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OFFICE OF THE VICE PRESIDENT – RESEARCH & INNOVATION

OFFICE OF THE PRESIDENT
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Oakland, California 94607-5200

May 22, 2020

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

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

Dear Acting Administrator Dhillon:

I write on behalf of the University of California (UC) system in response to the Notice of Proposed Rulemaking (NPRM), "Controls To Enhance the Cultivation of Marihuana for Research in the United States," published in the *Federal Register* on March 23, 2020.

The UC system is comprised of ten research-intensive campuses, six medical schools, three affiliated U.S. Department of Energy national laboratories, and a Division of Agriculture and Natural Resources. UC has established an unparalleled reputation for research and innovation, contributing to the state and nation through discoveries and new technologies that improve health, the environment, public safety, and quality of life. Specific to cannabis research, UC is well equipped to conduct research with cannabis research centers and initiatives located at UC Berkeley (Cannabis Research Center), UC Davis (UCD Cannabis and Hemp Research Initiative), UC Irvine (Center for the Study of Cannabis), UC Los Angeles (Semel Cannabis Research Initiative), UC Merced (UC Nicotine and Cannabis Policy Center), UC Riverside (Center for Cannabis Research and Regulation), UC San Diego (Center for Medicinal Cannabis Research), and UC Santa Cruz (Cannabis & Hemp Initiative for Interdisciplinary Plant Studies), UC San Francisco (Cannabis Research Group in the Center for Tobacco Control Research and Education) in addition to renowned cannabis researchers at UC Santa Barbara, and the Lawrence Berkeley National Laboratory.

UC strongly supports increasing the lawful supply of marijuana available for research, including by increasing the number of registered manufacturers who can provide research materials to U.S. investigators. While UC appreciates the DEA moving forward on the processing of manufacturing registrations to grow marijuana for research purposes, we ask that the DEA consider the following in its rulemaking: 1) expeditious action on processing applications to cultivate marijuana for research; 2) need for varied cannabis research material, including clarifying specifically that universities be permitted to conduct research with cannabis products that are legally available in states (e.g., California) and that universities not be subject to

prosecution, withdrawal of Federal funds, or other sanctions, as a result; 3) clarification around the DEA's possession of cannabis research materials; 4) timely access to needed marijuana for research; 5) standardized analyses of research materials; 6) cost considerations; and 7) clarification on the regulatory status of cannabidiol (CBD). Further details on each of these points appear below.

Expeditious Action on Processing Application to Cultivate Marijuana for Research

On August 12, 2016, the DEA published a notice, "Applications To Become Registered Under the Controlled Substances Act To Manufacture Marijuana To Supply Researchers in the United States" (Docket No. 81 FR 53846), soliciting applications for registrations under the Controlled Substances Act (CSA) to manufacture marijuana for research purposes. The DEA stated that its intent was to "increase the lawful supply of marijuana available to researchers" and to "increase the number of registered growers who will be supplying U.S. researchers." However, as of the date of this comment letter, the DEA has yet to approve any of the applications it has received in response to the 2016 Federal Register notice.

UC recognizes that this NPRM is a part of the DEA's efforts to move forward with its review of applications for those who seek to grow marijuana legally to support research. UC urges the DEA to conduct a timely review of applications for registrations to manufacture marijuana for research purposes. We believe that expeditiously authorizing additional marijuana manufacturers in the U.S. will enhance researchers' capacity to conduct legitimate investigations into the potential health effects of cannabis use, impacts that use and cultivation may have on public safety including differences in health impacts due to the widespread different varieties of cannabis available in the United States today, and other important areas to public policy and public welfare. We also urge the DEA to prioritize authorization to applicants that have partnerships with universities that have robust programs of research that require these products.

The Need for Varied Cannabis Research Materials

The NPRM is currently silent on where manufacturers may obtain seeds and cultivars for their cannabis grows. We urge the DEA to allow marijuana manufacturers to acquire seeds and cultivars from a variety of sources, including domestic sources operating consistent with the law of their states, international sources (via importing seeds and cultivars from abroad), and that the DEA make available to manufacturers plants that it may have in its possession from law enforcement or other agency activities. In order to advance knowledge regarding the potential negative and positive effects of cannabis that is currently in use across the country, it is important that researchers be able to study the actual strains that are available in different states, particularly those with robust regulatory systems; and researchers analyze and administer these products under approved protocols without federal sanctions. Allowing for a variety of products available to the research community would further the overarching intent of the DEA's policy to meet the demand for research-grade marijuana and advance knowledge.

The current limitation regarding the source of cannabis that can be used for research is a significant impediment to advancing knowledge. To date, the form and content of the marijuana available through the NIDA Drug Supply Program reportedly has not been comparable to some of the marijuana that is being consumed by medicinal and recreational users, including those

available in our state. While cannabis products are legal in states that have passed adult use marijuana laws, the fact of the matter is that there are more questions than answers about the safety, benefits, and risks associated with marijuana use.

Questions about the opioid epidemic and cannabis' role in either reducing or exacerbating the problem remain unanswered. Investigations into how best to detect cannabis intoxication in motor vehicle drivers need to be furthered. Uncertainties persist about the health impact of new cannabis products with high THC content in pregnant women and adolescents.

The recent outbreak of severe lung disease in young people using e-cigarettes, the majority of which have occurred in users of cannabis-based products, is extremely frightening yet the issue cannot be effectively studied because researchers cannot work directly with cannabis products that are in actual use. The urgency of conducting sound research to address these questions cannot be overstated and our researchers need to be able to work with products representative of what is currently available in states that have passed marijuana laws. Because researchers have been effectively barred from studying the products that people are actually consuming, the research void has inevitably been filled by claims that are not backed by science, to the detriment of the public's capacity to make informed decisions, the economy of our country, and most importantly, the health of our citizens.

We believe making varied cannabis sources available for research (including by ensuring that manufacturers can grow research marijuana from seeds and cultivars obtained from a variety of sources) as well as allowing researchers to purchase and study products that are legally available to the general public in their states is crucial for enabling meaningful studies that yield results that are practically valuable to protect the public's safety, generate intellectual property, and ensure informed public policymaking. Thus, we ask that the NPRM address new manufacturer's ability to utilize source seeds and cultivars that do not come from the current NIDA program, as well as permit universities researchers to conduct research with cannabis products that are legally available in states (e.g., California) without being subject to prosecution, withdrawal of federal funds, or other sanctions.

Clarification around Possession of Cannabis Research Materials

The DEA stressed in the NPRM that it will have sole ownership over marijuana that is cultivated for research purposes and will hold the exclusive right to import, export, wholesale trade, and maintain stocks of cannabis and cannabis resin to distribute to researchers. This is a fundamental shift in policy compared to the current arrangement with the NIDA Drug Supply Program. UC's understands that this policy shift stems from the DEA's interpretation of the Single Convention on Narcotic Drugs of 1961.

As part of this policy shift, the DEA states that it will "maintain possession of such crops at the registered location of the registered manufacturer authorized to cultivate cannabis." The NPRM also states that "DEA shall purchase and take **physical possession** of such crops as soon as possible, but not later than four months after the end of the harvest." [emphasis added].

These two statements are confusing. Does the DEA intend to take ***physical*** possession of the crops? Or did the DEA mean to state that it will maintain ***legal*** possession over cannabis products while manufacturers will hold ***physical*** possession of the products since the material will remain at the DEA registered sites? We ask the DEA to provide clarification over its possession of cannabis research materials, particularly in terms of storage requirements for manufacturers.

Whichever entity maintains physical possession, it is essential to ensure the quality of marijuana crops that will be distributed for research purposes, as tainted marijuana compromise the integrity of research and can have detrimental effects on research participants' health and safety. Marijuana that is improperly packaged, stored, or shipped can become contaminated, ineffective, or worse, harm people who might receive them. In cases where the DEA maintains both legal and physical possession of marijuana crops, we believe that the DEA should assume some measure of liability for the quality of the product it distributes to researchers. In that regard, **§ 1318.07** stating that the DEA shall have no liability, including with respect to the quality of any cannabis delivered to a buyer, should be revised. Alternatively, if the DEA will ***not*** be assuming physical control of marijuana crops, please clarify this in the proposed rule.

Timely Access to Needed Marijuana for Research

Under the proposed policy, it is unclear how long it will take for researchers to apply for and receive marijuana distributed by the DEA, and how proactive the DEA will be to make specific marijuana research materials available to investigators. It should be noted that the NIDA Drug Supply Program has been responsive to the researchers' needs for specific cannabis research materials, for example providing 1:1 THC:CBD vaporized marijuana for specialized studies, but there have been significant delays, we assume due to difficulties a sole source may have in addressing varied requirements quickly. In order for the DEA's new policy to be a success, UC strongly recommends that the DEA be equally responsive to investigators, both in terms of providing needed research materials and doing so in a timely manner, including without delay during the transitional period to implement this policy. Adding more time to a system that is already fraught with regulatory hurdles puts the DEA in a position vulnerable to allegations of mismanagement.

Standardized Analyses of Research Materials

The NIDA Drug Supply Program currently provides detailed analyses of product content to ensure the standardization of research materials. This information is imperative for researchers in understanding the product that they are working with and making comparisons across results. The NPRM does not specify whether the DEA will require such detailed product information to be provided for marijuana manufactured under the new rule, or if the DEA will, instead, as the physical and legal owner of the product conduct the necessary analyses of materials to ensure their quality, but UC strongly advises that not providing this information will be detrimental to research. We ask the DEA to clarify how manufacturers will be expected to work with NIDA and the DEA to provide detailed product analyses.

In addition, it should be noted that drug master files (DMFs) are submitted to the FDA to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products. The DMFs are critical for conducting human subjects research, as they are required in connection with the review of IND applications. We ask that the DEA provide clarification on how DMFs would be handled under the proposed rule and which party (the DEA or registered marijuana manufacturers) would be responsible for conducting testing as part of the information needed for the DMFs.

Cost Considerations

There are two new proposed costs in the NPRM, including a "variable administrative fee" that would be used to recover the costs of carrying out the proposed rule. It is unclear whether the proposed policy changes and the new fee structure would mean an end to the current system where many researchers are able to receive research materials for free. UC is concerned that an administrative fee, if passed down to researchers, could thwart the goal of encouraging more research in this area. If the administrative fee is passed down to researchers, which UC strongly cautions against, it would be contrary to the interest of advancing research in this field where funding is already seriously limited.

We also ask the DEA to provide clarification on whether manufacturers who want to conduct their own research on materials they grow would need to pay this "variable administrative fee." It would seem more prudent to forgo this cost and, therefore, negate the need for the DEA to purchase marijuana grown by DEA-registered manufacturers and subsequently sell the marijuana back to them.

Clarification on the Regulatory Status of Cannabidiol (CBD)

Within this NPRM, the DEA quoted the 2018 Farm Bill definition of hemp without offering any clarification of whether it should be interpreted to apply to extracts or derivatives, such as CBD, of high-THC marijuana plants if the extract or derivative themselves contain no more than 0.3% THC. We believe the DEA should provide guidance on whether CBD extracted from cannabis plants (whether from marijuana or hemp plants) "falls outside the definition of marihuana in section 102(16) of the Controlled Substances Act (the Act (21 U.S.C. 802(16)," as referenced in **§ 1318.02**, which this NPRM proposes to add to the Controlled Substances Act. UC would support the DEA adding language to that section of the NPRM or otherwise issuing guidance clarifying that any CBD product that has less than 0.3% THC (whether derived from a marijuana plant, a hemp plant, or synthetically derived) is hemp and, therefore, is not regulated as a controlled substance. Additionally, it would be beneficial to identify industrial cannabis that is specifically not intended for purposes of human consumption (i.e., for building materials, fibers, textiles, etc.) to not be considered subject to the Controlled Substances Act.

We appreciate the opportunity to comment on this NPRM and commend your diligence in facing the challenging task of overseeing the manufacture of controlled substances in the U.S. in order to meet obligations set forth in the CSA and relevant international treaties. The UC would be happy to further engage with you in finding workable solutions should any additional information be helpful to the DEA.

Sincerely,

Theresa A Maldonado

Theresa A. Maldonado, Ph.D., P.E.
Vice President for Research & Innovation

Cc:
The Honorable Dianne Feinstein
The Honorable Kamala Harris
The Honorable Karen Bass
The Honorable Ted Lieu
The Honorable Zoe Lofgren
The Honorable Eric Swalwell
The Honorable Luis Correa
The Honorable Tom McClintock