



University of Colorado

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To: University of Colorado Research Faculty

From: President Bruce D. Benson
University Counsel Patrick T. O'Rourke

Date: March 11, 2014

Re: Legality of Marijuana Research

Colorado is one of twenty states that have passed laws that allow marijuana to be used for medical purposes. Colorado is one of two states that have passed laws that decriminalize the possession of small amounts of marijuana and create a regulatory system for production, processing and sale.

With these changes to Colorado's legal system, we have received inquiries from faculty members about their ability to conduct marijuana-related research. Colorado's General Assembly is also currently exploring its ability to fund marijuana-related research. Our governmental relations professionals are working with the legislators to define the legal framework by which this funding could be distributed, including engaging with federal agencies that have regulatory authority over marijuana-related research.

No University of Colorado faculty member has authority to conduct marijuana-related research that has not been approved through the appropriate federal, state, and University of Colorado processes applicable to research upon controlled substances.

I. Legal Framework for Marijuana-Related Research

The Controlled Substance Act creates a comprehensive federal framework that categorizes drugs and other controlled substances into five "schedules." At the high end of the spectrum, and most tightly regulated, are Schedule I controlled substances, which are those substances that: (1) have a high potential for abuse; (2) have no currently accepted medical use in treatment in the United States; and (3) have a lack of accepted safety under medical supervision. Last year, a federal court recognized that "there is a serious debate in the United States over the efficacy of marijuana for medicinal uses," but nonetheless upheld the Drug Enforcement Agency's refusal to change marijuana's classification as a Schedule I controlled substance. As such, it remains illegal under federal law for any person to import, manufacture, distribute, possess, or use marijuana. The Department of Justice recently issued a memorandum denying that "any state or local law provides a legal defense to a violation of federal law, including any civil or criminal provision of the [Controlled Substance Act]."

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Under the federal Drug Free Schools and Communities Act, institutions of higher education have an obligation to comply with federal drug laws as a condition of receiving grant funding or other financial assistance under any federal program. Consequently, conducting unapproved marijuana-related research could adversely affect the University of Colorado's ability to seek federal research funding or federal financial aid. To prevent this possibility, all marijuana-related research must be conducted in strict compliance with federal, state, and University of Colorado processes.

Notwithstanding the Controlled Substance Act's general prohibition upon any marijuana-related activities, federal law provides the Food and Drug Administration with the ability to approve research using Schedule I controlled substances. Currently, across the United States, more than 100 researchers have obtained registrations to conduct marijuana-related research, including clinical studies involving smoked marijuana. The process by which a researcher obtains permission to conduct marijuana-related research varies according to the nature of the study:

A. Human Subjects – Under federal law, a researcher who wishes to use marijuana in research involving human subjects must:

- a. Submit an Investigational New Drug application to the FDA.
- b. Obtain a registration from the Drug Enforcement Administration.
- c. Obtain approval from the appropriate Institutional Review Board.
- d. Receive a determination from the Department of Health and Human Services that the investigator is qualified and the proposed research has merit.
- e. Acquire the drug from the National Institute on Drug Abuse's approved source.
- f. Follow DEA regulations and guidelines for storage and prescription.

B. Human Observational Studies – Human observational studies are those where subjects use marijuana, but the researcher does not procure the marijuana for the subjects, the marijuana is not used on the campus, and the marijuana is not consumed on the campus. For such human observational studies, the researcher must:

- a. Obtain approval from the appropriate IRB.

C. Animal Studies – A researcher who wishes to use marijuana in research involving animal studies must:

- a. Obtain a registration from the DEA.
- b. Obtain approvals from the appropriate campus Institutional Animal Care and Use Committee.
- c. Acquire the drug from the NIDA approved source.
- d. Follow DEA regulations and guidelines for storage and prescription.

D. Basic Research – For research that does not involve human subjects or animals, yet is directed toward greater knowledge or understanding of the fundamental aspects of marijuana, the researcher must:

- a. Obtain a registration from the DEA.
- b. Acquire the drug from the approved source.
- c. Follow DEA regulations and guidelines for storage and prescription.

Because federal law prescribes these mechanisms for conducting marijuana-related research, they are binding upon the University of Colorado, and, with the potential exception of research involving industrial hemp, represent the exclusive means of conducting marijuana-related research on University of Colorado campuses. No University of Colorado faculty member has authority to conduct marijuana-related research that has not been approved through the appropriate processes. If you have any question about whether a course of research is subject to these processes, please direct those questions to the Office of University Counsel.

II. Industrial Hemp-Related Research

Very recently, the United States Congress passed a new law that allows the cultivation of "industrial hemp," which is "the plant *Cannabis sativa L.* and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis" The law provides that, notwithstanding any other provision of federal law, an institution of higher education may grow or cultivate industrial hemp for "purposes of research conducted under an agricultural pilot program or other agricultural or academic research."

This exception has the potential to allow research on strains of low-THC marijuana, but the framework for conducting this research has not yet been fully determined. Currently, the Colorado Department of Agriculture is advising parties that, notwithstanding the new research exception, "importation of viable industrial hemp seed across State lines and Country boundaries is illegal under the Federal Controlled Substances Act."

Various state and federal agencies are currently attempting to determine the process by which researchers should conduct industrial hemp-related research. At a minimum, for any industrial hemp-related research involving human or animal subjects, a researcher must obtain approval from the appropriate IRB or IACUC. The Colorado Department of Agriculture will also need to inspect and approve any facilities in which industrial hemp is cultivated, grown, or studied. Once those approvals are obtained, the University of Colorado may need to enact additional policies to ensure that research in approved facilities complies with federal law.

Until these processes are designed and agreed upon by the various governmental actors, there is not an approved framework for conducting research on industrial hemp. If you are considering any industrial hemp-related research, please coordinate that research and the necessary applications with the appropriate campus officials and the Office of University Counsel.

III. Private Research Funding

We have recently received questions related to whether researchers may accept research funding from private organizations within an interest in marijuana research. Answering those questions is difficult and depends upon the nature of the organization, the mechanism by which the research is funded, the type of research that might be performed, any potential restrictions upon the publication of the research, and whether the organization wishes to claim any interest in intellectual property derived from the research. If you wish to discuss a particular research funding proposal, please contact the Office of University Counsel.

IV. Limitations Upon Research

We recognize that the current system under which the federal agencies are willing to approve marijuana-related research will limit the types of research that faculty members may legally perform. For example, under the processes that we've described, researchers must obtain marijuana from NIDA approved facilities, and the University of Mississippi is the only currently approved facility. Because the University of Mississippi does not produce the same strains of marijuana that are prevalent in Colorado and used by many Colorado patients, there is not a clear pathway towards conducting potentially valuable research.

V. Seeking Additional Ability to Conduct Marijuana-Related Research

We understand that many researchers are eager to begin research in this area and have expressed your interest to lawmakers and governmental agencies. We will continue to explore mechanisms that will allow you to perform marijuana-related research within the boundaries of the law. We will be seeking guidance on the state and federal processes and will update you as any developments occur

The United States Congress's recent law creating a mechanism for industrial hemp-related research demonstrates that lawmakers are becoming aware of the need for additional research. The United States Department of Justice has also instructed United States Attorneys that they should exercise discretion in initiating marijuana-related civil and criminal actions. Even more recently, federal authorities provided banks with permission to provide financial services to marijuana-related businesses.

Each of these actions had a consistent feature, however, which is that they depended upon the federal government's action. The United States Supreme Court recognized that federal law creates a "closed regulatory scheme" governing controlled substances, and additional avenues for research require federal approval. Until the federal

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government examines and modifies its practices for marijuana-related research, the current laws remain in effect, and noncompliance could have serious consequences.

If you have any questions about this guidance or about marijuana-related research, please do not hesitate to contact University Counsel Patrick O'Rourke at Patrick.orourke@cu.edu or 303-860-5686.