comer and M Haney in a 2013 Neuropsychopharmacology article entitled "*Comparison of the analgesic effects of dronabinol and smoked marijuana in*

daily marijuana smokers" paper compared oral dronabinol (in 1, 10 or 20 mg doses) to smoked marijuana (0%, 1.98% or 3.56% THC). The result showed NO difference in pain relief between the maximum products - 3.56% THC smoked and the 20 mg oral product. This was a randomized, placebo controlled, double blinded study. This **proved** that one does NOT need all of the components of marijuana to produce any pain effect over using oral dronabinol (THC) alone. Both oral and smoked THC version produced the same level of analgesia. Actually, the oral dronabinol produced longer-lasting analgesia than the smoked version (as noted in P Drum Ex.15). The **smoked** version had a **higher abuse-related** subjective effects (i.e. euphoria and craving) than the oral dronabinol, which raises the addiction potential for smoked marijuana over an oral THC, as discussed by Dr Drum during his testimony. Both had similar cardiovascular effects (as noted in P Drum Ex 10 and 11). As Dr Drum stated, if there is belief of the need for all 300 + ingredients – what are the **doses** of each active ingredient? What are the **drug interactions** of each active ingredient (as noted in P Drum Ex 4 & 5)? What are the **side effects** of each active ingredient? What are the **toxic levels** of each active ingredient? HHS and FDA have NOT provided any of this information for marijuana to become a true medication as has been required for decades. The industry claim the marijuana plants maintain the same THC amounts and other 300+ active ingredients for it to be medicine (fraudulent statement #8). Expert testimony in this case have stated there are considerable component (THC and others) differences in a the marijuana plant (see pg 1219:9-11 and 1366:16-20) that do not make marijuana a drug to be defined as medicine. This is also obvious by the studies of the mislabeling of THC and CBD as discussed by P. Drum Ex. 25 & 26.

The Governments claims pictures were AI and cartoon images

The Government lawyer claimed Dr Randall's pictures were AI generated (fraudulent statement #9). The burden of proof for such claim is on the Government and they provided NO such evidence. There are pictures from a baby's use of a marijuana product. The court can find in a 2013 episode from a Nancy Grace program a child using marijuana and this was prior to ANY AI being used. The incidence of child use by parents has only been increasing ever since states claim medical indications for marijuana as is evident by the increasing calls to poison control centers. False claims are NOT the same as evidence.

The American youth and adolescents are experiencing both medical and psychological harms because marijuana is so prevalent in their online and social environments. These promote the use and provide ease of sale. If a short google search can produce a quantity of pro-marijuana use images, imagine what a longer search would display. The cartoon pictures of marijuana use are also clear examples attracting a younger population to marijuana products on the internet. The tobacco marketing agents learned this technique with Joe Camel in the 1980's. Again, Dr. Randall extends an invitation to spend a day in any the emergency department in the US in a state with legalized marijuana to see the endpoint of legislation. According to the marijuana industry, marijuana has never killed anyone (fraudulent statement #10). Dr Randall discussed how Cannabis Hyperemesis Syndrome (CHS) has killed people due to blood electrolyte disturbances leading to a heart attack and kidney failure. There are also many others that have been killed including those committing suicide, in car crashes, strokes and heart attacks, including babies.

Medical Community is AGAINST Marijuana Use as Medicine

The court must use science in its decision. The industry has been allowed to repeatedly and widely advertise unproven claims of cures/benefits of cannabis products (fraudulent statement #11). They have been misleading the American public (view the wheel of disease treatments on Dr. Randall's slide 14). The DEA's Pharmacologist testified that marijuana is not a medicine and does not meet the standard requirements. An overwhelming list of U.S. medical community is firmly against marijuana being deemed medicine. As is seen on the International Academy on the Science and Impact of Cannabis (at https://iasic1.org/library/), of which Drs Drum and Randall are both volunteer members. Medical organizations are ALL AGAINST the use of marijuana as medicine.

Here are their statements:

- Alzheimer's Association Statement on Cannabis: medical cannabis is not FDA approved to treat Alzheimer's or its symptoms. Phase 2 LiBBY trial indicated that a "carefully purified and controlled combination of THC and CBD" can reduce severe end of life agitation in hospice eligible dementia patients. Over the counter or dispensary products vary widely and are nor proven equivalents. They go on to state there is no scientific proof that cannabis or cannabis-derived products can prevent, slow, or reverse the underlying pathology of Alzheimer's Disease. https://www.alz.org/news/2020/cannabis-helpful-or-harmful

- American Academy of Neurology – medical research does not support cannabis-based products as treatment options for the majority of neurological disorders, psychiatric and neurologic adverse effects have been described in recreational AND MEDICAL USE, which is particularly problematic in a population with compromised neurological function, the interaction of cannabis products and neurological prescriptions is uncertain,

- American Academy of Ophthalmology – based on reviews by the National Eye Institute (NEI), the Institute of Medicine (IOM) and on available scientific evidence, the American Academy of Ophthalmology Complementary Therapy Task Force finds no scientific evidence demonstrating increased benefit and/or diminished risk of marijuana use in the treatment of glaucoma compared with the wide variety of pharmaceutical agents now available,
- American Academy of Pediatrics (AAP) – opposes marijuana use in ages 0 – 21 due to negative effects on the developing brain, opposes "medical marijuana" outside the regulatory process of the US FDA, discourages the use of marijuana by adults in the presence of minors, strongly opposes the use of smoked marijuana because smoking is known to cause lung damage,
- American Association of Clinical Endocrinologists highlights that chronic cannabis use can cause serious endocrine complications - notably suppressing hypothalamic pituitary pathways. https://www.nature.com/articles/s43856-026-01469-x https://www.medcentral.com/meds/cannabinoids/cannabis-and-endocrine-care
- American Cancer Society – opposes the smoking or vaping of marijuana and other cannabinoids in public places because carcinogens in marijuana smoke poses numerous health hazards to the patient and others in the patient's presence,American College of Emergency Physicians (ACEP) – passed a resolution on the Complications of Marijuana Use on 10/24/21. This resolution directs ACEP to develop practice guidelines on the treatment and complications of marijuana use as seen in emergency medicine presentations, that ACEP provide education and guidance to emergency physicians in relationship to documentation and overall awareness of cannabis related ED diagnosis and that ACEP develop and disseminate public facing information on the complications of marijuana use as seen in the emergency departments,

- American College of Medical Toxicology (ACMT) – calls upon stakeholders to implement measures to prevent cannabis exposure in children less than 12,
- American College of Obstetricians and Gynecologists (OCOG) – OBGYN should be discouraged from prescribing or suggesting the use of marijuana for medical purposes during preconception, pregnancy and lactation,
- American Dental Association – points out several oral health risks associated with cannabis smoking. This includes gum disease (periodontal complications), dry mouth (xerostomia), and white plaques in the mouth (leukoplakia), as well as, increased risk of mouth and neck cancers,
- American Epilepsy Society – the term "medical marijuana" is a legal definition, purified CBD, available by prescription as Epidiolex, may be effective in treatment of Lennox-Gastaut syndrome and Dravet syndrome. The purified, pharmaceutical formulation of CBD cannot be obtained from a marijuana dispensary. Products from a dispensary may not contain just CBD, but also THC, pesticides, bacteria, and other dangerous impurities,
- American Glaucoma Foundation – marijuana or its components are not recommended for the treatment of glaucoma due to lack of evidence, short duration of action in lowering intraocular pressure, and lack of long-term trials that evaluate the health of the optic nerve,
- American Heart Association – patients with underlying heart disease could experience increase angina when cannabis is smoked, continual cannabis use is associated with increased risk of metabolic syndrome compared to no use, the risk of stroke was higher among frequent marijuana users age 18 – 44 with concomitant e-cigarette use, the public needs high quality information about cannabis, which can help counterbalance the proliferation of rumor and false

claims about the health effect of cannabis products, there is a need to create knowledge and automated warnings around drug-drug interactions,

- American Lung Association – Smoke from marijuana combustion has the same toxins, irritants and carcinogens as tobacco smoke, Marijuana smokers have a greater exposure of tar per breath than tobacco smokers, Smoking marijuana clearly damages the human lung, and regular use leads to chronic bronchitis and can cause an immune-compromised person to be more susceptible to lung infections, No one should be exposed to secondhand marijuana smoke, Secondhand marijuana smoke contains the same toxins and carcinogens found in directly inhaled marijuana smoke, in similar amounts if not more, The American Lung Association strongly cautions the public against smoking marijuana as well as tobacco products,
- American Medical Association – Cannabis is a dangerous drug and as such is a serious public health concern, The sale of cannabis for adult use should not be legalized, States that have legalized cannabis for medical or adult use should be required to take steps to regulate the product and protect public health and safety,American Psychiatric Association – "There is currently no scientific evidence to support the use of cannabis as an effective treatment for any psychiatric illness. Several studies have shown that cannabis use may in fact exacerbate or hasten the onset of psychiatric illnesses, as evidence by both international trials and meta-analyses. This includes the contribution of cannabis to symptoms of mood disorders, anxiety and psychosis, particularly in young adulthood",
- American Society of Addiction Medicine (ASAM) - Cannabis and cannabis-derived products recommended for medical indications should be subject to FDA review and approval to ensure their safety and effectiveness, Healthcare professionals should not recommend cannabis use for treatment of opioid use disorder, Non-FDA approved cannabis

recommendations by clinicians should be reported to Prescription Drug Monitoring Programs (PDMPs),

- American Society for Regional Anesthesia – published a consensus guidelines for managing perioperative patients on cannabis or cannabinoids. The recommendations include: Universal screening of cannabinoids before surgery, Counseling patients with frequent, heavy cannabis use on the negative effects of post-operative pain control, postponing elective surgery on patients who are impaired or intoxicated on cannabis Association for Addiction Professionals (NAADAC) – cannabis needs to be subject to the same research, consideration and study as any other medicine through the FDA Autism Science Foundation – does not recommend medical marijuana for the treatment of Autism Spectrum Disease, Crohn's & Colitis Foundation state that cannabis does not treat or reduce gut inflammation in Crohn's disease. There is no decreased markers of inflammation and there is no improvement of healing. Conversely, it may mask symptoms and delay care.

https://www.crohnscolitisfoundation.org/patientandcaregivers/complementary-medicine/medical-cannabis

- International Association for the Study of Pain – Review of preclinical research and clinical safety and efficacy of cannabis and cannabinoids for pain relief have identified important research gaps. Due to the lack of high-quality clinical evidence, the International Association for the Study of Pain (IASP) does not currently endorse general use of cannabis and cannabinoids for pain relief. International Association for the Study of Pain recognizes the pressing need for preclinical and clinical trials to fill the research gap, and for education on this topic.

- The Parkinson's Foundation notes a lack of conclusive scientific evidence to endorse its

use for Parkinson's disease. Cannabis can worsen thinking and memory problems, confusion and executive function. Also, many drug interactions. Official recommendation: NO ENDORSEMENT.

- State Medical Societies Concerns with State Legalization of Recreational Marijuana (Delaware, New Jersey, New York, Ohio, Pennsylvania) – Of behalf of the tens of thousands of physicians we represent, the medical societies of Delaware, New Jersey, New York, Ohio, and Pennsylvania, are again joining together to express mutually shared concerns about state governments; efforts to legalize marijuana for recreational use. Legalization continues to present serious public health concerns.

- US Surgeon General's Advisory: Marijuana Use and the Developing Brain (2019) - Marijuana can enter the fetal brain from the mother's bloodstream, THC has been found in breast milk for up to 6 days after the last recorded use, Marijuana use in pregnancy is associated with adverse outcomes, No one should smoke marijuana around a baby; Frequent marijuana use during adolescents is associated with: Changes in the brain involved in attention, memory, decision-making, and motivation, Impaired learning, decline in IQ, school performance and life satisfaction, Increased rates of school dropout and suicide attempts, Risk of early onset psychotic disorders such as schizophrenia, Greater likelihood of misusing opioids

- Vermont Medical Society – passed a resolution on Commercial Sales of Cannabis on 11/17/21. It contains opposition to advertisement. Limits on potency and warning label requirements.

These are only a few of the medical societies or associations that have issued warnings about the harms and mistruths of marijuana. Clearly, by the number of medical professional associations that DO NOT recommend marijuana products (especially those products sold in

This is seen with codeine, barbiturates, etc. The maximum CS III dronabinol dose allowed in a day is 20 mg given in divided doses. The CS III substance maximum strength is 10 mg for the oral product. A 28 mg dronabinol dose in a 70 kg adult causes significant CNS effects (as seen in P. Drum Ex 6 & slide #28) The reason the government has admitted needing a CS III status is for financial reasons (ability to write off business taxation allowed with CS III substances), not scientific reasons. This should not have any bearing on which CS level is selected. The marijuana industry and proponents claim that, as a CS I substance, marijuana cannot undergo scientific study (fraudulent statement #14). Dr Drum discussed the vast number (nearly 10,000 government funded marijuana studies) at a cost of $4.2 Billion since 1985 in a search performed on a Government database. Quite the contrary, Dr Drum showed these numbers of studies and financial support far exceed studies performed on other more common drugs that have received FDA approval status. Marijuana still has not received one indication despite decades of study. dispensaries). It is a shame to continue to promote marijuana as a medication (fraudulent statement #1). Decreasing the schedule of this drug will only serve to promote the public's belief that there are therapeutic benefits of dispensary marijuana.

Daily use leads to Cannabis Use Disorder

The marijuana industry claims their substance is not addictive (fraudulent statement #12) The incidence in marijuana chronic user disorder reported in testimony to be found in 30% of daily users (as also reported by Dr Madras pg 1252:17-20). This is higher than the incidence of opiate use (CS II substances) disorder in chronic users (see pg 1643:1-7). The abuse potential for daily morphine (a CS II substance) has been seen to be 3% of the general chronic pain population from the College of Family Practice Physicians of Canada from 2019 https://cfclearn.ca/tfp40/ . This addiction rate for an opiate is one-tenth the risk seen with

marijuana. This high cannabis addiction rate would then prohibit the ability to use marijuana daily for such medical disorders as pain and anorexia (fraudulent statement#1). These indications would require daily use and thus providing a hallucinogenic substance that has a 30% addiction rate.

False claim on benefit of medical marijuana preventing opiate deaths

The court was witness to the deception that the marijuana industry has been perpetrating for years with their false claims confusing the public. This was seen in their testimony by C. Burchman's cross examination pg 853: 1 through pg 854:4. He even stated on pg 853:1-2 "Well, the landmark one and the one I used to hang my hat on is Bachhuber from JAMA…" and later on pg 853: 25 through pg 854: 1- 6 "That's exactly correct, but the Bachhuber study, and the reason it was refuted was, you know, the operative word is people, and they looked at populations. They looked at numbers. They didn't examine people." "And that's really the sticking point" (fraudulent statement #13) That as not the reason the study was completely refuted. It as because the authors repeatedly failed to acknowledge the other aspects of opiate controls that were being simultaneously implemented such as the initiation of state generated Prescription Drug Monitoring Programs (as mentioned by both Drs. Drum and Randall). The Bachuber paper also failed to also acknowledge pill-mill regulations and harm-reduction strategies that were implemented so that these overlapping policies made it hard to isolate cannabis laws as a causal factor. Burchman failed to acknowledge the 2019 C Shover, et al. Proceedings of the National Academy of Sciences (PNAS) entitled "*Association between medical cannabis laws and opioid overdose mortality has reversed over time*". That study extended the original dataset through 2017 and found not only did a protective association from marijuana disappear, but the outcome reversed from a 21% lower opioid-overdose mortality to a

23% higher mortality in medical cannabis states. The authors found **NO evidence that recreational or medical laws affected opioid mortality**. This is consistent with the falsehood that marijuana community have claimed for decades. The marijuana use actually increased the deaths due to fentanyl. The presentation by Burchman was BIASED with one-sided views and was obvious. He also admitted to having marijuana financial interests. Both Drs. Drum and Randall admitted NO financial interest in marijuana.

Speaking of fentanyl deaths, the DEA court building had pictures of those who have died from fentanyl use in the lobby, which was extremely concerning. In light of the potential change in marijuana from a CS I substance to a CS III substance, will the DEA also post the pictures of those who have died from marijuana-impaired driving automobile crashes, suicides, and mass killings performed by marijuana users who have gone psychotic? These cases were pointed out by multiple witnesses during this hearing.

CS III status is the wrong choice

The proposal to change marijuana from a CS I to CS III in not consistent with multiple issues. Dronabinol as a liquid formulation 5 mg/ml (as seen in P Drum slide # 14) is FDA-approved as a CS II. Dronabinol oral capsules are a CS III product (as seen in P Drum Ex. 6). As discussed by Dr Drum, the liquid formulation is more consistent with a smoked version as seen in P Drum slides #13 & 39 and exhibit P Drum #15. Dr Drum also thoroughly discussed on slide # 14 about how more than 10 FDA-approved substances have multiple CS status. The higher the dose of the controlled substance product is associated with the CS II status rather than CS III or IV or V.

The marijuana industry has yet to gain one site willing to follow all of the regulations required of such a site. Dr Drum discussed on slide # 43 of P Drum presentation how the Federal

Government allowed for additional sites to generate medical marijuana products. To date, there still is no other DEA approved sites by the marijuana cultivators to generate federally approved marijuana products. The industry has claimed it is too difficult to follow the rules and regulations.

HHS Misrepresentation of generalized anorexia in place of anorexia associated with AIDS

The government claims that marijuana is indicated for anorexia, without any qualifications (fraudulent statement #15). From P Drum's slide #14 and Ex #6, dronabinol is FDA approved for a specific weight loss syndrome – "anorexia associated with weight loss in patients with AIDS" – NOT generalized anorexia weight loss. A provider would not prescribe daily dronabinol for anorexia due to the elevated risk of cannabis hyperemesis syndrome and addiction with chronic daily use as described by Dr Randall and others.

State Regulations are Failing to protect the public

The industry claimed they will follow state approved regulations (labeling, accuracy, testing, devoid of toxic materials) if approved (fraudulent statement #16). They have not been able to accurately label the products which is required in regulations – as discussed by P Drum in slides 50 – 51 and P Drum # 25 - 26. The marijuana industry has also failed to assure timely recalls as discussed in P Drum slides # 56 – 61 and P Drum Ex. #31 - 35. Finally, there products have also been identified to have bacteria, mold, fungi and heavy metals as discussed in slides 62 – 68 and P Drum Ex. #36 - 51. These products are NOT safe for the American public and is returning to a practice specifically prohibited by the 1906 Food and Drug Act (as seen in P Drum slide #6). The states are poorly controlling these products and providing safety to the public. The accuracy of the content amounts are not at FDA-accepted rates. The laboratories have been caught falsifying reports, not testing for all required pesticides and heavy metals and the states

have even not created enough testing requirements. Companies have been allowed by the states to continue to provide toxic marijuana products even while under investigation.

Marijuana is a known Carcinogen and Mutagen

Marijuana smoke and THC has been identified by the State of California Environmental Protection Agency as a carcinogen and reproductive toxicant in Prop 65 (as seen in P Drum Ex. 27 slide #52). The marijuana industry claim it is natural and safe (fraudulent statement #17). Breast and testicular cancer rate are climbing in North America is areas with liberalized marijuana use compared to those areas not allowing or with lower use. This was discussed by Dr Drum. As such, how can the Federal Government move forward with approving, as a medicine, a known carcinogen equal to tobacco on a chronic basis for anorexia or pain? This is also stated by multiple medical personnel.

Conclusion

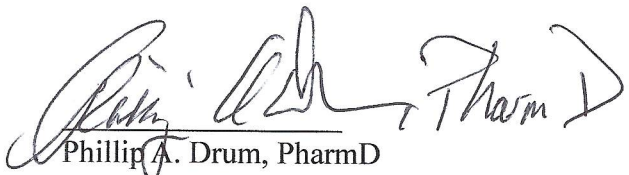
As we demonstrated during testimony, there are many ways that marijuana products harm children and adults. It is a very potent hallucinogen, is more addictive than CS II substances and should be handled and treated as such. There are innumerable significant consequence/harms that should appear as a black box warning as on a traditional FDA approved and regulated medication. Decisions being made today will have effects on children/adolescents for the duration of their life times (psychosis, cannabinoid hyperemesis syndrome, addiction, cannabis use disorder, etc). Clearly the few cases discussed displayed how children are being affected for their lives. Please don't ignore this heighten risk and severe consequences. Marijuana is not a medicine. It has not been approved by HHS and has had no/little FDA and DEA oversight. The testimony from the DEA pharmacologist made it very clear, marijuana is not a medicine and does not meet the standard requirements (see pg 1365:23-25 through 1366:1-6). With the DEA

making marijuana a CS III indicates to professionals and the public that marijuana has been deemed a medicine by the DEA. As discussed by Dr Drum, CBD/Epidiolex was FDA-approved as a CS V substance. The DEA subsequently changed CBD to a non-controlled substance. The DEA should NOT act on changing marijuana's CS status without marijuana first being FDA-approved as medicine. They are the medical/science experts. That has not been done to date. For marijuana to be medicine it must have an approved dose, dosing schedule, evidence of efficacy over adverse effects, safety precautions, and warnings. Currently none of these standards are being met. Therefore, marijuana should not be made a "medicine" at a CS II or CS III level. No medicine should be smoked or vaped - as both these mechanisms of delivery are known to cause lung disease. Additionally, there is no FDA-approved package insert for marijuana to date.

This may be a medical-legal decision. Only an extremely small minority of the medical professionals (mostly those with a biased financial interest) agrees that marijuana is medicine. The vast majority, especially those with knowledge of addiction and the requirements for a medicine, agree that marijuana is NOT a medicine for any indication, and as such, must remain a CS I substance. In addition, the addiction profile (cannabis use disorder) from daily marijuana use is 30% which is higher than CS II opiates.

August 14, 2026

Respectfully submitted,



Phillip A. Drum, PharmD
Designated Party, Pro se

CERTIFICATE OF SERVICE

I hereby certify that, on August 14, 2026, I caused a copy of the foregoing document to be delivered by email to the following recipients:

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7. DUID Victim Voices, by email to
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8. Kenneth Finn, M.D., by email to
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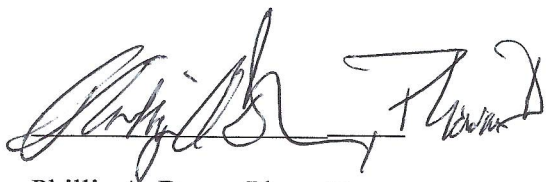
August 14, 2026



Phillip A. Drum, PharmD

Designated Party, Pro se