Congress of the United States
Washington, DC 20510

July 10, 2024

The Honorable Merrick Garland
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, D.C. 20530

RE: Comment on Proposed Rule: Schedules of Controlled Substances: Rescheduling of Marijuana, 21 CFR 1308, 89 FR 44597

Attorney General Garland:

We write to express our concerns with the Drug Enforcement Administration's (DEA) Proposed Rule "Schedules of Controlled Substances: Rescheduling of Marijuana."

The Proposed Rule would transfer marijuana from schedule I of the Controlled Substances Act (CSA) to schedule III of the CSA. The rule fails to provide adequate science and data to support moving marijuana to schedule III and should not have been signed or published.

The background section of the Proposed Rule begins by noting that 38 states and the District of Columbia have legalized the use of medical marijuana. This should be irrelevant to the analysis conducted by the Department of Health and Human Services (HHS) and the Department of Justice (DOJ). Nothing in the CSA requires or suggests that DOJ should consider a drug's popularity or legal status at the state level when determining a drug's schedule. It is clear that HHS and DOJ chose the desired conclusion first and worked backwards, since the rule does not provide sufficient reason to move marijuana to schedule III.

It is also clear that DEA was not properly consulted in the drafting of the Proposed Rule. DEA Administrator Milgram did not sign the rule and it states many times that DEA believes additional information is needed regarding the appropriate schedule for marijuana. The Proposed Rule references DEA's findings from 2016, when it rejected two petitions to remove marijuana from schedule I. It seems that DEA stands by its findings from 2016- all the more reason why this rule should not have been published without sign off from the DEA Administrator.

The CSA lists five categories of controlled substances that correspond with the restriction level placed on specific drugs. Schedule I drugs have a high potential for abuse, no currently accepted medical use, and a lack of accepted safety under medical supervision.[1] Schedule III drugs have a potential for abuse that is less than schedule I and II, a currently accepted medical use, and a

[1] 21 U.S.C. § 812 (b)(1).

moderate or low physical dependence or high psychological dependence.[2] The CSA also requires consideration of eight factors to determine whether a substance should be rescheduled.[3]

Under the potential for abuse factor, HHS considered whether individuals are taking the drug in amounts sufficient to create a hazard to their health. HHS found that the vast majority of marijuana use does not lead to dangerous outcomes. It is irresponsible for HHS to make this determination when emerging research shows that there are significant health concerns associated with marijuana use. A study published last year in Psychological Medicine found that as many as 30% of schizophrenia cases in young men might have been prevented if they had not abused marijuana.[4]

Another recent study found a clear association between cannabis use and psychosis, anxiety, cognitive failures, respiratory adverse events, cancer, cardiovascular outcomes and gastrointestinal disorders.[5] Another study on the cardiovascular effects of marijuana noted that the negative impact of marijuana on the cardiovascular system is "extremely worrisome" and needs more attention given the high rate of marijuana use.[6] Another study in the American Journal of Men's Health found that sexual disfunction was twice as high in men who used marijuana.[7] Another recent study found that legalization of marijuana was associated with a 6.5% increase in car crashes that resulted in injuries and a 2.3% increase in car crashes that resulted in fatalities.[8] Finally, a study found that marijuana use among veterans with PTSD was associated with worse PTSD symptoms, more violent behavior, and alcohol use.[9]

DEA correctly notes in the Proposed Rule that by 12th grade, 20.2% of students reported using marijuana in the past month. DEA also notes that 11.9% of drug-related emergency room visits involve marijuana and these visits are highest among young Black men. DEA suggests that more data is needed- we agree. Despite marijuana's prevalence and high rate of use, we still lack adequate and robust research on the drug. For several decades, there was only one university that was authorized by the federal government to grow marijuana for research. In recent years and because of a change in the law, DEA has approved more entities to provide marijuana for research. It is imperative that the marijuana provided for research is the same potency and product as the marijuana that is actually being consumed by Americans. While progress has been

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[2] 21 U.S.C. § 812 (b)(3).
[3] 21 U.S.C. § 811 (c).
[4] *Young men at highest risk of schizophrenia linked with cannabis use disorder* (2023), https://www.nih.gov/news-events/news-releases/young-men-highest-risk-schizophrenia-linked-cannabis-use-disorder.
[5] *The blind men and the elephant: Systemic review of systemic reviews of cannabis use related health harms* (2020) https://pubmed.ncbi.nlm.nih.gov/32165103/.
[6] *The Cardiovascular Effects of Marijuana: Are the Potential Adverse Effects Worth the High?* (2019) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6461323/.
[7] *Relationship between Cannabis Use and Erectile Dysfunction: A Systemic Review and Meta-Analysis* (2019) https://pubmed.ncbi.nlm.nih.gov/31795801/#:~:text=The%20overall%20prevalence%20of%20ED,1.30%2D11.28%3B%20p%20%3D%20.
[8] *Changes in Traffic Crash Rates After Legalization of Marijuana: Results by Crash Severity* (2022) https://pubmed.ncbi.nlm.nih.gov/35838426/.
[9] *Marijuana use is associated with worse outcomes in symptom severity and violent behavior in patients with posttraumatic stress disorder* (2015) https://pubmed.ncbi.nlm.nih.gov/26455669/.

made, these changes are very new and we still lack a robust body of research on the long-term health impacts of marijuana use or potential medical use.

DOJ concurs with HHS's conclusion that marijuana has a currently accepted medical use despite finding no accepted medical use in its 2016 analysis. In the past, marijuana has not been able to pass DEA's long established five-part test to determine whether there is an accepted medical use. Marijuana still could not pass this test in 2024, so HHS decided to change the test to produce the desired outcome. The analysis provides no justification for dispensing with the longstanding precedent of the five-part test, other than claiming it is "too narrow." This is not sufficient justification to alter a process that has worked for decades. If the five-part test were to be abandoned, it calls into question the scheduling of other substances. The new and less stringent two-part test only considers whether there is "widespread current experience" with medical use of the substance by health care practitioners in states where medical use is recognized and some credible scientific support for at least one of those medical uses.

Under part one of this new test, HHS notes that there are 30,000 health care practitioners that are authorized to recommend the use of marijuana for more than six million registered patients in the United States. It should be noted that a very small percentage of practitioners are responsible for tens of thousands of these recommendations.[10] Most states that have legalized medical marijuana do not make it difficult for individuals to access the product. Many websites boast that you can get a medical marijuana card in as little as thirty minutes. Individuals can claim they have anxiety or headaches and gain access to dispensaries for long periods of time with no dosage recommendations or caps. Medical marijuana dispensaries sell edibles and vapes that come in flavors like passion raspberry, blueberry calm, wild cherry, and sour apple. Pretending that these products are medicine that can treat health conditions is doing a disservice to Americans. HHS also claims that because no medical associations specifically advise against the use of marijuana for medical purposes, this means it has accepted medical use. In fact, no major medical association has supported the use or legalization of "medical" marijuana and some of the most prestigious institutions in this country, such as the Cleveland Clinic, explicitly forbid recommending marijuana for medical use.

Under part two of the new test, HHS heavily relies on a systemic review of scientific and medical literature that was conducted by the University of Florida in 2023. HHS concludes that some credible science exists to support medical use of marijuana despite the University of Florida finding that the scientific and medical literature is inconclusive or mixed. It is not clear how HHS jumps from inconclusive data to declaring there is credible science supporting the medical use of marijuana.

It remains the case that marijuana has no currently accepted medical use. The fact that states have labeled marijuana as "medicine" does not change the nature of the drug. The FDA has approved one marijuana-derived drug and three synthetic marijuana-related drugs.[11] The FDA

[10] Physicians' Attitudes and Practices Regarding Cannabis and Recommending Medical Cannabis Use (2023), https://pubmed.ncbi.nlm.nih.gov/37098170/

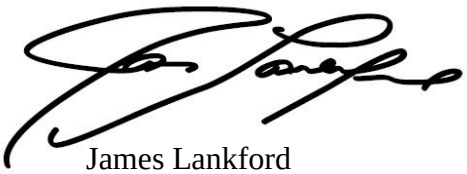
[11] FDA and Cannabis: Research and Drug Approval Process, U.S. Food and Drug Administration, (2023), https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process.

has never approved the marijuana that is being sold in dispensaries across the country as "medicine" for any disease or condition.

Finally, DOJ concurs with HHS's finding that marijuana has a moderate to low physical dependence or a high psychological dependence. HHS concludes that the likelihood of serious outcomes due to dependence is low. However, according to the National Institute on Drug Abuse (NIDA), 30% of marijuana users have marijuana use disorder which includes individuals who are severely addicted to the drug.[12] The amount of tetrahydrocannabinol (THC) in marijuana has significantly increased in recent years. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), a higher concentration of THC is likely linked to higher rates of addiction.[13]

It is clear that this Proposed Rule was not properly researched, circumvented DEA, and is merely responding to the popularity of marijuana and not the actual science. We urge you to withdraw this proposal and maintain marijuana as a schedule I drug.

Sincerely,



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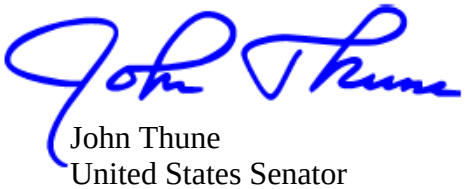

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[12] *Is Marijuana Addictive?,* National Institute on Drug Abuse, (2021), https://nida.nih.gov/publications/research-reports/marijuana/marijuana-addictive.
[13] *Know the Risks of Marijuana,* Substance Abuse and Mental Health Services Administration, (2023), https://www.samhsa.gov/marijuana.

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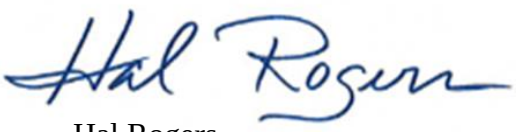

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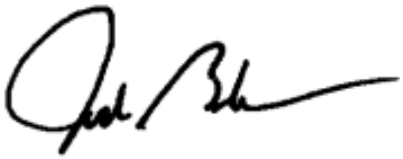

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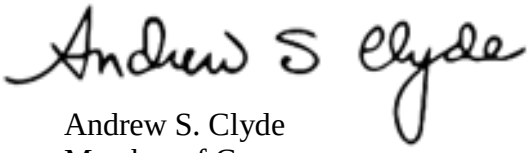

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