Issues in the U.S. Drug Enforcement Administration's Notice of Proposed Rule Making Concerning the Rescheduling of Marijuana

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It is intended for reference purposes only to assist members of the National Drug and Alcohol Screening Association (NDASA)

[Don't feel pressure to respond to all – hitting a few key points that stick out to you would be helpful]

The following are the eight factors that must be addressed to reschedule marijuana. NDASA has included some quotes upon which the U.S. Attorney General and the DEA will rely on to make a final decision. If you have studies, data, articles and/or thoughts about the following, you may copy relevant the quote(s) included in this document to your draft comment under the appropriate factor(s). (Don't feel pressure to respond to all factors listed, stick to hitting few key points that are important to you.)

Factor 1: Marijuana's Actual or Relative Potential for Abuse

- "As part of its analysis, HHS [U.S. Department of Health and Human Service] concluded that evidence shows that, although some individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community, the vast majority of individuals who use marijuana are doing so in a manner that does not lead to dangerous outcomes to themselves or others. HHS Basis for Rec. at 6–7." – 99 FR 44601 (May 21, 2024))

- "HHS also concluded that the public-health risks posed by marijuana are lower compared to those posed by other drugs of abuse (e.g., heroin, oxycodone, cocaine), based on HHS's evaluation of various epidemiological databases for emergency department (''ED'') visits, hospitalizations, unintentional exposures, and most importantly, overdose deaths." – 99 FR 44601 (May 21, 2024)

- "In addition to the data considered by the HHS Basis for Recommendation, the data considered by HHS and DEA in their 2015 eight-factor analysis, and the additional data discussed above, DEA anticipates that additional data on seizures of marijuana by law enforcement, cannabis-related ED visits, as well as updated epidemiological survey data since 2022, may be appropriate for consideration." – 99 FR 44602 (May 21, 2024) [NOTE: The DEA is begging for assistance here! There are many more places in this document where you will find such requests by DEA for assistance.]

- "HHS found that there is a lack of evidence of significant diversion of marijuana from legitimate drug channels." – 99 FR 44602 (May 21, 2024) [NOTE: ARE THERE "legit" drug channels for this Schedule I drug? Here is a DEA report on the subject released May 23, 2024: https://www.dea.gov/sites/default/files/2024-05/5.23.2024%20NDTA-updated.pdf]

- "Given this unique landscape, DEA believes that the lack of data indicating diversion of marijuana from federally sanctioned drug channels to the illicit market is not indicative of a lack of potential for abuse of the drug. DEA anticipates that additional data on diversion from State programs and DEA-registered manufacturers may aid in a determination of whether diversion is taking place." – 99 FR 44602 (May 21, 2024)

- "HHS Conclusion With Respect to Factor 1 HHS determined that epidemiological data indicate that marijuana has the potential for creating hazards to the health of the user and to the safety of the community. However, as a relative finding on abuse liability, when comparing marijuana to heroin, oxycodone, hydrocodone, fentanyl, cocaine, ketamine, benzodiazepines, zolpidem, tramadol, and alcohol in various epidemiological databases that allow for some or all of these comparisons, marijuana is not typically among the substances producing the most frequent incidence of adverse outcomes or severity of substance use disorder." – 99 FR 44603 (May 21, 2024)

Factor 2: Scientific Evidence of Its Pharmacological Effect, if known

- There is an extensive discussion on pages 44603- 44606 about studies HHS conducted through SAMHSA and FDA. They delve deeply into the science of cannabinoid receptors, etc. They admit marijuana is addictive. AND:

- "DEA believes that additional data on marijuana's pharmacological effects may be appropriate for consideration in assessing this factor." – 99 FR 44606 (May 21, 2024) [Do you know of scientific studies help DEA here?]

Factor 3: The State of Current Scientific Knowledge Regarding the Marijuana

- "Products sourced from State-authorized adult-use and medical-use programs are subject to a patchwork of inconsistent product standards and safety requirements. Although some State programs have a set of standards (for example, on manufacturing, testing, labeling, and packaging), each program's controls are different, leading to a wide variation of products across State-authorized programs. And the illicit marketplace is not subject to any standards or oversight. As a result, the range of products within the CSA's definition of marijuana encompasses a large degree of variation in forms for consumption, composition of biologically relevant constituents, potency, and contaminants." – 99 FR 44606 (May 21, 2024) [**NOTE:** Doesn't this seem to lead to a conclusion of "No!" on this factor? It is an opportunity to say the stated inconsistencies of product standards and safety requirements should lead to the conclusion that there is not enough scientific knowledge about this drug and that rescheduling it is premature.]

NOTE: At the end of the discussion of Factor 3, DEA lays groundwork for what they need: "DEA likewise notes that there is considerable variability in the cannabinoid concentrations and chemical constituency among marijuana samples and that the interpretation of clinical data related to marijuana is complicated. A primary issue is the lack of consistent concentrations of D9-THC and other substances in marijuana, which complicates the interpretation of the effects of different marijuana constituents. Additionally, the non-cannabinoid components in marijuana may potentially modify the overall pharmacological and toxicological properties of various marijuana strains and products. DEA anticipates that additional data on other marijuana constituents, routes of administration of marijuana, and the impact on D9-THC potency may be appropriate for consideration." 99 FR 44607 (May 21, 2024)

Factor 4: Marijuana's History and Current Pattern of Abuse

In response to data and inconsistent conclusions by HHS on pages 44607-44610, DEA said: "DEA anticipates that additional information arising from this rulemaking will further inform the findings that must be made to reschedule marijuana, including with respect to this factor. DEA also notes that, according to the World Health Organization, cannabis is globally the most commonly used psychoactive substance under international control.22 Accounting for half of all drug seizures worldwide, the global annual prevalence of cannabis consumption is 2.5 percent or about 147 million people.23 In 2016, an estimated 28.6 million individuals age 12 or older were current (in the past month) illicit drug users.24 By 2020, approximately 59.3 million individuals age 12 or older reported using an illicit drug within the past year; 83.6 percent (49.6 million) of those past-year illicit drug users reported using marijuana.25 In

2022, the Domestic Cannabis Eradication and Suppression Program was responsible for the eradication of 4,435,859 illegally cultivated outdoor cannabis plants and 1,245,980 illegally cultivated indoor plants for a total of 5,681,839 illegally cultivated marijuana plants.26 DEA believes that additional data on marijuana's pattern of abuse may be appropriate for consideration in assessing this factor. " – 99 FR 44610 (May 21, 2024) [NOTE: Thus, DEA is pointing to its last evaluation on this subject, global data and asks for additional information. At the very least, public comments can address the contradictory interpretation of the data by HHS in this, Factor #4.]

Factor 5: The Scope, Duration, and Significance of Abuse

To address Factor 5, "HHS analyzed the consequences over time of marijuana abuse compared to the abuse of other substances…" – 99 FR 44610 (May 21, 2024) [**NOTE:** Their data actually indicates the criteria for this factor was not met because the data listed below shows marijuana is highly addictive, causes Substance Abuse Disorder (SUD) and that marijuana is the 1st or 2nd most common drug for which people are admitted for in-patient treatment.]

Their facts simply do not support their conclusions on this factor. For example:

- HHS decided that, based on Poison Control (PC) data, fentanyl was the reason for more PC calls and, although it was the 5th most frequently called about drug, the medical outcomes for marijuana were not as serious as for fentanyl. – 99 FR 44611 (May 21, 2024).

- HHS cited the National Survey of Drug Use and Health (NSDUH) data to say: "Although the 2021 NSDUH data showed that the likelihood of meeting the criteria for a SUD was highest for heroin, followed by marijuana, cocaine, and alcohol, the absolute number of individuals who met the criteria had a different order." – 99 FR 44611 (May 21, 2024). [In other words, although the likelihood of having a SUD from marijuana use was secondary only to heroin use (for drugs), HHS would discount this fact because there are actually more people with an alcohol SUD. HHS admitted the number of people with a marijuana SUD was second only to the number with an alcohol SUD. The reasoning is flawed in so many ways. The truth is that abuse of marijuana ranks second to heroin, a Schedule I drug. Marijuana is a highly addictive substance and you can reasonably say that, based on these facts, marijuana does not belong outside Schedule I.]

- Much more data is cited on pages 44611-44612, but HHS concluded that other drugs were greater in the "scope, duration, and significance of abuse", DEA countered with their reasoning from their 2016 denial of a request to reschedule marijuana to Schedule III. Specifically, DEA explained:
  - "According to the NSDUH, in 2022, among people aged 12 or older in the United States, an estimated 61.9 million people (22 percent) had used marijuana in the past year, and 42.3 million (15.0 percent) had used it in the past month. DEA notes that, according to one National Institutes of Health-supported study, the prevalence of daily marijuana use reached its highest level reported in 2021, at 11 percent of Americans aged 12 or older, a 3 percent increase from 2017 and a 5 percent increase from 2012." – 99 FR 44613 (May 21, 2024)

- "TEDS data showed that, in 2020, marijuana was the primary drug of admission in approximately 10 percent of all admissions to substance abuse treatment among patients aged 12 and older… DEA also notes that TEDS data for 2021 reported that marijuana/hashish was the primary substance of abuse in 10.2 percent of all admissions to substance abuse treatment among patients aged 12 and older." – 99 FR 44613 (May 21, 2024).

- "The 2021 TEDS data further reported that New York, California, Georgia, North Carolina, New Jersey, Texas, Minnesota, South Carolina, Florida, and Connecticut accounted for 55.9 percent of admissions to substance use treatments services where marijuana/hashish was listed as the primary substance." – 99 FR 44613 (May 21, 2024)

- "DEA also believes that additional information regarding the scope, duration, and significance of marijuana abuse may be appropriate for consideration in assessing this factor." – 99 FR 44613 (May 21, 2024)

Factor 6: What, If Any, Risk There Is to the Public Health

HHS did not provide their reasoning within the NPRM on this issue, instead they referred to supporting materials in their materials submitted to the Attorney General. In their conclusion, HHS stated:

- "HHS found that the risks to the public health posed by marijuana are low compared to other drugs of abuse (e.g., heroin (schedule I), cocaine (schedule II)), based on its evaluation of various epidemiological databases for ED visits, hospitalizations, unintentional exposures, and, most importantly, for overdose deaths." – 99 FR 44614 (May 21, 2024)

Conversely, DEA noted:

- "In 2016, DEA found that, ''[t]ogether with the health risks outlined in terms of pharmacological effects above, public health risks from acute use of marijuana include impaired psychomotor performance, impaired driving, and impaired performance on tests of learning and associative processes. Chronic use of marijuana poses a number of other risks to the public health including physical as well as psychological dependence.'' 81 FR 53739–40." – 99 FR 44614 (May 21, 2024)

- DEA also set out a road map for commenters:
    - "In addition to the data provided in the HHS Basis for Recommendation and the data considered by HHS and DEA in their prior eight-factor analyses, DEA anticipates that additional data on public safety risks, risks from acute and chronic marijuana use via oral and inhaled administration routes, and the impact of D9-THC potency may be appropriate for consideration." – 99 FR 44614 (May 21, 2024)

- "DEA notes that studies have examined the risk associated with marijuana use and driving… The Rocky Mountain High Intensity Drug Trafficking Area reported in a publication that traffic deaths in Colorado in which drivers tested positive for marijuana more than doubled from 55 in 2013 to 131 in 2020, although other evidence in the same report suggests that driving under the influence citations involving marijuana have grown at a rate similar to the rate for citations involving other drugs." – 99 FR 44614 (May 21, 2024)

- "DEA also identified some evidence suggesting that, among drivers who test positive for at least one drug in a traffic stop, a growing share test positive for cannabis." – 99 FR 44614 (May 21, 2024)

Factor 7: Marijuana's Psychic or Physiological Dependence Liability

Regarding psychic dependence:

- HHS admits: "In some individuals, extensive use of marijuana can lead to SUD." – 99 FR 44614 (May 21, 2024)

- However, HHS also says cannabis is less addictive than alcohol or tobacco. – 99 FR 44614 (May 21, 2024)

- Importantly, HHS concluded: "Among those individuals who seek admission for treatment for SUD associated with a drug of abuse, marijuana was the third most frequently reported primary substance of abuse. Thus, marijuana can produce psychic dependence in some individuals who use the drug." – 99 FR 44614 (May 21, 2024)

Regarding physiological dependence:

- "HHS reported that up to 40 to 50 percent of individuals who use marijuana on a regular basis may experience physical dependence." – 99 FR 44615 (May 21, 2024)

Regarding Factor 7 – "In conclusion, HHS found experimental and clinical evidence that chronic, but not acute, use of marijuana can produce both psychic and physical dependence in humans." – 99 FR 44615 (May 21, 2024)

DEA provides the following to assist commenters:

- "In 2016, DEA found that ''[l]ong-term, heavy use of marijuana can lead to physical dependence and withdrawal following discontinuation, as well as psychic or psychological dependence.'' 81 FR 53740." – 99 FR 44615 (May 21, 2024)

- "DEA notes that some physicians have argued that CUD is underdiagnosed and undertreated in the medical setting, and that other medical professionals have noted that CUD needs to be

better understood and characterized to better inform users and treatment professionals." – 99 FR 44615 (May 21, 2024)

- "DEA anticipates that additional psychic or physiological dependence liability may be appropriate for consideration." – 99 FR 44615 (May 21, 2024)

Factor 8: Whether Marijuana Is an Immediate Precursor of a Substance Already Controlled Under the CSA

There is no real discussion here, only: "HHS concluded that marijuana is not an immediate precursor of another controlled substance. HHS Basis for Rec. at 61. This finding is consistent with DEA's finding in 2016. 81 FR 53740. DEA welcomes additional information on this factor." – 99 FR 44615 (May 21, 2024)

Determination of Appropriate Schedule for Marijuana

This is a good place to make alternate suggestions, such as: retaining marijuana in Schedule I; moving it to Schedule II, where it would still be tested for under the DOT's regulations and where HHS will be able to continue to certify laboratories for it; or if the Attorney General and DEA move marijuana to Schedule III, there needs to be some form of a Safety Carve-Out to allow HHS to continue to test for substances below Schedules I and II. That Safety Carve-Out could be as simple as an Executive Order to say that HHS has the authority to test for and certify laboratories for drugs below Schedules I and II.]

Here is what the NPRM says

"After conducting the eight-factor analysis in 2023, HHS has recommended three findings regarding the appropriate schedule in which to place marijuana. The three findings relate to: (1) a substance's abuse potential; (2) whether the substance has a CAMU; and (3) the safety or dependence potential of the substance." – 99 FR 44615 (May 21, 2024)

Findings

1.Potential for Abuse

"In 2016, HHS found that many factors indicated marijuana's high abuse potential, 'including the large number of individuals regularly using marijuana, marijuana's widespread use, and the vast amount of marijuana available for illicit use.' 81 FR 53688 at 53706. As a result of its most recent evaluation, which incorporates post-2016 data into its analysis, HHS has recommended a finding that marijuana has a potential for abuse less than the drugs or other substances in schedules I and II." – 99 FR 44615 (May 21, 2024)

"Despite the high prevalence of nonmedical use of marijuana, HHS observed that an overall evaluation of epidemiological indicators suggests that it does not produce serious outcomes compared to drugs in schedules I or II. HHS found this especially notable given the availability of marijuana and marijuana-derived products that contain extremely high levels of D9-THC. Due to such availability, the epidemiological data described in HHS's evaluation inherently include the outcomes from individuals who use marijuana and marijuana-derived products that have doses of D9-THC that range from low to very high, and yet the data demonstrate that these products overall are producing fewer negative outcomes than drugs in schedules I or II." – 99 FR 44615 (May 21, 2024)

Also, in its conclusory approach, "HHS evaluated the totality of the available data and has concluded that it supports the placement of marijuana in schedule III" – 99 FR 44616 (May 21, 2024)

2. Currently Accepted Medical Use (CAMU) in Treatment in the United States

"Applying this test, HHS recommended a finding that marijuana has a currently accepted medical use in the United States, specifically for the treatment of anorexia related to a medical condition, nausea and vomiting (e.g., chemotherapy-induced), and pain. According to HHS, its evaluation also supported a finding that there is accepted safety for the use of marijuana under medical supervision for the treatment of anorexia related to a medical condition, nausea and vomiting (e.g., chemotherapy-induced), and pain." – 99 FR 44616 (May 21, 2024) [NOTE: Marinol (generic for dronabinol), a Schedule II drug, can be used for these same reasons – but can be dosed in exact quantities (how does one dose a plant?). Isn't this ironic that Marinol will be a Schedule II drug but marijuana will be Schedule III? This is entirely inconsistent. Marinol is reduced to a pill form and is dosed and dispensed by licensed pharmacists. There is nothing in the NPRM to say marijuana will be dosed and dispensed by licensed pharmacists.]

"The Assistant Secretary for Health concluded that an FDA assessment under Part 2 of the CAMU test was warranted to determine if credible scientific support exists for the use of marijuana to treat at least one of the medical conditions identified by OASH under Part 1…"– 99 FR 44617 (May 21, 2024) [NOTE: to override the 5-part test DEA has always applied to determining CAMU, HHS and the Attorney General simply set aside the DEA's 5-part analysis and FDA said all was well with using marijuana medically.]

"FDA's review of the available information identified mixed findings of effectiveness across indications, ranging from data showing inconclusive findings to considerable evidence in favor of effectiveness, depending on the source." – 99 FR 44617 (May 21, 2024) [NOTE: Then why are they making changes based on mixed findings?]

"As of August 2023, FDA reported that the real-world data sources available to FDA, in general, lack the necessary elements to identify the exposure (i.e., to marijuana), to distinguish the reason for use (medical vs. recreational) and, if applicable, the condition that prompted its medical use, and to permit sound inferential analyses. Therefore, they were not included in HHS's review." – 99 FR 44617 (May 21, 2024) [NOTE: They are admitting that there are not clear data to support this change to Schedule III. Doesn't it seem appropriate to call this out in comments?]

"According to FDA, data from United States national surveys, in general, lacked details on patient characteristics and factors that prompted the use of marijuana for medical purposes…" – 99 FR 44618 (May 21, 2024)

"Only data from one survey provided information on the intended indication for use, suggesting that individuals often use marijuana to improve or manage conditions such as depression, anxiety, PTSD, pain, headaches or migraines, sleep disorders, nausea and vomiting, lack of appetite, and muscle spasms, but only approximately half of them reportedly had ever asked a health care professional for a recommendation to use medical marijuana." – 99 FR 44618 (May 21, 2024) [NOTE: Perhaps comment on this lack of data and drawing conclusions from one survey?]

"On balance, FDA found the available data indicated that there is some credible scientific support for the use of marijuana in the treatment of chronic pain, anorexia related to a medical condition, and nausea and vomiting, with varying degrees of support and consistency of findings. Additionally, no safety concerns were identified in FDA's review that would indicate that medical use of marijuana poses unacceptably high safety risks for the indications where there is some credible scientific evidence supporting its therapeutic use…" – 99 FR 44619 (May 21, 2024) [NOTE: You can have fun with this one – unsupported conclusions about the medical aspects and then a jump to the conclusion of "no safety risks" to those who use it.]

3. Level of Physical or Psychological Dependence

"As a result of its most recent evaluation, which incorporates post 2016 data into its analysis, HHS has recommended a finding that abuse of marijuana may lead to moderate or low physical dependence or high psychological dependence." – 99 FR 44619 (May 21, 2024)

"The Attorney General concurs with HHS's conclusion that the abuse of marijuana may lead to moderate or low physical dependence, depending on frequency and degree of marijuana exposure." – 99 FR 44619 (May 21, 2024)

4. Determination To Propose Rescheduling Marijuana to Schedule III

"After considering the foregoing facts and data and the recommendation of HHS, and after according binding weight to HHS's scientific and medical determinations, the Attorney General concludes that there is, at present, substantial evidence that marijuana does not warrant control under schedule I of the CSA. Accordingly, the Attorney General is issuing this notice of proposed rulemaking to initiate rulemaking proceedings to reschedule marijuana. 21 U.S.C. 811(b)." – 99 FR 44619 (May 21, 2024)

NOTE: The following is a conclusory and unsupported statement: "Consistent with HHS's analysis, the Attorney General has determined at this initial stage that marijuana does not appear to meet the elements of a schedule II drug, which include a high potential for abuse and a likelihood of severe physiological or physical dependence from such abuse." – 99 FR 44620 (May 21, 2024)

5. Types of Marijuana to Be Rescheduled

All of the following are from the 99 FR 44620 (May 21, 2024)– the rescheduling would apply to:

- marijuana as listed in 21 CFR 1308.11(d)(23).
- marijuana extracts as defined in 21 CFR 1308.11(d)(58) because they meet the statutory definition of marijuana and, prior to 2017, were included in 21 CFR 1308.11(d)(23).
- D9-THC derived from the marijuana plant (other than the mature stalks and seeds) that falls outside the definition of hemp, because it meets the statutory definition of marijuana.

6. The rescheduling would not apply to

- synthetically derived THC, which is outside the CSA's definition of marijuana.
- Those tetrahydrocannabinols that can be derived only through a process of artificial synthesis (e.g., delta-10-tetrahydrocannabinol)
- synthetic THC (will remain in schedule I).
- the status of hemp (as defined in 7 U.S.C. 1639o), because hemp is excluded from the definition of marijuana.
- any drug product containing marijuana or THC that previously has been rescheduled out of schedule I (e.g., Marinol and Syndros).
- previously scheduled synthetic cannabinoids.

7. International Treaty Obligations – 99 FR 44620-21 (May 21, 2024)

The arguments in this section are based on a platform of "because I said so, as the Attorney General." They make the argument that, as long as marijuana remains Schedule III, most of the treaty obligations are fulfilled.

8. Requirements for Handling Marijuana and Other Applicable Controls

"If marijuana is transferred to schedule III, the regulatory controls applicable to schedule III controlled substances would apply, as appropriate…" 99 FR 44623 (May 21, 2024) [NOTE: There is no mention of dosing, dispensing by pharmacists, etc.]

"DOJ is seeking comment on the practical consequences of rescheduling marijuana into schedule III under the relevant statutory frameworks." – 99 FR 44621 (May 21, 2024)– [NOTE: There is much to comment upon here. You are experts on this!!!]

9. Regulatory Analysis

"DOJ is specifically soliciting comments on the economic impact of this proposed rule. DOJ will revise this section at the final rule stage if warranted after consideration of any comments received." – 99 FR 44621 (May 21, 2024) [NOTE: Is there anything you want to tell them about the economics of the impact of this rule – on safety, on insurance rates, on your business?]

- What impact would the rule have on your business if it were to take effect?
- Provide actual cost numbers or be as specific as possible.

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