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Administrator Anne Milgram
Drug Enforcement Administration
8701 Morrissette Dr
Springfield, VA 22152

Dear Administrator Milgram,

On December 19, 2023, the Drug Enforcement Administration (DEA) informed certain members of Congress that it is now conducting its official review of the Department of Health and Human Services' (HHS) recommendation to reschedule marijuana. I write to urge you to abide by our nation's international treaty obligations and consider the true harms of marijuana when making your final determination.

As you know, in 1967, the Senate ratified the Single Convention on Narcotic Drugs by a vote of 84-0. This treaty established widely agreed upon methods of drug control that are still used today. As outlined in the Obama Administration's 2016 marijuana scheduling review, classifying marijuana as anything but a Schedule I or II drug would constitute a violation of the Single Convention.

Section 811(d)(1) of the Controlled Substances Act (CSA) states, "If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section."

As explained by the Supreme Court in *Chan v. Korean Air Lines, Ltd*., 490 U.S. 122, 134 (1989), "where the text [of a treaty] is clear . . . we have no power to insert an amendment." Not only is the text of the Single Convention treaty clear, but this fact was clearly affirmed in *NORML v. DEA*, 559 F.2d 735, 751 (D.C. Cir. 1977). According to the opinion of the court, "several requirements imposed by the Single Convention would not be met if cannabis and cannabis resin were placed in CSA Schedule III, IV or V."

The Obama Administration acknowledged the legal limitations of marijuana rescheduling and explicitly stated in its 2016 review, "Therefore, in accordance with section 811(d)(1), DEA must place marijuana in either schedule I or schedule II."

In a 2018 opinion titled "Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs," the DEA Office of Legal Counsel (OLC) again affirmed that the United States is required to abide by the Single Convention. In the opinion, OLC cited S. Rep. No. 91-613, at 4 (1969): "The United States has international commitments to help control the worldwide drug traffic. To honor those commitments, principally those established by the Single Convention on Narcotic Drugs of 1961, is clearly a Federal responsibility."

In addition to considering international treaty obligations, I urge you to consider that HHS' justification for making its recommendation to reschedule marijuana was flawed in many respects.

First, the FDA ignored several important factors when considering marijuana's potential for abuse and harm to public health. The recommendation did not sufficiently examine the effect of daily marijuana use, a key indicator of addiction. The recommendation also failed to consider the public health damage caused by traffic fatalities due to individuals driving under the influence of marijuana. Notably, FDA did not discuss the impact of marijuana use on pregnant women and children, despite a warning from SAMHSA that states, "Marijuana use during pregnancy can be harmful to a baby's health and cause many serious problems, including stillbirth, preterm birth, and growth and development issues." Further, they explained, "THC and other chemicals in marijuana can be passed to a baby through breast milk, increasing the baby's risk for problems with brain development."

The FDA also failed to compare marijuana's potential for abuse to many other Schedule I drugs, instead opting to hand-select drugs that appear more harmful. For example, the only comparator substance in Schedule I in the recommendation was heroin— the agency could have included at least one Schedule I hallucinogen, such as LSD or ecstasy. The review even compared marijuana to alcohol, a substance that is not controlled, but did not review any stimulants, such as Adderall or Ritalin in Schedule II. They reviewed nine scheduled substances, of which five were opioids, which had the effect of skewing the presentation of the data.

The FDA mischaracterized the data on marijuana's harms. The review stated, "The risks to the public health posed by marijuana are lower compared to other drugs of abuse (e.g., heroin, oxycodone, cocaine), based on an evaluation of various epidemiological databases for emergency department (ED) visits..." In fact, marijuana ranks as the fourth most common drug causing emergency department visits. According to the most recent SAMHSA data, marijuana use resulted in 804,285 emergency department visits, only fewer than methamphetamine (811,464), opioids (1,062,864), and alcohol (2,996,516). Marijuana resulted in *more* visits than heroin (506,355) and cocaine (342,770), a fact that runs counter to the claim in the FDA's review.

Additionally, the FDA review did not use the five-factor test that has been used to determine a drug's "currently accepted medical use" for the past thirty years. The five-factor test was determined to be an acceptable form of analysis by the United States Court of Appeals, District of Columbia in the 1994 case, *Alliance for Cannabis Therapeutics v. Drug Enforcement Administration*. Instead, the FDA used a new two-factor test, which allows for the use of "not necessarily adequate and well-controlled clinical studies" to support claims of medicinal value. Further, the test allows for the use of existing state-legal medical marijuana programs (which are

often the result of ballot initiatives rather than rigorous scientific review) as evidence of "currently accepted medical use."

In the FDA review, three studies are used to support the claim that marijuana has currently accepted medical use. The first study, conducted by the University of Florida, yielded inconclusive or mixed results. The second study, conducted by the National Academies of Sciences, Engineering, and Medicine, relied primarily on another study (Whiting et al. 2015) with statistically insignificant results. In the third study, conducted by the Agency for Healthcare Research and Quality, the FDA noted that while there were some small positive effects of marijuana, "the increased risk of dizziness, nausea, and sedation [resulting from marijuana use] may limit the benefit."

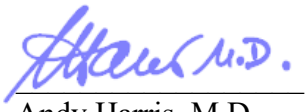
The lack of rigor in the studies used by the FDA is concerning and led to a misguided conclusion.

Please respond to the following questions no later than February 16, 2024:

1. Will the DEA abide by the legally binding treaty obligations related to drug scheduling as outlined in the Single Convention when determining marijuana's schedule?
2. Does the DEA believe that our international treaty obligations can be met if marijuana is placed in Schedule III, despite the fact that *NORML v. DEA (1977)* ruled otherwise?
3. Does the DEA consider FDA's new two-factor test an adequate method for determining a drug's currently accepted medical use? If so, why?
4. Will the DEA use the five-factor test to establish "currently accepted medical use" in its own scheduling review?
5. Does the DEA consider it acceptable to use studies that had inconclusive and/or not statistically significant findings as justification for marijuana having currently accepted medical use?
6. Does the DEA consider daily marijuana use, impacts on pregnancy and children, and effects of driving under the influence of marijuana necessary elements to consider when measuring marijuana's abuse potential? If not, why?

Thank you in advance for your consideration. I look forward to receiving your response no later than February 16, 2024.

Sincerely,



Andy Harris, M.D.
Member of Congress

cc: Secretary of Health and Human Services Xavier Becerra, Assistant Secretary for Health Rachel Levine, Attorney General Merrick Garland, Health and Human Services General Counsel Samuel Bagenstos