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