United States Senate
WASHINGTON, DC 20510

August 12, 2024

VIA ELECTRONIC TRANSMISSION

The Honorable Merrick Garland
Attorney General
U.S. Department of Justice
Washington, DC 20530-0001

Dear Attorney General Garland,

I have long advocated for safe medical treatment options, which could include those derived from marijuana. To that end, Senator Feinstein and I introduced the Cannabidiol and Marijuana Research Expansion Act, which streamlined the registration processes to study the medical benefits of marijuana and became law last Congress. Health policy should be based on sound scientific data, which is why I write raising concerns the Justice Department bypassed traditional safeguards in its haste to reschedule marijuana.

In May, the Justice Department issued a Notice of Proposed Rulemaking (NPRM) transferring marijuana from Schedule I of the Controlled Substances Act to Schedule III.[1] The Justice Department pushed forward with the NPRM even though the "DEA has not yet made a determination as to its views of the appropriate schedule of marijuana."[2] Additionally, the Department of Health and Human Services developed a novel two-part test to determine marijuana has a currently accepted medical use.[3] The test ignored "that no professional medical organization currently recommends use of marijuana (and that one recommends against its use)…"[4] In fact, the DEA requested additional scientific input to determine if marijuana has an accepted medical use, but Justice Department attorneys deemed the request "impermissibly

[1] Lindsay Whitehurst, *Justice Department Formally Moves to Reclassify Marijuana as A Less Dangerous Drug in Historic Shift*, Associated Press (May 16, 2024), https://apnews.com/article/marijuana-rescheduling-drug-policy-biden-15b43441670757b0c2bfa36731e47d07#
[2] Schedules of Controlled Substances: Rescheduling of Marijuana, 88 FR 44597, at 44501 (proposed May 21, 2024) (to be adopted at 21 CFR 1308).
[3] 88 FR 44597, at 44617.
[4] Memorandum Opinion for the Attorney General, Questions related to the Potential Rescheduling of Marijuana, at 4 (Apr. 11, 2024), https://www.dea.gov/sites/default/files/2024-05/2024-04-11%20-%20AAG%20Fonzone%20-%20Marijuana%20Rescheduling.pdf [hereinafter "Memorandum Opinion"]

narrow."[5] After apparently rejecting DEA's concerns, you signed the NPRM instead of the DEA Administrator.[6] This is a break from tradition.[7]

In a rush to reschedule, it appears the Justice Department disregarded at least ten additional categories of information relevant to—but missing from—the Justice Department's rescheduling determination:

1. "DEA believes that factual evidence (including scientific data) and expert opinions, including additional data regarding different forms, formulations, and delivery methods for marijuana, as well as evidence regarding the effects of marijuana at various dosages or concentrations, may be relevant."[8]

2. "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."[9]

3. "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."[10]

4. "DEA believes that additional data [on marijuana seizures] may be appropriate for consideration in assessing marijuana's actual or relative potential for abuse."[11]

5. "DEA believes that additional data on marijuana's pharmacological effects may be appropriate for consideration in assessing this factor."[12]

6. "DEA believes that additional data on marijuana's pattern of abuse may be appropriate for consideration in assessing this factor."[13]

7. "DEA also believes that additional information regarding the scope, duration, and significance of marijuana abuse may be appropriate for consideration in assessing this factor."[14]

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[5] 88FR 44597, at 44501; Memorandum Opinion at 4.
[6] Joshua Goodman and Jim Mustian, *Top US Drug Agency A Notable Holdout in Biden's Push To Loosen Federal Marijuana Restrictions* (May 20, 2024), https://apnews.com/article/marijuana-pot-dea-legalization-biden-cb7869d3286094f0124de728320d89c1
[7] *Id*.
[8] 88 FR 44597 at 44601.
[9] *Id*. at 44602.
[10] *Id*.
[11] *Id*. at 44603.
[12] *Id*. at 44605.
[13] *Id*. at 44610.
[14] *Id*. at 44613.

8. "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 Δ9-THC potency may be appropriate for consideration."[15]

9. "DEA anticipates that additional psychic or physiological dependence liability may be appropriate for consideration."[16]

10. "DEA welcomes additional information on [whether marijuana is an immediate precursor of a substance already controlled under the CSA]."[17]

The Justice Department deprived the DEA and the public of key categories of information, including by ending its own practice of evaluating the hazards of marijuana. For example, under the Biden-Harris Administration, the Rocky Mountain High Intensity Drug Trafficking Area (RMHIDTA) program stopped publishing its annual report tracking the impact of recreational marijuana use in Colorado.[18] Those reports had been released since 2013, so that others could "make informed decisions on the issue of marijuana legislation."[19] The last report, published in 2021, found a 138% increase in traffic deaths where drivers tested positive for marijuana and a 48% increase in seizures of black market marijuana.[20]

Decisions to reschedule controlled substances should be well-reasoned and thoroughly vetted. So that the public and Congress can make informed policy decisions on a complete record, please provide the following information by September 12, 2024:

1) Why did the Attorney General, instead of the DEA Administrator, sign the proposed rule?

2) Why did the RMHIDTA stop publishing its annual report tracking the impact of recreational marijuana use in Colorado? If this information was sent somewhere else for publication, please provide those reports.

3) Please provide the 10 categories of information identified by DEA in the NPRM and reproduced above. If this information is not available, please explain why the Justice Department issued an NPRM before the information became available.

4) Please provide the agency submissions underlying the April 11, 2024, Memorandum Opinion for the Attorney General on "Questions Related to the Potential Rescheduling of Marijuana," including:

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[15] *Id*. at 44614
[16] *Id*. at 44615
[17] *Id*. at 44615.
[18] Rocky Mountain High Intensity Drug Trafficking Area, *The Legalization of Marijuana in Colorado: The Impact*, Volume 8 (September 2021), 4a67c3_b391ac360f974a8bbf868d2e3e25df3d.pdf (rmhidta.org)
[19] Rocky Mountain High Intensity Drug Trafficking Area, *The Legalization of Marijuana in Colorado: The Impact*, Volume 8 (September 2021), 4a67c3_b391ac360f974a8bbf868d2e3e25df3d.pdf (rmhidta.org)
[20] *Id*. at 5.

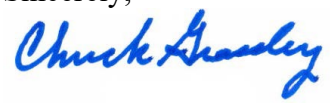
a. Memorandum for the Office of Legal Counsel from DEA (Jan. 30, 2024);

b. Memorandum for Gillian E. Metzger, Deputy Assistant Attorney General, Office of Legal Counsel, from Samuel R. Bagenstos, General Counsel, HHS; and

c. Single Convention Requirements for Cannabis and Scheduling Under the Controlled Substances Act (Feb. 12, 2024).

5) If marijuana is re-scheduled, please explain the Justice Department's plan for pursuing recourse against individuals who distribute marijuana products without Food and Drug Administration approval. Please detail the Justice Department's plan for removing those products from the market in the event that marijuana is rescheduled.

Sincerely,



Charles E. Grassley

United States Senate
WASHINGTON, DC 20510

August 12, 2024

VIA ELECTRONIC TRANSMISSION

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
Washington, DC 20201

Dear Secretary Becerra:

I write with questions about the Department of Health and Human Services (HHS) efforts to reschedule marijuana from Schedule I to Schedule III under the Controlled Substances Act. I have long supported expanding treatment options for families but believe those decisions should be based on sound scientific data. That is why I co-led the Medical Marijuana and Cannabidiol Research Expansion Act (MMCREA) with Senator Feinstein.

On December 2, 2022, the MMCREA became law, requiring HHS to submit a report on specific therapeutic and adverse effects of marijuana by December 2023.[1] HHS missed its deadline by 6 months, and submitted its report on June 11, 2024.

On August 29, 2023—roughly four months before HHS's MMCREA report deadline—HHS recommended the Drug Enforcement Administration reschedule marijuana from a Schedule I controlled substance to Schedule III.[2] However, HHS's MMCREA report seems at odds with its recommendation to reschedule marijuana in Schedule III in at least two key respects.

First, HHS's MMCREA report raises questions about HHS's new two-part test for determining whether marijuana has a currently acceptable medical use. That test evaluates "(1) whether there is a widespread medical use of a drug under the supervision of licensed health care practitioners under state authorized programs and, (2) if so, whether there is credible scientific evidence supporting such medical use."[3] To satisfy the first prong, HHS relied on licensed practitioners operating in accordance with state-authorized programs.[4] However, HHS's MMCREA report notes "that the U.S. jurisdictions that have legalized the use of cannabis products for medicinal purposes have often done so with inadequate scientific research to

[1] Public Law No. 117-215 Section 401.
[2] https://www.dea.gov/sites/default/files/2024-05/2016-17954-HHS.pdf
[3] Schedules of Controlled Substances: Rescheduling of Marijuana, Vol. 89, No. 99, May 21, 2024, Page 44617. https://www.govinfo.gov/content/pkg/FR-2024-05-21/pdf/2024-11137.pdf
[4] Page 63, https://www.dea.gov/sites/default/files/2024-05/2016-17954-HHS.pdf

support all allowable uses."[5] The MMCREA report further disclaimed, "[m]ore research is needed to evaluate the therapeutic potential of cannabis and cannabinoids as a means of safely and effectively treating various indications." These findings appear to cut against the first factor of HHS's new analysis.

HHS then turned to the second factor of its new two-factor test, which leans on the Federal Drug Administration (FDA) for scientific evidence supporting medical use. HHS looked at FDA approvals for THC products because "to date, FDA has not approved an NDA (New Drug Application) for a drug product containing botanical marijuana."[6] However, HHS's MMCREA report states that research on THC products is limited, and the "Centers for Disease Control and Prevention (CDC) and FDA have issued advisories about Δ^8-THC citing adverse events, unsafe manufacturing processes, and other concerns."[7] This statement raises questions about whether THC was a sufficient substitute for HHS's analysis or whether it lacked too much data to provide insight.[8]

Second, HHS concluded the risks to public health posed by marijuana are low despite the concerning statements about marijuana in HHS's MMCREA report.[9] Among other things, the MMCREA report found "acute and chronic adverse effects of cannabis" while also noting there is "insufficient evidence to conclude that cannabis improves mental health conditions, quality of life, or well-being."[10] The MMCREA report further found that, "exposure to cannabis during critical periods of development (e.g., prenatal, adolescence) could alter the [bodies' natural endocannabinoid system]." Serious cardiovascular effects, including stroke and heart attacks, have been reported with long-term use. In fact, in 2016, HHS concluded that marijuana had a high potential for abuse and lacked an acceptable level of safety for use even under medical supervision.[11] Warnings within the MMCREA report about the dangers of marijuana raise more questions about HHS's about-face in marijuana re-scheduling and require further explanation.

Despite these gaps between HHS's rescheduling recommendation and the MMCREA report, HHS began the MMCREA report by stating its "conclusions about therapeutic potential and adverse effects are consistent with those in the recommendation from HHS to the [DEA] regarding scheduling of botanical cannabis. . . ."[12] HHS does not explain the basis for this opinion, and the opinion seems unsupported by the body of its report.

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[5] Dep't of Health and Human Services, Health Effects of Cannabis and Cannadinoids and Barriers to Research Report to Congress Pursuant to Requirements of the Medical Marijuana and Cannabidiol Research Expansion Act, page 6 [Hereinafter "MMCREA report"]

[6] Page 4, Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act (dea.gov)

[7] MMCREA report at 7.

[8] *Id*. at 8.

[9] Proposed Rule at 44516-17.

[10] MMCREA report at 1, 5.

[11] Denial of Petition to Initiate Proceedings To Reschedule Marijuana, Vol. 81, No. 156, Aug. 12, 2016, page 53767, https://www.govinfo.gov/content/pkg/FR-2016-08-12/pdf/2016-17960.pdf

[12] MMCREA report at 3.

So that Congress can better understand HHS's recommendation, please provide a response accounting for the apparent discrepancies between HHS's rescheduling recommendation and its MMCREA report by September 12, 2024.

Sincerely,

Charles E. Grassley