Congress of the United States
Washington, DC 20515

December 6, 2019

The Honorable William P. Barr
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Dear Attorney General Barr:

We write to ask for clarification in the Justice Department's current and proposed policies regarding the access to research-grade cannabis, including forthcoming new regulations governing schedule I licenses to manufacture cannabis for research.[1]

In response to a congressional inquiry, both the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA) discussed how federal restrictions inhibit marijuana research in a variety of ways, including limitations on the diversity and quality of research-grade cannabis.[2] The agencies stated that "[a] larger body of rigorous research, including on cannabis and cannabinoid products that are already in use or that could be developed into FDA-approved medications, is key to furthering our understanding of their potential medical benefits and risks."

One barrier to research is that the Drug Enforcement Administration (DEA) has registered one entity to produce research-grade marijuana—the University of Mississippi. Both NIH and FDA note that having one source producing the marijuana necessary for research limits "the diversity of products and formulations available to researchers" and slows "the development of cannabis-based medication." Due to the limitations associated with cultivating all research-grade marijuana at a single facility, the agencies "support licensing additional entities to supply cannabis, including extracts and derivatives, to legitimate researchers and drug product developers in the United States."

As recently as 2016, DEA has acknowledged the need for increased diversity and quality of research-grade cannabis.[3] However, both DEA and the Justice Department have delayed the approval of licenses to manufacture marijuana for over three years. Furthermore, the Justice Department is now considering a new regulatory scheme to govern how additional manufacturers for research will operate.

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[1] Drug Enforcement Administration, "Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana," 84 FR 44920, 28 Oct. 2019, https://www.federalregister.gov/documents/2019/08/27/2019-18456/bulk-manufacturer-of-controlled-substances-applications-bulk-manufacturers-of-marihuana.

[2] "FDA and NIH on Marijuana," https://www.scribd.com/document/425284413/FDA-And-NIH-On-Marijuana#from_embed.

[3] Drug Enforcement Agency, "Applications To Become Registered Under the Controlled Substances Act to Manufacture Marijuana To Supply Researchers in the United States," 81 FR 53846 12 Aug. 2016, https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to.

At the same time, the status quo does not address a barrier to research raised by both NIH and FDA: "under federal law, researchers are unable to purchase strains of marijuana or products containing marijuana from state dispensaries (even with non-federal funds), resulting in a significant gap in our understanding of these products and their impact on health." Both agencies recommended that researchers should be able to obtain cannabis from state-legal sources.

Additionally, NIH and FDA jointly recognized the problems in industry development of licensed drugs with data from products obtained from third-parties, such as the University of Mississippi. In many states, cannabis law and regulations already provide for licensing of industrial manufacturing activities, and products are available for medical use in those states, but not for research leading to FDA licensure.

There is a need for a greater diversity of cannabis products so that research on benefits and risks reflects the realities of what consumers and patients are using. NIH and FDA have strongly recommended streamlining the process for conducting research and product development activities with cannabis and other Schedule I substances, and that the DEA take action to assure that interpretations of processes and policies are universally applied in local DEA jurisdictions.

We request the following:

1) That the DEA amend, in light of the strong statements of continued research needs by both NIH and FDA and without need for further legislative action, its current policies so as to allow researchers with Schedule I licenses to obtain cannabis-derived products from state authorized dispensaries for research purposes.[4]

2) That the DEA issue in the near future a public clarification of its interpretation of the hemp provision in the *Agricultural Improvement Act of 2018*—which removes "hemp" from the definition of "marihuana" under the *Controlled Substances Act*. Cannabis preparations that conform to the hemp definition should not require a Schedule I research registration, regardless of the classification of the cannabis source ingredients used in the final preparation.[5]

Please respond in writing by December 20, 2019. Thank you for your attention to this matter.

Sincerely,

BRIAN SCHATZ
United States Senator

HARLEY ROUDA
Member of Congress

[4] Under 21 U.S.C. § 822(d), "The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety."

[5] Under P.L. 115-334, hemp is defined as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

KAMALA D. HARRIS
United States Senator

CORY GARDNER
United States Senator

MATT GAETZ
Member of Congress

EARL BLUMENAUER
Member of Congress

TONY CÁRDENAS
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Member of Congress

JOE NEGUSE
Member of Congress

DAVID E. PRICE
Member of Congress

cc: Uttam Dhillon
Acting Administrator
Drug Enforcement Administration