



SRA INTERNATIONAL
ANNUAL MEETING
SEATTLE 2023
OCTOBER 14-18

Cannabis Research & the Regulatory Landscape

SRAI Presentation
October 18, 2023

Who We Are

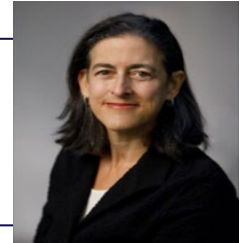


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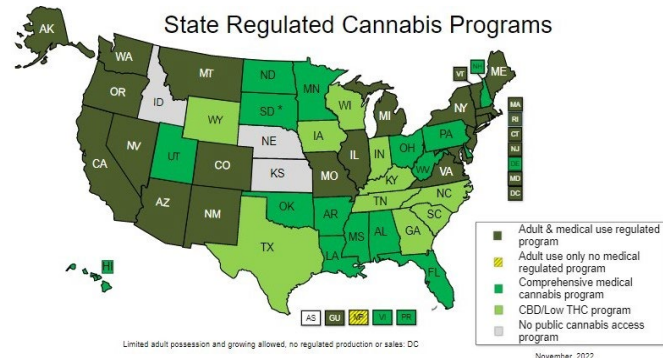


Presentation Objectives

1. Describe the laws and regulations in place for researchers conducting cannabis research;
2. Share strategies considered by the University of California to support cannabis research; and
3. Foster collaboration among and problem solve with other university researchers and research administrators facing similar issues.

Current Regulatory Landscape

- Despite state legalization, most marijuana use, possession, distribution, cultivation remains **illegal** under the federal Controlled Substances Act (CSA).
- Marijuana is *currently* classified as a Schedule I drug by DEA (i.e., no currently accepted medical use and high abuse potential).
- The Agricultural Improvement Act of 2018 (i.e., 2018 Farm Bill) amended the CSA to exclude hemp (i.e., cannabis with $\leq 0.3\%$ THC) and hemp derivatives from the definition of “marihuana,” thus removing them from regulation as Controlled Substances.



* = Measures approved by voters in Mississippi for medical use and South Dakota for non medical use were overturned in 2021. The Mississippi legislature passed new medical cannabis legislation which the governor signed on Feb. 2, 2022.

Source: Chart from the National Conference of State Legislatures (NCSL), November 9, 2022. <https://www.ncsl.org/health/state-medical-cannabis-laws#undefined>. **Note that since the chart was published, DE and MN moved to join other states with legalized adult & medical use regulated programs.**

Current Regulatory Landscape

- Although most marijuana use, possession, distribution, cultivation remains illegal under federal law, there are limited exceptions that do allow for certain research activities:
 - ✓ **Research conducted under a Schedule I DEA Registration** (must comply with regs re: record-keeping, inspections, security, limitations on sources)
 - ✓ **Research with parts of the marijuana plant that are excluded from the definition of marijuana** (e.g., mature stalks)
 - ✓ **Research that doesn't involve use/ possession/ contact with marijuana** (e.g., studies of self-reported data; certain observational studies)
 - ✓ **Research with "hemp"** (i.e., low-THC cannabis), which is excluded from the definition of marijuana
- Failure to comply with federal legal requirements puts institutions at risk of criminal and civil penalties, loss of federal funding, and jeopardizes existing DEA licenses.

Current Regulatory Landscape

What about research with marijuana extracts, derivatives, cannabinoids (e.g., CBD)?



➤ Schedule I req'ts may apply unless substance qualifies as “hemp.” Considerations include:

- **THC content.** If $>0.3\%$ THC, Schedule I applies, regardless of source. For substances with $\leq 0.3\%$ THC, consider:
 - *Non-hemp-derived synthetic cannabinoids:* not covered by “hemp” exclusion: Schedule I requirements apply.
 - *Derived from Hemp plant:* qualifies as hemp. Not controlled (unless containing $>0.3\%$ THC).
 - *From Marijuana plant:* may/ may not qualify as hemp.

Current Regulatory Landscape: Federal Limitation on Sources of Research Marijuana

Marijuana used in research must be from one of the following federally-approved sources:

NIDA (National
Institute on Drug
Abuse)

Other DEA-
approved
manufacturers*

FDA-approved
drugs (e.g.,
Marinol, Syndros,
Epidiolex)

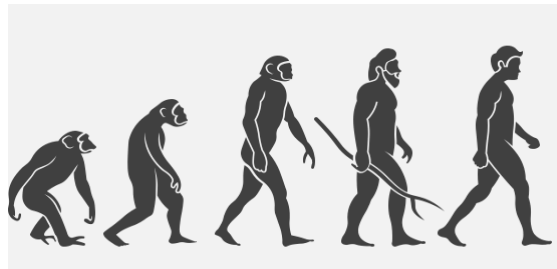
Import from
abroad under a
DEA import
license



Currently, it is NOT permissible to conduct research using marijuana from state dispensaries or other domestic sources not on the DEA-approved list.

* DEA-approved bulk manufacturer marijuana growers are listed at <https://www.deadiversion.usdoj.gov/drugreg/marihuana.htm>. Currently includes: Biopharmaceutical Research Co. LLC, Bright Green Corp., Groff NA Hemplex LLC, Irvin Labs, Inc., Maridose LLC, National Center for Development of Natural Products, Royal Emerald Pharmaceuticals R&D, and Scottsdale Research Institute.

Evolving Regulatory Landscape



LEGISLATION:

Medical Marijuana and CBD Research

Expansion Act (H.R. 8454), signed into law 12/2/22

- First standalone cannabis reform bill to pass both houses; seen as helpful evolution in federal policy re: medical marijuana research.
- *BUT:* While it included streamlining provisions to facilitate research, it was not a sea change (e.g., researchers still can't work with "real world" marijuana from state dispensaries).

RE-SCHEDULING PROPOSAL: On 8/29/23, HHS recommended DOJ move marijuana and its derivatives from Schedule I to Schedule III.

- Under the CSA, it is up to the Attorney General to decide on re-scheduling. Look for Federal Register notice before end of 2023.



If re-scheduling occurs, it likely will lead to increased access/ reduced barriers for research.

Other considerations regarding conducting marijuana research



- Obtaining proper reviews/approvals prior to conducting research, including:
 - DEA (securing and maintaining a Schedule I registration)
 - FDA (Investigational New Drug Application for clinical/ drug research; note that even hemp research may require an IND if human/ animal studies are involved)
 - National Institute of Drug Abuse (NIDA)
 - State review requirements (e.g., RAPC in California)
 - Local institutional requirements:
 - IRB/ IACUC review, for human and animal studies
 - Compliance with local controlled substance policies
- Storage, record-keeping, inspection, security requirements
- Contracting/funding issues

Federal Funding for Cannabis Research

NIH Funding for Cannabis Research

Research Areas	FY 2019 Actual	FY 2020 Actual	FY 2021 Actual	FY 2022 Actual	FY 2023 Estimated	FY 2024 Estimated
	(Dollars in millions and rounded)					
Cannabidiol Research	\$31	\$29	\$36	\$43	\$45	\$45
Cannabinoid Research	\$189	\$184	\$198	\$202	\$210	\$212
Endocannabinoid System Research	\$73	\$71	\$70	\$75	\$77	\$79
Therapeutic Cannabinoid Research	\$46	\$54	\$65	\$70	\$73	\$74
Total	\$339	\$338	\$369	\$390	\$405	\$404

Funding from the Marijuana Industry

- Because the marijuana industry is engaged in activities that are criminally prohibited under federal law, there are concerns about accepting funding from this industry:
 - Aiding and abetting
 - Money laundering
 - Reputational risks of working with an illegal industry
 - Loss/ forfeiture of federal funding

What's UC Doing?

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THE PRESIDENT
Street, 11th Floor
formia 94607-5200

7, 2018

and Adult-Use
Section 26000

Uttam D

For nearly fifty years, researchers located at the University of California have been studying the negative impacts of drug abuse (NIDA). At a meeting in 2019, we discussed the negative impacts of drug abuse and how to enhance research to finalize a timely report on the purposes.

April 19, 2018

Senate Majority Leader Mitch McConnell
S-230, The Capitol
Washington, DC 20510

Senate Minority Leader Charles Schumer
S-221, The Capitol
Washington, DC 20510

House Speaker Paul Ryan
H-232, The Capitol
Washington, DC 20515

House Minority Leader Nancy Pelosi
H-204, The Capitol
Washington, DC 20515

Dear Leader McConnell, Leader Schumer, Speaker Ryan and Leader Pelosi:

Funding from the Marijuana Industry

- **RPAC Guidance Memo 18-01:** Before applying for and before accepting non-governmental research funding, whether through a grant or a gift, that comes from individuals or entities whose funding is known to be derived from marijuana activities that appear to fall outside of what is permitted under federal law, researchers must consult with their respective campus Contracts and Grants/Sponsored Programs Office or external relations/development office, who in turn must contact the UCOP's RPAC office.

Marijuana Industry Tiers

1

Non-governmental entities or individuals that appear to directly derive all or most of their funding from conducting marijuana-related activities that are illegal under federal law.

2

Non-governmental entities or individuals that appear to derive their funding from multiple income streams, where one such source of funding is directly from conducting marijuana-related activities that are illegal under federal law.

3

Non-governmental entities or individuals indirectly tied to the marijuana industry, such as a company that derives its profit from providing services to entities conducting illegal activities under federal law.

UC Pilot Approach when Considering Funding from the Marijuana Industry

1

UC may not accept donations, grants or other funding from entities or individuals known to directly derive most or all of their funding from conducting marijuana-related activities that are illegal under federal law.

2

UC campuses must conduct due diligence and obtain written assurance that the funds provided to UC are not derived from activities that are illegal under federal law, including that the funds are not derived from the sale, distribution, or cultivation of marijuana.

3

UC campuses may conduct due diligence and obtain written assurance that the funds provided to UC are not derived from activities that are illegal under federal law.

Open Discussion

What approach are others taking in supporting their cannabis researchers?

THANK YOU!

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