To: University of Colorado Research Faculty

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

Date: March 10, 2014 Revised January 22, 2018

Re: Legality of Marijuana Research

As of September 13, 2017, Colorado is one of twenty-nine states, along with the District of Columbia, that have adopted measures legalizing marijuana use and sale for medical and/or recreational purposes. Beginning with the statewide legalization of marijuana sale and use for medical purposes in 2014, Colorado’s legislative and executive branches have implemented a robust regulatory system for production, processing, sale, and taxation of marijuana, and the Colorado General Assembly has established statewide funds to support marijuana-related research. Colorado has also regulated and established research funds related to industrial hemp pursuant to Section 7606 of the federal Agricultural Act (a/k/a the “Farm Bill”) of 2014.

In light of the rapidly changing regulatory landscape governing marijuana and hemp related research, many faculty members and university research partners have inquired about the university's ability to conduct marijuana-related research. The purpose of this communication is to remind and update members of the university community regarding the current legal parameters surrounding marijuana and hemp-related research, including restrictions on funding of such research.

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. In 2013, 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 (DEA) refusal to change marijuana's classification as a Schedule I controlled substance. More recently, in May 2017 the Tenth Circuit Court of Appeals, which is the federal appellate court that has jurisdiction over federal matters in Colorado, reaffirmed the classification of marijuana as a Schedule I controlled substance and the DEA’s regulatory authority over the manufacture, distribution, and dispensing of marijuana, “[d]espite its legalization in twenty-eight states (and Washington, D.C.) for medical use and in eight states (and Washington, D.C.) for recreational use . . . .” Green Sol. Retail, Inc. v. United States, 855 F.3d 1111, 1113-14 (10th Cir. 2017). As such, it remains illegal under federal law for any person to import, manufacture, distribute, possess, or use marijuana, except as expressly allowed under federal law.

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, we believe that conducting unapproved marijuana-related research could adversely affect the University of Colorado’s ability to seek federal research funding or federal financial aid.
The Controlled Substance Act does include an exception that allows the Food and Drug Administration to approve research using Schedule I controlled substances under strictly limited conditions. 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. Importantly, however, the DEA and FDA operate under a United Nations Treaty known as the Single Convention on Narcotic Drugs, which allows the DEA and the National Institute on Drug Abuse (NIDA) within the National Institutes of Health (NIH) to oversee the cultivation of marijuana for medical research. NIDA contracts with the University of Mississippi for that purpose. And, although the DEA published a policy in August 2016 allowing additional universities or facilities to submit applications to cultivate marijuana for research purposes, the federal government has not approved any new facilities and appears unlikely to do so in the near future.

Other requirements of certain types of research studies include the following:

**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 DEA.
   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 a NIDA 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 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.

These federal approval mechanisms for conducting marijuana-related research are binding on the University of Colorado. Except as discussed below regarding research involving industrial hemp, the processes above 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.¹

II. Industrial Hemp-Related Research

As noted above, the United States Congress passed a law in 2014 that applies to research conducted upon “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 allows research on strains of low-THC. However, because it remains illegal under the Federal Controlled Substances Act to import viable industrial hemp seeds across state lines, industrial hemp research materials must be obtained or cultivated through the Industrial Hemp Regulatory Program implemented by the Colorado Department of Agriculture pursuant Title 35, Article 61 of the Colorado Revised Statutes. At a minimum, any facility that cultivates industrial hemp must be inspected and approved by the Department. Additionally, any industrial hemp-related research involving human or animal subjects will require approval from the appropriate IRB or IACUC.

Further information about the Department of Agriculture industrial hemp programs can be found at:

https://www.colorado.gov/pacific/agplants/industrial-hemp

Any industrial hemp-related research must be coordinated with the relevant campus research compliance office and the Office of University Counsel.

¹ Recently, questions have arisen concerning the impact of House Bill 17-1367, which was enacted by the Colorado General Assembly last year and goes into effect July 1, 2018. HB 17-1367 creates a “marijuana research and development license,” which allows a licensee to “grow, cultivate, possess, and transfer” marijuana to a “medical research facility, including at an institution of higher education,” for certain limited research purposes. The bill also contemplates that such research may “be conducted with a public institution or public money[.]” HB 17-1367 does not alter federal law, which continues to prohibit the University of Colorado from conducting research on Schedule I controlled substances without a DEA registration. Moreover, DEA regulations continue to prohibit federal fund recipients from procuring marijuana for research purposes from ANY source other than the University of Mississippi. Therefore, any state institution of higher education in Colorado that participates in the research program created under HB 17-1367 using marijuana not procured from the University of Mississippi in accordance with a valid DEA license would violate federal law.
III. Seeking Additional Ability to Conduct Marijuana-Related Research

We understand that many researchers are eager to begin research in this area and frustrated by the regulatory limitations. The University of Colorado is one of many voices across the country urging federal lawmakers and regulators to expand cannabis research opportunities, and Congress’ 2014 action related to industrial hemp signifies an increasing awareness at the federal level of the need for additional research. However, cannabis remains a controlled substance for which the federal government retains supreme regulatory jurisdiction and it is not clear that the current administration is interested in relaxing existing regulations.

Together with federal and state lawmakers, we will continue to explore mechanisms that will allow you to perform marijuana-related research within the boundaries of the law. We will continue to pursue guidance and clarity from relevant federal and state agencies and will update you as any developments occur.