

May 22, 2020

Uttam Dhillon Acting Administrator United States Drug Enforcement Administration 8701 Morissette Drive Springfield, Virginia 22152

RE: <u>Docket No. DEA-2020-0008</u>: Controls To Enhance the Cultivation of Marihuana for Research in the United States (March 23, 2020)

Dear Acting Administrator Dhillon:

The Council on Governmental Relations (COGR) is an association of 187 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. COGR currently convenes a cannabis workgroup consisting of approximately 25 members with diverse roles at various institutions across the U.S. that have a substantial interest in conducting valuable research about the efficacy, safety, and side effects of cannabis use, and its impacts on humans, animals and the environment.

Access to a Variety of Seeds and Cultivars

COGR appreciates the DEA moving forward on the expansion of the manufacturer registrant pool beyond what it is today, i.e., one single manufacturer for the entire U.S. research community. In order to conduct research that is relevant to the actual public use of cannabis, it critical that researchers have access to a wide variety of product. To that end, it is important that federally approved growers be able to obtain their seeds and cultivars from as wide a diversity of resources as possible, including both domestic and international sources (consistent with relevant local laws and treaties). FDA and NIH have also indicated support for a greater diversity of cannabis for research purposes, including from state authorized dispensaries. *See* Letter from FDA and NIH to Sen. B. Schatz (Aug. 27, 2019).

Pending Applications

We urge DEA to act expeditiously in the review of all pending applications. As of the writing of this letter, no applications have been approved since DEA's August 2016 Federal Register Notice soliciting applications for registration – almost four years ago now. The current limitation of being able to obtain cannabis from only one entity is no longer sufficient as states have moved forward with legalization of both medicinal and recreational use of marijuana, often including strains at significantly higher potency than researchers can obtain through the National Institute on Drug Abuse (NIDA) program. For example, effects of contamination of publicly

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available cannabis containing heavy metals and pesticides can only be done with access to publicly available cannabis.

Possession of Crops/Quality Control of Cannabis Materials

The NPRM states that DEA shall purchase and take physical possession of total crops from registered manufacturers as soon as possible, but not later than four (4) months after the end of the harvest. Furthermore, DEA may accept delivery and maintain possession of such crops at the registered location, consistent with the maintenance of effective controls against diversion. Taken together, the changes proposed above are confusing. It appears that DEA is taking "legal" possession as opposed to "physical" possession, with the expectation that the manufacturer would store the materials at the manufacturer's facility and potentially at the cost of the manufacturer. We ask that DEA clarify whether it truly intends to claim "physical possession," and if so, what are the implications for the manufacturer. For example, who is then responsible for physical security, as well as assuring that the materials have gone through the proper quality control inspections prior to distribution to researchers. According to <u>§ 1318.07</u>, the DEA asserts that it shall have no liability, including with respect to the quality of any cannabis delivered to a buyer, which is inappropriate if the DEA maintains physical ownership. We ask that this be addressed prior to implementation of the final rule.

Costs to Researchers

We recommend that DEA clarify the notion of a "variable administrative fee" for recovering costs as noted in the current proposed rule, both for registrants and purchasers of cannabis materials. We caution that passing down such fees to researchers would further deter them from conducting crucial scientific studies on cannabis when funding for cannabis-related research is relatively scarce.

Furthermore, we would hope that manufacturers who want to conduct their own research on materials they grow would not be required to pay the "variable administrative fee." Under the current system, most researchers are able to receive research materials at no cost, and it is not clear that there is cause to change that.

Again, we very much appreciate DEA moving forward with a process to expand the number of manufacturers that can provide product for desperately needed cannabis research and for the opportunity to provide our comments on the proposed rule. If you have any questions please contact Jackie Bendall, Director of Contracts and Grants Administration, at jbendall@cogr.edu.

Sincerely,

Wendy D. Streitz President