COGR

Council On Governmental Relations

An Association of Research Institutions

July 16, 2019

Department of Health and Human Services
Food and Drug Administration
Attn: Beth F. Fritsch
10903 New Hampshire Avenue
Silver Spring, MD 20993

Reference: Docket No. FDA-2019-N-1482

Subject: Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments

Dear Ms. Fritsch,

The Council on Governmental Relations (COGR) is an association of 188 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.

As of June 2019, 33 states plus the District of Columbia have state laws allowing for the medical use of cannabis, while 11 of those states have legalized the recreational use of cannabis. With such expanded availability, there is a desperate need for more scientific information about the efficacy, safety, and side effects of cannabis use, and its public health and environmental impacts. We are pleased to see that the FDA is seeking scientific data and information to inform its consideration of appropriate regulations. However, the scope of work that researchers can conduct that would inform the FDA is significantly limited by the current status of marijuana as a Schedule I substance under the federal Controlled Substances Act.

One of COGR's roles is to work with research institutions in their efforts to comply with federal regulations, including providing guidance where possible. Given the increasing need for research, institutions are eager to contribute to the scant body of scientific knowledge while trying to navigate unclear and sometimes contradictory regulations surrounding cannabis and its compounds. If the FDA is to have sound scientific data on which to base its regulations, the legal landscape must change to allow a broader range of research to be conducted.

This comment letter serves to outline two major barriers associated with conducting research with cannabis and its compounds: the regulatory limitations on access to cannabis for research purposes and unclear regulatory requirements. We believe that if these barriers were reduced or eliminated, researchers would be better positioned to do research on cannabis and in turn could better address the questions the FDA is seeking input. Given the critical role academic medical centers and research institutions play in understanding the safety and efficacy of cannabis use, we recommend that the FDA solicit input from key stakeholders and experts in the academic research community and across federal agencies (e.g., DEA, NIDA) to assist with the Agency's inter-agency working group. Efforts should also be made to establish a stakeholder roundtable to identify and overcome the current regulatory barriers preventing institutions from conducting cannabis research.

Barriers to Cannabis Supply

Current research can only be conducted using cannabis obtained through a DEA-approved source or produced by a facility that holds a DEA-approved license to grow and distribute cannabis for research purposes under contract with the National Institute on Drug Abuse (NIDA). To date, the National Center for Natural Products Research at the University of Mississippi has been the only facility to hold such a license to grow cannabis for research purposes. Further, with such a limited supply of strains of diversity and quality, and a requirement that strains be processed according to HHS requirements, researchers are unable to study cannabis that is comparable with respect to content and ratio of THC and CBD to that currently available in states that have passed recreational or medicinal cannabis laws. This is a serious impediment to understanding pivotal emerging issues such as, for example, (a) the health risks associated with the escalating availability of very high THC content cannabis strains, and (b) the potential health benefits of varying THC/CBD ratios.

In an attempt to address this issue, the DEA, in 2016, released a new policy "Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States" noting the significant interest in conducting research with cannabis and cannabis extracts, stating:

> "A growing number of researchers have expressed interest in conducting research with extracts of marijuana that have a particular percentage of CBD and other cannabinoids. DEA fully supports research in this area. Based on discussions with NIDA and FDA, DEA has concluded that the best way to satisfy the current researcher demand for a variety of strains of marijuana and cannabinoid extracts is to increase the number of federally authorized marijuana growers. To achieve this result, DEA, in consultation with NIDA and FDA, has developed a new approach to allow additional marijuana growers to apply to become registered with DEA, while upholding U.S. treaty obligations and the CSA."

Almost three years later, despite over two dozen applications submitted to the DEA, there are still no federally approved growers outside of the University of Mississippi. Given the critical need for research on a variety of cannabis, we strongly urge the FDA to work with NIDA and the DEA to permit more manufacturers to grow cannabis for research purposes, increasing the diversity in cannabis strains and quality. Increasing the variety of approved cannabis manufacturers would benefit the FDA as it would allow for more research on cannabis and cannabis-derived compounds to better inform FDA in the development of regulations. This is a sentiment shared by several presenters at the FDA's May 31 public hearing, *Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds*.

Confusing Regulatory Requirements around CBD

There is significant interest within the academic research community in conducting research with CBD, however the regulatory requirements are unclear and confusing. CBD as a product derived from marijuana remains a Schedule I substance. Although CBD, as a product derived from hemp, is no longer categorized as a controlled substance pursuant to the 2018 Farm Bill, it remains unclear to the research community where they can obtain hemp-derived CBD products for research purposes and whether obtaining hemp-derived products from across interstate boundaries is permitted. We request that the FDA work with the DEA to provide additional clarity on this issue.

With the increase of unregulated hemp and/or CBD-oil products on the internet and at local retail outlets, it is essential that these issues are timely addressed. Research must be conducted to accurately characterize the varying contents of CBD products, levels of ancillary ingredients (e.g., pesticides, heavy metals, organic solvents), and validation of the therapeutic claims made by the manufacturers and retailers. Federal restrictions, based on scheduling guidelines, render these important studies very difficult if not impossible.

In closing, we agree with the National Academies report, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*, that substantial layers of bureaucracy are discouraging cannabis researchers from conducting work in this area and fully support the Academies' Recommendation No. 4. *Address Research Barriers*:

> "The Centers for Disease Control and Prevention, National Institutes of Health, U.S. Food and Drug Administration, industry groups, and nongovernmental organizations should fund the convening of a committee of experts tasked to produce an objective and evidence-based report that fully characterizes the impacts of regulatory barriers to cannabis research and that proposes strategies for supporting development of the resources and infrastructure necessary to conduct a comprehensive cannabis research agenda. Committee objectives should include, but need not be limited to:

- Proposing strategies for expanding access to research-grade marijuana, through the creation and approval of new facilities for growing and storing cannabis.
- Identifying nontraditional funding sources and mechanisms to support a comprehensive national cannabis research agenda.
- Investigating strategies for improving the quality, diversity, and external validity of research-grade cannabis products."

We appreciate the opportunity to provide comment on this important issue. To the extent COGR can help the Agency in its efforts to answer these questions, whether through a meeting or broader discussion with COGR's stakeholders and constituents, please contact Jackie Bendall at jbendall@cogr.edu.

Sincerely,

Wendy D. Streitz
President