

GENERAL COUNSEL'S CORNER

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Cannabis and Research on Campus

Cannabis—also known as marijuana—has been legalized in the last two decades in more than half of the states. Thirty-nine states allow the use of medical marijuana, while 18 states and the District of Columbia permit both medical and recreational marijuana.¹ Despite what would appear to be increasingly lawful access to cannabis, it is still classified by the Controlled Substance Act (CSA) as a Schedule I Controlled Substance,² which means that its possession, sale or use is prohibited by federal law, even in those states whose laws have decriminalized the use of cannabis. Furthermore, colleges and universities are subject to stricter federal restrictions than other organizations, in that cannabis cannot be grown, possessed or used on campuses if the institution receives federal funds.³ Failure to comply with this law risks the removal of federal funding administered by the U.S. Department of Education, including federal student aid funds.

The issue of concern regarding cannabis is the presence of tetrahydrocannabinol (THC), which can produce a “high” sensation and which some research has shown is addictive. Hemp, which is a form of cannabis, contains less than 0.3% THC, and has been removed from the federal schedule of controlled substances. But cannabis containing more than 0.3% THC, called marijuana, is strictly regulated under federal law.

Although the U.S. Food and Drug Administration (FDA) has approved three drugs derived from cannabis for specific medical uses,⁴ it has not approved the use of marijuana for either medicinal or recreational purposes. Therefore, any research involving marijuana must follow federal regulatory guidelines.

Legal Restrictions on Cannabis and the Campus

It may come as a surprise to learn that several colleges and universities around the U.S. offer programs about cannabis production, yet most are not authorized to grow or use cannabis for research purposes. The CSA’s designation of cannabis as a Schedule I drug dictates most, if not all, legal restrictions on the presence and use of marijuana at a college or university. More specifically, the agency charged with enforcing controlled substance laws in the U.S., the Drug Enforcement Administration (DEA), a unit of the U.S. Department of Justice, determines the extent to which marijuana may be used in research. The DEA controls who may grow marijuana, requires licensed growers to sell their product to the DEA,

¹ <https://mjbizdaily.com/map-of-us-marijuana-legalization-by-state/>.

² 21 U.S.C. §812.

³ The Drug-Free Schools and Communities Act Amendments of 1989, Public Law 101-226. Additionally, all persons entering in or on Federal property, recipients of federal funds administered by the U.S. Department of Education, and Federal Contractors at their workplace are prohibited from use or possession Schedule 1 controlled substances. See 41 CFR § 102-74.400; 48 CFR § 52.223-6; 34 CFR § 86.2.

⁴ The FDA has approved one cannabis-derived drug product: Epidiolex (cannabidiol), and three synthetic cannabis-related drug products: Marinol (dronabinol), Syndros (dronabinol), and Cesamet (nabilone). These approved drug products are only available by prescription. <https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process#:~:text=The%20agency%20has%2C%20however%2C%20approved,from%20a%20licensed%20healthcare%20provider.>

and requires organizations that wish to use marijuana for research to purchase the marijuana from the DEA. Although prior to 2020, the University of Mississippi was the only entity permitted to grow marijuana under federal law, the DEA changed its policy in 2020 to allow other growers to produce marijuana for research.⁵

The restrictions on marijuana are a result of the amount of THC it contains. Hemp is also classified as a cannabinoid, but it was removed from the list of controlled substances by the 2018 Agricultural Improvement Act (called the Farm Bill)⁶ because its THC content is below 0.3%. The Farm Bill currently restricts the growing of hemp to states that have established a Hemp Research Pilot Program.⁷ Its cultivation is regulated by the U.S. Department of Agriculture (USDA).⁸

College and university scientists may also be interested in conducting research on hallucinogenics, given the constraints on studying marijuana. Hallucinogenic drugs are growing in popularity as subjects of research based on evidence that they may be useful in treating mental illnesses such as depression and post-traumatic stress disorder (PTSD).⁹ For example, "psilocybin," the active hallucinogenic chemical in "magic mushrooms," belongs to a group of drugs known as psychedelics and is the lead agent in psychedelic research.¹⁰ Although psilocybin may have therapeutic benefits for individuals with mental disorders, psilocybin remains classified by the federal government as a Schedule I drug.¹¹ Due to these drugs' placement in the most restrictive category, laws involving psychedelic drugs such as psilocybin are very strict, and the vast majority of research is funded by private companies.¹² As a result, the federal laws and regulations governing campus research using psychedelic drugs are at least as restrictive as those involving cannabis.

Issues for Researchers on Campus

The FDA regulates research involving cannabis, whether at an institution of higher education, a private research organization, or a pharmaceutical company. The FDA considers cannabis containing more than 0.3% THC to be a regulated drug, and thus requires an individual or an organization wishing to conduct research on cannabis to submit a New Drug Application (NDA) proposing an Investigational New Drug (IND) to the FDA's Center for Drug Evaluation and Research (CDER), just as any other potential drug research would require. According to the FDA, the application includes the following:

An IND includes protocols describing proposed studies, the qualifications of the investigators who will conduct the clinical studies, and assurances of informed consent and protection of the rights, safety, and welfare of the human subjects. The FDA reviews the IND to ensure that the proposed studies, generally referred to as "clinical trials," do not place human subjects at an unreasonable risk of harm. The FDA also requires obtaining the informed consent of

5 https://www.science.org/content/article/dea-verdict-marijuana-research-draws-mixed-reaction?adobe_mc=MCMID%3D38819027563084264761732345099084602206%7CMCORGID%3D242B6472541199F70A4C98A6%2540AdobeOrg%7CTS%3D1655828552&_ga=2.206524759.57986618.1655818519-750665958.1654012576.

6 Public Law 115-334 §§ 10113, 12619.

7 <https://ovpr.uchc.edu/services/rics/research-involving-cannabis-hemp-and-marijuana/>.

8 <https://pharmacy.olemiss.edu/marijuana/faq/>.

9 <https://www.hopkinsmedicine.org/psychiatry/research/psychedelics-research.html>.

10 <https://adf.org.au/drug-facts/psilocybin/#:~:text=Psilocybin%20or%20magic%20mushrooms%20are,in%20magic%20mushrooms%20is%20psilocybin.>

11 https://www.dea.gov/sites/default/files/2020-06/Psilocybin-2020_0.pdf; <https://www.hopkinsmedicine.org/psychiatry/research/psychedelics-research.html>.

12 <https://www.bloomberg.com/news/articles/2021-10-04/seattle-votes-to-decriminalize-psylocybin-and-similar-substances>.

trial subjects and human subject protection in the conduct of the clinical trials. For research intending to develop an animal drug product, researchers would establish an INAD file with the Center for Veterinary Medicine (CVM) to conduct their research, rather than an IND with CDER.¹³

Furthermore, a scientist, whether at an institution of higher education or elsewhere, must obtain a license to conduct research on cannabis from the DEA. The DEA has issued regulations and guidelines for holders of such licenses, who must agree to follow both DEA and FDA regulations.

The DEA license application process requires that the applicant demonstrate that their state has issued them a medical or controlled substance license or registration.¹⁴ The DEA will not issue a license to conduct cannabis research unless the applicant has received such a license or registration, which suggests that research on cannabis cannot be conducted at institutions in those states where cannabis possession or use is still illegal under state law. Cannabis used for research purposes may only be obtained from those sources approved by the DEA, which means that normally a researcher may not accept cannabis for research purposes directly from a grower, but only from the National Institute on Drug Abuse.¹⁵ According to one source, “Under the regulations published in December 2020, and the processes laid out [on the DEA website]¹⁶ DEA will purchase the cannabis from growers and provide it to National Institutes of Health–funded and other researchers, although in some cases growers will supply small amounts directly to labs.”¹⁷

As part of an institution’s strict adherence to federal regulations and guidelines, researchers will need to be vigilant with respect to the storage of cannabis and attendant security concerns. Clearly, the college or university’s office that oversees research regulatory compliance will need to be closely involved in planning for and monitoring cannabis-related research.

For individuals who wish to conduct research independent of their employing college or university, the institution’s conflict of interest and conflict of commitment policies are relevant. Institutions will need to ensure that these policies address both types of possible conflicts, particularly if a faculty or staff member decides to work with a cannabis producer or dispenser in a “consulting” role. Institutions will need to require employees (and students) to state to the outside entity that they are engaged in these activities as a private citizen and not as an institutional employee or student. Institutions should also make it clear to their employees and students that cannabis-related work, whether compensated or not, is outside the scope of their employment or enrollment and could subject these individuals to criminal penalties even in states where cannabis possession is now legal for both medical and recreational purposes.

Implications and Suggestions

By now it must be obvious that engaging in cannabis-related research—whether on or off campus—is difficult, complicated and risky. For a college or university, the penalties for violating federal laws, especially those directly related to the receipt of federal funds, are serious, and could have adverse budgetary consequences, as well as public relations repercussions. Given the current size of the

13 <https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process>.

14 <https://apps.dea.diversion.usdoj.gov/webforms2/spring/main?execution=e1s1>.

15 <https://www.science.org/content/article/us-set-allow-more-facilities-produce-marijuana-research>. See also <https://nida.nih.gov/research-topics/marijuana/nidas-role-in-providing-cannabis-research>.

16 <https://www.dea.gov/stories/2021/2021-05/2021-05-14/dea-continues-prioritize-efforts-expand-access-marijuana-research>.

17 <https://www.science.org/content/article/us-set-allow-more-facilities-produce-marijuana-research>.

cannabis industry and its projected growth,¹⁸ members of the cannabis industry may be eager to engage institutional researchers in studies of its effectiveness and safety, and these pressures may be difficult to resist. Nevertheless, until and unless federal law changes, especially those directly aimed at higher education, counsel should be wary of allowing cannabis research on campus.

¹⁸ One source estimates that global cannabis sales will reach \$33.6 billion by 2025. <https://www.investopedia.com/biggest-challenges-for-the-cannabis-industry-in-2019-4583874#:~:text=The%20legalization%20and%20sale%20of,to%20%2433.6%20billion%20by%202025>.



General Counsel's Corner is a publication presented by one of Bond's former general counsels and academic administrators of higher education institutions: [Monica Barrett](#) (Rutgers); [Sandra Casey](#) (SUNY and Siena College); [Shelley Sanders Kehl](#) (Pratt Institute); [Barbara Lee](#) (SVP for Academic Affairs at Rutgers); [Sarah Luke](#) (Governors State University); [Gail Norris](#) (University of Rochester); and [Jane Sovern](#) (CUNY). In each issue, a different attorney from this team will share with you recent legal developments, tips, strategies and useful information to assist you with your daily work on campus.

This post is brought to you by [Barbara A. Lee, Ph.D.](#) and Camisha Parkins in our New York City office. Barbara previously served as Senior Vice President for Academic Affairs at Rutgers University where she continues on as a Distinguished Professor of Human Resource Management. She is a former director for the National Association of College and University Attorneys (NACUA), and a prolific author, speaker and editor. Barbara is also the former chair of the New Jersey Bar Association's Higher Education Committee. Camisha is a current Summer Law Clerk and assisted in co-authoring this article.

