



Cannabis Research in California - Legal Status and Issues



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LEGAL LANDSCAPE

- **Despite legalization in CA and many other states, most use, possession, distribution, and cultivation remains ILLEGAL (Criminal) under Federal Law.**
- **Research can be done, but there are limitations and restrictions, making it important for researchers and research administrators to be aware of the legal landscape and of the need to comply with both Federal and State law.**



LEGAL LANDSCAPE

- **This is an evolving area:**
 - **Uncertainty RE: Current Administration's Approach to Enforcement;**
 - **Pending Legislative and Regulatory Reform Proposals;**
 - **Some "Gray" Areas (particularly given inconsistencies between state and federal law)**
- **When in doubt, consult campus counsel/OGC. Other resources: Controlled Substances Program coordinators; RPAC**
<https://www.ucop.edu/research-policy-analysis-coordination/>.



LEGAL LANDSCAPE: FEDERAL LAW

- **Most Possession, Use, Cultivation, Distribution, etc. is Still Illegal under Federal Law (notwithstanding state law)**
 - **Controlled Substances Act of 1970 - Marijuana regulated under Schedule I (like heroin!) – for drugs with high abuse potential; no currently accepted medical use; lack of accepted safety for use under medical supervision**
 - **Safe and Drug-Free Schools and Communities Act**
 - **Drug-Free Workplace Act**



LEGAL LANDSCAPE: FEDERAL LAW

- **Limited Exceptions:**
 - **Research conducted under a Schedule I license from DEA**, using product obtained via NIDA process (*not ideal for all research*), in compliance with applicable DEA, FDA rules (*approvals not quick or easy to obtain*)



LEGAL LANDSCAPE: FEDERAL LAW

- **Limited Exceptions:**
 - **Industrial Hemp: Fed'l Ag. Approp. Bill, Section 7606 –Allows (only) institutions of higher ed (and state Depts. Of Ag under a “pilot program”) to grow cannabis i.e., industrial hemp with low THC (delta-9 tetrahydrocannabinol) concentration of not more than 0.3 percent on a dry weight basis for agricultural research.**
 - **DEA license may still be needed to import the hemp seed or cultivars to be used.**



LEGAL LANDSCAPE: FEDERAL LAW

- **Agencies Involved in Regulation:**
 - **Drug Enforcement Agency** – enforcement of CSA. Oversees PI registration and site licensure to conduct studies w/marijuana
 - **NIDA/NIH** -- supports scientific research; designated by DEA as single source of marijuana
 - **FDA** – scientific assessment used for scheduling; regulates research on potential therapeutic uses; enforcement re products containing MJ compounds (health risks; illegal claims in labeling).



LEGAL LANDSCAPE: FEDERAL LAW

- **8/12/2016 DEA Fed. Reg. Notice – new policy inviting applications from other entities that wish to become registered under CSA to grow (manufacture) marijuana to supply legitimate researchers. (DEA Form 225; at least 26 apps pending, no Fed'l action yet.**
- **Consolidated Approps. Act of 2017 – Congress said none of the funds made available to DOJ may be used to prevent states (including CA) from “implementing their own laws authorizing use, distribution, possession or cultivation of medical marijuana.”**
 - However, it was reported that “President Donald Trump signaled he may ignore a congressional ban on interfering with state medical marijuana laws, arguing in a lengthy signing statement that he isn’t legally bound by a series of limits lawmakers imposed on him.”



LEGAL LANDSCAPE: CA STATE LAW

- Medicinal marijuana -- legal under CA law since 1996 (via Prop 215)
- Industrial hemp – legal under CA law (SB 566, 2013).
 - Commercial growers must register with county ag commissioner before cultivation.
 - Registration is not yet available. Registration requirement does not apply to “established agricultural research institutions” (like UC).



LEGAL LANDSCAPE: CA STATE LAW

State regulations currently under development:

- **Bureau of Cannabis Control – the lead agency**
- **Dept. Food & Agriculture- cultivation licensing, tracking – tracing systems**
- **Dept. of Public Health -licensing of manufacturers of cannabis products**



Federal Government Marijuana

- All federal marijuana is grown at a single facility at the University of Mississippi, overseen by the National Institute on Drug Abuse (NIDA). The plants grown there maxes out at about 13% THC. However testing found that one of NIDA's strains purported to be 13 percent THC was actually closer to 8 percent.
- In comparison, the average commercial weed available in Colorado is at about 19 percent THC with some strains reaching 30%THC and more according to the laboratory that tests commercial marijuana in Colorado.
- Additionally NIDA marijuana is not even tested for some common contaminants, like yeast and mold, that many states now check for as part of their regulatory regimes.



Commercial vs. Fed'l Government Marijuana



Photos via Oliver Contreras/Washington Post (left) and MAPS (right) 2017. 03.13

- Federal restriction prohibiting researchers from using anything other than federally-supplied marijuana makes it difficult or impossible to reliably conduct certain studies seeking to assess medical efficacy and/or health effects of marijuana that is actually in use in “real-world” environments



LEGAL RISKS/CONSIDERATIONS FOR DIFFERENT RESEARCH

- **Research that involves researcher/UC possession/distribution/cultivation of Marijuana**
 - **Requires compliance with applicable DEA, FDA, NIDA rules (including rules restricting source of marijuana)**
 - **Requires Research Advisory Panel of California (RAPC) application and approval**
 - **Requires Schedule I DEA license**
 - **Requires DEA site visit**

Note -there is debate about federal classification of certain substances (cannabidiols CBDs , cannabis extracts and oils) – DEA’s position is they are Schedule I if they come from cannabis

LEGAL RISKS/CONSIDERATIONS FOR DIFFERENT RESEARCH

- **Academic or agricultural research that involves researcher/UC possession/distribution/cultivation of industrial hemp (non-psychoactive, less than 0.3% THC)**
 - Permissible without Schedule I DEA license (though a DEA license may be needed to import/obtain the seeds/plants)
 - State Industrial Hemp IH registration program not yet effective (but there is an exemption for “established agricultural research institutions, a term that includes UC, so UC need not wait).
 - Considerations: Testing for THC content (and plan for destruction if limit is exceeded?); security

LEGAL RISKS/CONSIDERATIONS FOR DIFFERENT RESEARCH

- **Purely observational research, that does not involve researcher/UC possession, etc. (e.g., observing/interviewing patients at a dispensary)**
 - No DEA license needed
 - Considerations: Human subjects protection; avoidance of potential “**inducement**” issues

LEGAL RISKS/CONSIDERATIONS: PARTNERING WITH THE CANNABIS INDUSTRY

- **POTENTIAL ISSUES:**
- **Source of funding: Money Laundering? (Due diligence re: source of funds?)**
- **Aiding and Abetting violations of Controlled Substances Act or Money Laundering? Conspiracy?**
- **IP Issues? Accepting royalties; patent protection.**
- **Optics: Note that public perception and public policy concerns exist on both sides (UC aiding and abetting violations of the Controlled Substances Act vs. UC declining to lend its considerable research expertise to an area that has significant potential to advance public health/welfare)**

Resources

- **UC Guidance on Use and Possession of Marijuana on UC Property**
 - <http://www.ucop.edu/marijuana-and-drug-policy/>
 - UC prohibits the use, possession and sale of marijuana in any form on all university property, including university-owned and leased buildings, housing and parking lots. Marijuana is also not permitted at university events or while conducting university business
 - Academic research involving marijuana may be conducted at UC to the extent authorized under both federal and state law; must be conducted in compliance with all applicable regulations and policies, including but not limited to federal registration and licensing requirements administered by the U.S. DEA and applicable to research use of controlled substances.
 - Includes links to other policies/laws: UC Policy on Controlled Substances, UC Policy Against Substance Abuse, UC Smoke and Tobacco Free Policy, the U.S. Safe and Drug-Free Schools and Communities Act, and the U.S. Drug-Free Workplace Act



Resources

- **RPAC Memo 17-01: Information for Researchers on the Effect of Prop 64 on Marijuana Research at UC**
 - <http://researchmemos.ucop.edu/php-app/index.php/site/document?memo=UIBBQy0xNy0wMQ==&doc=3663>
- Among other things, requires that **“Before applying for and before accepting research funding that comes directly from individuals or entities (e.g., companies, associations) whose funding is derived from the marijuana industry (for example, from a professional association of marijuana growers legally licensed in the state of California) campuses must contact the UC Office of the President’s Research and Graduate Studies Office, which may seek advice from the Office of General Counsel as needed. In evaluating requests to accept funding from such sources, a significant consideration is the need to comply with applicable money laundering laws and laws re: aiding/abetting illegal activities.”**





Questions?