



July 19, 2024

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The Honorable Anne Milgram  
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DEA Federal Register Representative/DPW  
US Drug Enforcement Administration  
U.S. Department of Justice  
8701 Morrisette Drive  
Springfield, Virginia 22152

**Re: ASAM's Comments in Response to the Proposed Rule on  
Schedules of Controlled Substances: Rescheduling of Marijuana**

Dear Administrator Milgram and DEA Federal Register  
Representative/DPW:

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 7,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction, thank you for the opportunity to provide comments to the Drug Enforcement Administration (DEA) on the Notice of Proposed Rulemaking (NPRM) regarding the rescheduling of marijuana.<sup>1</sup>

Under the NPRM, the Department of Justice (DOJ) through the DEA proposes to transfer marijuana from schedule I of the Controlled Substances Act (CSA) to schedule III. This proposed transfer is based on a determination by the US Department of Health and Human Services (HHS) that marijuana has a currently accepted medical use (CAMU) and lower "abuse potential and level of physical and psychological dependence" than other controlled substances that are in schedule I. If finalized, such a rule would be the most significant change in the federal regulation of marijuana since the passage of the CSA.

While such a "wholesale" transfer may result in beneficial impacts to scientific research and/or pharmaceutical development, the DEA should consider the possible failure of marijuana with higher tetrahydrocannabinol (THC) concentrations<sup>2</sup> to meet HHS' alternative test for CAMU. In addition, significant, negative public health ramifications are likely to result if Internal Revenue Service (IRS) Code Section 280E no longer applies, and thus marijuana companies/dispensaries were allowed to take advantage of

various federal tax deductions and credits due to a transfer of marijuana to Schedule III. **For these reasons, ASAM could support a final rule that transfers only marijuana with lower THC concentrations<sup>3</sup> to Schedule III, so long as any such final rule clearly states that (1) the Food, Drug, and Cosmetic Act (FDCA)<sup>4</sup> will continue to apply, and (2) Schedule III requirements/controls will be enforced for those who take advantage of federal tax benefits due to 280E no longer being applicable after such a rescheduling.**

#### HHS' New CAMU Analysis: An Attempt to Course Correct; A Failure to Address Potency

Today, in the United States, we have a patchwork of state laws<sup>5</sup> - with minimal to no federal oversight - governing marijuana used for medical purposes. This unusual state of affairs exists amidst a lack of sufficient scientific evidence for the effectiveness of marijuana (that is covered by the proposed rescheduling)<sup>6</sup> as a medicine for any indication that either (1) is "approved by [the Food and Drug Administration] FDA for marketing under the FDCA, either through the [New Drug Application] NDA process or by meeting the criteria to be recognized as a 'Generally Recognized as Safe and Effective' ('GRASE') drug" or (2) meets the DEA's five-part CAMU test,<sup>7</sup> which "was based on the core FDCA standards for acceptance of drugs for medical use."<sup>8</sup>

In fact, people across this country are using marijuana today for both medical and non-medical purposes;<sup>9</sup> however, we are not systematically capturing the data on benefits or harm. Additionally, researchers' efforts to better understand the mechanisms of marijuana's benefits and harms and potentially identify new compounds that could be useful for the treatment of diseases, including addiction, are stifled by Schedule I status. In the absence of a thoughtful rescheduling, we will never escape the following paradox: there is not enough research to justify certain FDA approvals, so we live with an underregulated system that provides even less protection for its people. In short, this country's current regulatory framework for marijuana used for medical purposes has failed.<sup>10</sup>

Nearly five years ago, ASAM released a Public Policy Statement on Cannabis<sup>11</sup> in which the society recommended that (1) marijuana used for medical purposes be rescheduled from Schedule 1 of the CSA to promote more clinical research and FDA oversight typical of other medications and (2) marijuana and marijuana-derived products used for medical indications be subjected to FDA review and approval to ensure their safety and effectiveness. Notably, ASAM's public policy statement did not specify to which schedule marijuana used for medical purposes should be transferred. This lack of specificity was purposeful, because marijuana could not (and still cannot) meet the DEA's historical criteria for CAMU. In 2020, none of the existing statutory schedules was appropriate, and in the absence of Congressional action creating a new scheduling option, ASAM's recommendation remained nonspecific.

In its recent rescheduling memorandum,<sup>12</sup> however, HHS has now promulgated an alternative, two-part test for establishing a CAMU. Part 1 evaluates "whether there is widespread current experience with medical use of marijuana in the United States by licensed HCPs [health care providers] operating in accordance with implemented state-authorized programs, where such medical use is recognized by entities that regulate the practice of medicine under these state jurisdictions." Part 2 evaluates "whether there exists some credible scientific support for at least one of the medical conditions for which the Part 1 test is satisfied." Importantly, HHS states that "factors considered in favor of a positive finding includes whether: 1) favorable clinical studies of the medical use of marijuana, *although not necessarily adequate and well-controlled clinical studies that would support approval of a new drug application (NDA) (emphasis added)*, have been published in peer-reviewed journals and/or 2) qualified expert organizations (e.g., academic groups,

professional societies, or government agencies) have opined in favor of the medical use or provided guidance to HCPs on the medical use.”

Despite HHS’ acknowledgement of potency/dose concerns, HHS does not appear to have considered potency/dose in the context of its CAMU analysis, nor does it appear that HHS accounted for the varying ways in which potency/dose is calculated based on the product.<sup>13</sup> This lack of specificity is a glaring exclusion from HHS’ CAMU determination, particularly considering studies have indicated that the use of higher potency marijuana has been associated with increased frequency of use, marijuana use-related problems, and increased likelihood of anxiety disorder.<sup>14</sup> Increased potency of marijuana also raises additional health concerns, because its potency has been associated with more adverse reactions, particularly marijuana-induced psychosis.<sup>15</sup>

**Therefore, if the DEA accepts HHS’ alternative CAMU test as sufficient under the CSA, ASAM strongly suggests that the DEA (1) consider the possible failure of marijuana with higher THC concentrations to satisfy HHS’s own alternative CAMU test, and (2) appropriately limit any potential rescheduling of marijuana to lower potency marijuana. As a result, higher potency marijuana would remain in schedule I in the absence of Congressional action.**<sup>16</sup> There is precedent for such a nuanced scheduling approach; for example, see products and preparations containing distinct levels of codeine found in Schedules III and V.

#### Newly Available Federal Tax Benefits: A Potential Accelerant for Marijuana Commercialization

Internal Revenue Service (IRS) Code Section 280E bars all federal deductions or credits for any amount paid or incurred in carrying on a business that consists of illegally trafficking in a Schedule I or II controlled substance within the meaning of the CSA. Currently, this prohibits state marijuana companies/dispensaries from taking advantage of these federal tax deductions and credits. A transfer of marijuana to Schedule III, however, would mean that this statutory ban may no longer apply to marijuana companies/dispensaries. ASAM is concerned about the negative impact this would have on public health - further fueling commercialization of the marijuana industry. **Therefore, ASAM urges any final rule transferring marijuana to Schedule III to state clearly that Schedule III requirements/controls will be enforced for those taking advantage of federal tax benefits that result from 280E no longer being applicable after such a rescheduling.** Notably, the DEA rigorously enforces the CSA’s Schedule III requirements/controls applicable to buprenorphine, for which there are products approved by the FDA for the treatment of opioid use disorder (OUD). It would be tragically ironic not to enforce such requirements/controls on marijuana while enforcing them on a substance used in lifesaving, FDA-approved OUD medications.

In conclusion, ASAM appreciates the opportunity to outline its comments and concerns regarding the NPRM. We hope this regulation, if finalized in a manner incorporating the recommendations herein, will mark the beginning of positive change in our nation's regulation of marijuana. If you have any questions, please do not hesitate to contact Corey Barton, Director of Advocacy at [cbarton@asam.org](mailto:cbarton@asam.org).

Sincerely,



Brian Hurley, MD, MBA, FAPA, DFASAM  
President, American Society of Addiction Medicine

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<sup>1</sup> As noted in the NPRM: the proposed “rescheduling of marijuana would apply to marijuana as listed in 21 CFR 1308.11(d)(23),” including “marijuana extracts as defined in 21 CFR 1308.11(d)(58) . . . .” It also “would apply to D9-THC derived from the marijuana plant (other than the mature stalks and seeds) that falls outside the definition of hemp. . . .” However, it “would not apply to synthetically derived THC, which is outside the CSA’s definition of marijuana” or “any drug product containing marijuana or THC that previously has been rescheduled out of schedule I . . . . [n]or does it impact the status of any previously scheduled synthetic cannabinoids.” Although ASAM uses the term “marijuana” throughout this letter to align with language in the NPRM and statute, ASAM’s preferred term is “cannabis,” as reflected in its policy documents.

<sup>2</sup> Stuyt E. The Problem with the Current High Potency THC Marijuana from the Perspective of an Addiction Psychiatrist. *Mo Med*. 2018 Nov-Dec;115(6):482-486. PMID: 30643324; PMCID: PMC6312155 (noting “there is no good research on concentrations greater than this [10%] for any medical condition and there is significant literature on the negative effects of high potency THC.”). DEA should also consider the varying ways in which potency/dose is calculated based on the product (e.g. flower, concentrates, edibles, topicals) before finalizing any rescheduling, and whether certain products (e.g. edibles) should be entirely excluded from any such rescheduling per HHS’s own alternative CAMU test.

<sup>3</sup> *Id.*

<sup>4</sup> As noted in the NPRM: “. . . marijuana would remain subject to applicable provisions of the FDCA. For example, under the FDCA, a drug containing a substance within the CSA’s definition of “marijuana” would need FDA approval to be lawfully “introduce[d] or deliver[ed] for introduction into interstate commerce,” unless an IND is in effect for that drug. See 21 U.S.C. 355(a), 355(i), 331(d). To date, although there have been INDs for drugs containing a substance within the CSA’s definition of “marijuana,” no such drugs have been approved by FDA.”

<sup>5</sup> Bryan, K. (2024, June 20). Cannabis Overview. National Conference of State Legislatures.

<https://www.ncsl.org/civil-and-criminal-justice/cannabis-overview#:~:text=In%202020%2C%20Virginia%20adopted%20SJR.legalization%20by%20July%201%2C%202022.>

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<sup>6</sup> See supra note 1.

<sup>7</sup> As noted in the NPRM: historically, the DEA has determined a substance has a CAMU if it satisfies the following 5-part test: 1. There must be adequate safety studies; 2. The drug's chemistry must be known and reproducible; 3. There must be adequate and well controlled studies proving efficacy; 4. The drug must be accepted by qualified experts; and 5. The scientific evidence must be widely available.

<sup>8</sup> NPRM.

<sup>9</sup> ASAM's own assessment of state "adult use cannabis programs" paints a picture that is often inconsistent with public health. See American Society of Addiction Medicine (ASAM). "ASAM State Cannabis Public Health Policy Guide." October 2023. [https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/advocacy/asam\\_state-cannabis-public-health-policy-guide\\_final.pdf?sfvrsn=630ba7e6\\_1](https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/advocacy/asam_state-cannabis-public-health-policy-guide_final.pdf?sfvrsn=630ba7e6_1).

<sup>10</sup> The United States' use of punitive systems to address substance use and substance use disorder has also been a remarkable failure and has had disproportionate impacts on people of color. A wholesale rescheduling of marijuana from Schedule I to Schedule III notably does nothing to right the wrongs of overcriminalization of the past or present.

<sup>11</sup> American Society of Addiction Medicine (ASAM). "Cannabis." October 10, 2020. <https://www.asam.org/advocacy/public-policy-statements/details/public-policy-statements/2020/10/10/cannabis>.

<sup>12</sup> Memorandum for DEA, from HHS, Re: Basis for the Recommendation to Reschedule Marijuana to Schedule III of the Controlled Substances Act. <https://www.dea.gov/sites/default/files/2024-05/2016-17954-HHS.pdf>

<sup>13</sup> HHS's memorandum notes that "[m]arijuana products can generally be categorized as one of four types: Flowers – includes dried herb that is smoked or vaped, and pre-rolls; Concentrates – includes products for inhalation referred to as shatter, wax, butter, sugar, hash, resin, and rosin via vaping (use of an electronic vaporizer) or via dabbing (use of other paraphernalia such a pipe or "dab rigs") (Colorado Department of Revenue, 2021; Drug Enforcement Administration, 2023); Edibles – includes infused food, beverage, and tincture products (e.g., baked goods, chocolate, drinks, candies, and snacks); Topicals – includes infused ointments, lotions, creams, or transdermal products"

<sup>14</sup> Hines LA, Freeman TP, Gage SH, et al. Association of High-Potency Cannabis Use With Mental Health and Substance Use in Adolescence [published online ahead of print, 2020 May 27]. *JAMA Psychiatry*. 2020;e201035. doi:10.1001/jamapsychiatry.2020.1035

<sup>15</sup> Petrilli K, Ofori S, Hines L, Taylor G, Adams S, Freeman TP. Association of cannabis potency with mental ill health and addiction: a systematic review. *Lancet Psychiatry*. 2022 Sep;9(9):736-750. doi: 10.1016/S2215-0366(22)00161-4. Epub 2022 Jul 25. PMID: 35901795.

<sup>16</sup> See supra note 11. (ASAM public policy statement (1) supporting the decriminalization of marijuana possession for personal use; (2) recommending that the CSA be amended so that – as long as states and tribes comply with substantial public health protections – its provisions no longer apply to any person acting in compliance with state or tribal laws relating to the manufacture, production, possession, distribution, dispensation, administration, or delivery of cannabis for non-medical purposes, and (3) providing specific recommendations on a strong public health-based regulatory framework to minimize harms related to marijuana legalization and models other than commercialization to the extent States or jurisdictions decide to legalize marijuana).