A UC Perspective on Regulatory Barriers to Cannabis Research

Agnes Balla, Research Policy Manager, University of California Office of the President
UC System

- 10 Campuses
- 5 Medical Centers
- 3 National Labs
  - Lawrence Berkeley
  - Lawrence Livermore
  - Los Alamos
- Agriculture and Natural Resources
Research Policy Analysis and Coordination, UC Office of the President

RPAC Provides Expertise and Assistance Across a Broad Range of Issues:

- Animal Research
- Biodiversity/Genetic Resources
- California Institute for Regenerative Medicine (CIRM)
- Cannabis Research
- Citizenship Restrictions
- Clinical Trials
- Conflict of Interest
- Copyright
- Data Rights
- Export Control Regulations
- Federally Sponsored Research
- Gifts and Grants Classification
- HIPAA in Research Agreements
- Human Subjects/Institutional Review Boards
- Indirect Cost Policy
- Industry Sponsored Research
- Intellectual Property (IP)
- IP Issues in Global Health Access
- International Research Collaborations
- Legislation
- Material Transfer Agreements
- Multi-campus Research
- Native American Graves Protection and Repatriation Act National Laboratory/Campus Awards
- Non-profit Sponsored Research
- Publication Restrictions
- State-sponsored Research
- Tax Exempt Bonds: Intellectual Property
- UCOP Contracts & Grants Administration
Overview

1. Current Federal Regulatory Landscape
   • Challenges with Conducting Schedule I Research
   • Concerns over Funding from the Marijuana Industry

2. What’s UC Doing?
   • Impressive Research!
   • RPAC’s efforts
Current Regulatory Landscape

- Despite state legalization, most marijuana use, possession, distribution, cultivation remains categorized as a Schedule I drug by the federal DEA under the Controlled Substances Act (CSA).

- CSA does not permit the use, production, processing, sale or growth of marijuana, except under limited circumstances:
  - Research conducted under Schedule I DEA Registration

Challenges with Conducting Schedule I Research

- Obtaining proper approvals prior to conducting research:
  - DEA
  - Food and Drug Administration (FDA)
  - National Institute of Drug Abuse (NIDA)
  - State requirements (e.g., RAPC in California)
  - Local review (e.g., IRB/IACUC)

- Securing and maintaining a Schedule I Registration

- Using federally-approved marijuana in research
### Challenges with Conducting Schedule I Research: Funding

#### NIH Funding for Cannabis Research

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(Dollars in millions and rounded)

Source: https://report.nih.gov/categorical_spending.aspx
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 is UC Doing?
Dear Leader McConnell, Leader Schumer, Speaker Ryan and Leader Pelosi:

April 19, 2018

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

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

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

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

For nearly fifty years, the National Institute on Drug Abuse (NIDA) has been leading and supporting research into the causes, consequences, and cures of drug abuse problems. A strong and effective voice in Congress, meeting the 2019 goals of increasing funding, expanding research, enhancing research, and reducing the negative impacts and stigma associated with drug abuse, is critical.

As you finalize a timely reauthorization of the 21st Century Cures Act (Public Law 114-255) for 2019 and 2020, we encourage the renewal of the Patient-Centered Outcomes Research Institute (PCORI) and the implementation of the Bono Family Veterans Alcohol Abuse and Mental Health Act.

Thank you for your leadership, and we look forward to working with you to ensure robust funding, increased resources, and improved policies to address this crisis. We look forward to working with you to ensure robust funding, increased resources, and improved policies to address this crisis.
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.
Proposed 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.
Thank You!

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