November 17, 2023

The Honorable Anne Milgram
Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Administrator Milgram:

One year ago, President Joseph Biden requested that the U.S. Secretary of Health and Human Services (HHS) and the U.S. Attorney General "initiate the administrative process to review expeditiously how marijuana is scheduled" under the federal Controlled Substances Act (CSA).[1] [2] HHS has recently completed an important part of that review. Leading press outlets reported that HHS has recommended that marijuana should be moved from Schedule I to Schedule III under the CSA.[3]

An HHS recommendation of Schedule III could provide hope for millions of Americans suffering from serious medical conditions. Many of these Americans have found that other pharmaceutical substances provide no relief for their symptoms while triggering serious and potentially devasting side effects. But until marijuana is rescheduled, anyone who uses this product as a medicine is branded an outlaw, subject to severe criminal penalties and the loss of basic civil rights.[4] If the news reports are accurate, the HHS scheduling recommendation recognizes that the federal ban on the medical use of marijuana is inconsistent with the latest scientific research concerning the drug's health benefits and risks, and the 38[5] state programs that have listed marijuana as a beneficial medical treatment.

We encourage you, as Administrator of the DEA, to accept the recommendation of HHS without delay. In this memo, we briefly explain why we believe the DEA should follow the HHS recommendation.

1. *THE HHS RECOMMENDATION INDICATES THAT THE CRITERIA FOR MOVING MARIJUANA TO SCHEDULE III HAVE BEEN SATISFIED.*

Marijuana was placed on Schedule I by Congress when it passed the CSA in 1970. Congress knew that the scientific evidence underlying its decision was not well developed, and it did not intend for that initial scheduling decision to be permanent. Rather, it empowered HHS and the Attorney General to update those decisions when scientific research on the medical benefits and harms of scheduled drugs so warranted. In effect, the CSA dictates that if a Schedule I drug is shown to have medical utility (i.e., "accepted medical use"), it must be moved to another schedule (II-V)[6] based on an assessment of the drug's relative abuse potential and its dependence liability.[7]

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[1] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/

[2] *The CSA is codified at 21 U.S.C. §801 et seq.*

[3] https://www.bloomberg.com/news/articles/2023-08-30/hhs-calls-for-moving-marijuana-to-lower-risk-us-drug-category

[4] *E.g., 21 USC §§841,844 (specifying sanctions for possession, manufacture, and distribution of marijuana); See also, 18 USC §922(g) (barring marijuana users from purchasing or possessing firearms).*

[5] https://www.ncsl.org/health/state-medical-cannabis-laws

[6] *By default, a Schedule I drug that is shown to have medical utility must be moved to another schedule, because Schedule I drugs by definition have "no accepted medical use." 21 USC 812.*

[7] *21 USC 812.*

If HHS is recommending to move marijuana to Schedule III, it necessarily must have concluded that the drug has medical utility. Had it not reached this conclusion, the agency would have been obliged to recommend keeping marijuana on Schedule I.[8]

An HHS conclusion on medical utility would mark a notable milestone. Since HHS completed its last review in 2016, which resulted in a finding of marijuana remaining Schedule I, the evidence demonstrating marijuana's medical utility has continued to grow. Indeed, in 2017, an expert panel of the National Academy of Sciences, Engineering, and Medicine completed its own comprehensive review of research, including research postdating the last review conducted by HHS. The National Academy panel concluded there was "conclusive or substantial evidence" that cannabis was an effective treatment for medical conditions like the nausea associated with chemotherapy and chronic pain.[9] In 2019, the World Health Organization (WHO) Expert Committee on Drug Dependence (ECDD) completed its own critical review of research on cannabis. The ECDD reached the same conclusion as the National Academy panel: marijuana has therapeutic value.[10] As global research develops and evolves at the United Nations, so too should the position of the United States – especially as it looks to maintain its position as a leader in global health diplomacy.[11] Thus, while the recent HHS conclusion marks a milestone, the development is far from surprising; a growing consensus of authorities, both at home[12] and abroad[13], has recognized that marijuana has viable medical applications.

Second, a recommendation from HHS of Schedule III would indicate the agency concluded that marijuana has less abuse potential and dependence liability than drugs found on Schedule II. As noted above, the CSA assigns drugs with medical utility to Schedules II-V based on an assessment of their relative abuse potential and dependence liability. Schedule II is reserved for drugs that have a "high potential for abuse" which "may lead to severe psychological or physical dependence."[14] Schedule III drugs have a potential for abuse "less than the drugs on Schedule I or II" and which "may lead to moderate or low physical dependence or high psychological dependence."[15] Schedule IV drugs, in turn, have a "low potential for abuse" compared to drugs on Schedule III, with only "limited physical dependence or psychological dependence" relative to drugs on Schedule III. Based on these statutory criteria, the findings by HHS reflect a determination that marijuana is less prone to abuse and dependence than Schedule II drugs like fentanyl and cocaine.

In short, if HHS has recommended moving marijuana to Schedule III, it had to have made the key scientific determinations necessary to move marijuana from Schedule I to Schedule III.

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[8] *81 FR 53688, Denial of Petition of Proceedings to Reschedule Marijuana, DEA, available at https://www.federalregister.gov/documents/2016/08/12/2016-17954/denial-of-petition-to-initiate-proceedings-to-reschedule-marijuana*

[9] *https://nap.nationalacademies.org/catalog/24625/the-health-effects-of-cannabis-and-cannabinoids-the-current-state*

[10] *The WHO's First Ever Critical-Review of Cannabis, Mar. 19, 2019, available at 81 FR 53688, Denial of Petition of Proceedings to Reschedule Marijuana, DEA, available at https://www.federalregister.gov/documents/2016/08/12/2016-17954/denial-of-petition-to-initiate-proceedings-to-reschedule-marijuana*

[11] *https://www.hhs.gov/about/agencies/oga/global-health-diplomacy/index.html*

[12] *Timeline of Cannabis Laws in the United States, available at https://time.com/4298038/marijuana-history-in-america/, (last edited September 30, 2023), (Internal Citations Omitted) (Noting 13 states have legalized medical marijuana since 2015).*

[13] *Timeline of Cannabis of Law, available at https://en.wikipedia.org/wiki/Timeline_of_cannabis_law#:~:text=2013%3A%20Uruguay%20legalized%20cannabis%2C%20becoming,legalized%20cannabis%20for%20medical%20use, (last edited July 29, 2023), (Internal Citations omitted) (Noting more than 40 countries have legalized medical marijuana (internal citations omitted).*

[14] *21 USC §812(b)(2).*

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2. THE DETERMINATIONS BY HHS THAT KEY SCHEDULING CRITERIA HAVE BEEN SATISFIED ARE BINDING ON THE DEA.

Although the DEA also plays a role in scheduling, the DEA may not disregard the determinations made by HHS concerning the medical utility of marijuana, its relative abuse potential, and its dependence liability. Congress stipulated in the CSA that the findings and recommendations from HHS on such "scientific and medical matters" are binding on the DEA.[16] This arrangement no doubt reflects the comparative expertise of the two agencies on matters.[17] Indeed, as far as we are aware, the DEA has never made a scheduling decision that departed from HHS recommendations.

3. INTERNATIONAL LAW CONSIDERATIONS DO NOT PREVENT THE DEA ADMINISTRATOR FROM ISSUING A FINAL RULE MOVING MARIJUANA TO SCHEDULE III.

If HHS has already made the key determinations necessary to move marijuana to Schedule III, and because the DEA would be bound by those determinations, there would be only one remaining issue the DEA needs to address before acting on the HHS scheduling recommendation: the obligations of the United States under international drug conventions. The issue arises because the CSA stipulates that if control of a drug "is required by United States obligations" under international conventions, "the Attorney General shall issue an order controlling such drug under the schedule they deem most appropriate to carry out such obligations," without regard to other scheduling criteria (i.e., medical utility and abuse potential).[17]

Congress designed the scheduling system to help keep the U.S. in compliance with international treaties. Importantly, however, Congress did not intend for the treaties to dictate domestic scheduling decisions, to the exclusion of other considerations. Scheduling is not the only way to remain in compliance with international law. So long as the appropriate controls are placed on scheduled substances, treaty compliance is attainable as they were designed with flexibility in mind.

The 1961 Single Convention on Narcotic Drugs imposes a set of obligations on the United States regarding how it regulates marijuana. The treaties permit member states to legalize medical cannabis, so long as appropriate controls are put in place. While scheduling based on scientific considerations serves as one avenue to impose the requisite controls, treaty compliance may also be ensured by supplementing the regulations applicable under any Schedule.[18] With appropriate controls in place like what has been done in the states, there is no justifiable reason to reject a Schedule III determination as non-compliant with the treaties, as the treaty documents allow for flexibility of the signatory members. This flexibility was recently noted in October 2023 by Virginia Patton "Patt" Prugh, Attorney Adviser in the Office of the Legal Adviser, Law Enforcement & Intelligence, for the U.S. Department of State, in remarks before the Convention of Narcotic Drugs.[19]

States across the U.S. have developed their own robust regulatory and oversight programs for marijuana that would supplement federal regulations and help the United States to meet its treaty obligations. Additionally, states prohibit the importation and exportation of marijuana,[20] thereby obviating the need for export and import permits, and many states place caps on the amount of marijuana that licensed marijuana suppliers may cultivate,[21] thereby satisfying the quota requirement in Article 29 of the Single Convention.

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[16] *21 USC §811(b) (stipulating that the recommendations of HHS "shall be binding on the Attorney General as to such scientific and medical matters").*
E.g., Nat'l Org. for Reform of Marijuana L. (NORML) v. Drug Enf't Admin., U. S. Dep't of Just., 559 F.2d 735, 747 (D.C. Cir. 1977) (opining that the HHS Secretary predecessor agency was "manifestly more competent [than the Attorney General] to make these nonlegal evaluations and recommendations" required for scheduling decisions).

[17] *Single Convention on Narcotic Drugs, 1961, Art. 19, Art. 30, (detailing requirements for appropriate control including (1) Require that all manufacturers and distributors of medical marijuana obtain a license;(2) Impose quotas on the quantity of medical marijuana licensees are permitted to produce, (3) Require licensees to keep records of the quantity of medical marijuana they produce, distribute (etc); (4)Require prescriptions for dispensing medical marijuana to patients. (5) Require permits for importing and exporting medical marijuana; and (6) Furnish the International Narcotics Control Board with annual reports on the quantity of medical marijuana produced and consumed in the prior year, as well as estimates of the quantity of medical marijuana expected to be produced and consumed in the coming year).*

[18] *Robert A. Mikos, On the Limits of Supremacy: Medical Marijuana and the States' Overlooked Power To Legalize Federal Crime, 62 VAND. L. REV. 1421, 1422 (2009) [hereinafter Mikos, Limits of Supremacy](explaining why the federal government cannot force states to prohibit marijuana).*

[19] *https://media.un.org/en/asset/k18/k183ng5zxr*

An example of the way that the DEA recently endorsed this flexible approach to treaty compliance can be seen with the rescheduling of Epidiolex, an epilepsy drug comprised of CBD extracted from the cannabis plant.[22] At the time that the DEA made its scheduling decision, Epidiolex fell within the definition of marijuana under the CSA and international law. Nonetheless, the DEA decided to move Epidiolex off Schedule I and place it on Schedule V, the least tightly controlled schedule under the CSA. The DEA recognized that the move might put the United States out of compliance with the Single Convention because the CSA does not require permits for the importation and exportation of Schedule V drugs. But rather than insist that Epidiolex remain on a higher schedule to satisfy the demands of the Single Convention, the DEA amended the permit regulation to cover Epidiolex while moving the drug to Schedule V.[23] The Epidiolex decision, so close in time and similar in substance to the one now before the DEA, amply demonstrates that the agency need not ignore an HHS scheduling recommendation when there are readily available measures to ensure compliance with international requirements.

We applaud the willingness of the DEA to modernize our federal drug laws on this issue consistent with scientific information.. Although the DEA has at times suggested that it could not move marijuana below Schedule II because of U.S. treaty obligations, the Epidiolex decision suggests that the agency has determined another way forward to modernize medical treatments for its citizens and maintain its compliance under federal law. Put another way, even assuming that the litany of regulations applicable to Schedule III substances under the CSA would not satisfy our international law obligations, that is no reason to refuse to move marijuana to Schedule III, because the various U.S. states have promulgated appropriate controls.

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For all the foregoing reasons, we urge you to follow the recommendation from HHS and issue an Interim Final Rule rescheduling marijuana to Schedule III under the CSA. This change to federal law would enable millions of Americans to access marijuana to treat serious medical conditions – without having to sacrifice their freedoms. While we recognize that more needs to be done to rationalize and humanize federal cannabis policy, rescheduling marijuana represents an important and long overdue step in the right direction.

We thank you for your time and consideration. If you have any questions, please do not hesitate to contact us, or have a member of your team contact National Cannabis Roundtable Director of Policy David Mangone at David@theliaisongroup.com.

Sincerely,

Saphira Galoob
Executive Director
National Cannabis Roundtable

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[20] *Robert A. Mikos, Interstate Commerce in Cannabis, 101 B.U. L. Rev. 857 (2021).*

[21] *See e.g., Arkansas 2022 Operational Rules for Cultivators, Dispensaries and Processors, available at https://www.dfa.arkansas.gov/images/uploads/medicalMarijuanaCommission/2022_OperationalRuleBook_CDP.pdf (capping the total number of licensees at 40).*

[22] *83 Fed. Reg. 48,950*

[23] *Id.*