2017 to 2018: What’s New with the “Legal” Status of Cannabis?
A Review of Changes at the Federal Level
12:30-1:45 PM
HSB 111
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Today’s Focus

• Federal Law – what has happened since last year.
• Regulatory Issues that can impact cannabis research and use.
• An introduction to sponsoring cannabis research at a university.
The number of states with some form of “legal” cannabis is continuing to grow.
Gonzales v. Raich,
545 U.S. 1 (2005)
Supreme Court finds that Federal Drug Laws trump State Laws.

- California passed medical marijuana law.
- Two residents who used doctor-recommended marijuana had their plants destroyed by DEA.
- At the Supreme Court, the Controlled Substances Act prevailed over California’s medical marijuana law based on the Commerce Clause of the Constitution.
- WHY? Local activities can have a substantial effect on interstate commerce, if taken in the aggregate.
What did or did not change over the last year?

• Rescheduling high THC cannabis efforts failed but we are closing in on possible rescheduling for low THC cannabis (aka Industrial Hemp).

• Attorney General retracted the previously issued enforcement guidance – The Cole Memo – that had suggested that operating in compliance with State law reduced risk of Federal prosecution but there is some indication that the President will be taking steps to have something similar reinstated.

• Congress continued the defunding of enforcement of the CSA against state medical marijuana and hemp program participants.

• The DOJ “may” have scheduled CBDs.
Rescheduling High THC Cannabis?

A number of efforts were made since 1972 to reschedule high THC cannabis -- these have all failed.

In 2017, at least two pieces of legislation were proposed to move high THC cannabis to Schedule II or Schedule III. These failed.

On July 24, 2017, a lawsuit was filed against the Justice Department arguing that the Controlled Substances Act had “wrongfully and unconstitutionally criminalized the cultivation, distribution, sale, and possession of Cannabis….” The suit was dismissed by the judge in February of 2018 based on the failure of the plaintiffs to first petition the DEA to ask for a re-scheduling.

Not clear if they bothered as such petitions are frequently filed and always rejected.
Congress Steps In

The Farr-Rohrabacher Amendment

- In the Continuing Appropriations Acts of 2015 and 2016, Congress precluded the Department of Justice from using federal funds to “...prevent [states with medical marijuana laws] from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.”
- Similar legislation exists for Hemp.
- This measure, now called Rohrabacher-Blumenauer, was continued in the most recent budget but must be reapproved each year.
But that does not limit the ability of state and local law enforcement to make arrests - and they continue to do so.

If the funding is restored in the future, the federal government will be able to go back and prosecute cases up to five years after they occurred.

Federal Courts can still restrict the use of medical marijuana as a condition of probation or as a condition of receiving other federal benefits.
What’s up with Hemp and CBD

• Prior to 2014, the courts had held that the DEA had no authority to regulate: “…the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.”

• These were considered “non-psychoactive hemp” which are excluded from the definition of marijuana by Congress.
The Farm Bill, 2014

- This bill in effect expanded the prior “non-psychoactive hemp” definition to include viable seed.
- The DEA has taken the position that these seeds may only be procured by state departments of agriculture under a modified schedule one despite pretty clear language to the contrary in the bill.
- Despite this, the State of Colorado Department of Agriculture, has done a good job of navigating through this confusing and ever changing regulatory environment.
The DEA Tries Again

- December, 2016, the DEA issues a Federal Register notice that it was scheduling “Marihuana Extract”

(58) Marihuana Extract—(7350)
Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant.
Hemp Industries Association v. DEA

Hemp Industries Association and two other plaintiffs sued the DEA challenging the creation of a new drug code for marijuana extracts which appeared to “schedule” materials that could have been exempt as Industrial Hemp.

Initially the DEA argued that this did not represent a substantive change but merely the creation of a new drug code to help schedule 1 holders report their use of these materials.
The Amicus Brief

In January, a group of Members of Congress who had sponsored the Farm Bill filed a brief in support of the Plaintiffs in the Hemp Industries case.

While not binding guidance as an amicus brief, it does provide insight into how they had intended the Farm Bill to be interpreted and implemented – much more liberally than the DEA was suggesting.

The Members of Congress were very dismissive of the DEA’s conclusion that cannabinoids only come from the high THC portions of the plant.
The Hemp Farming Act of 2018
(AKA Sessions gets shot down)

• Introduced by McConnell on April 12, 2018 and is being fast-tracked through the Senate with bi-partisan support.

• Recognizes Hemp as an agricultural commodity which makes crop insurance available, stops any interference with interstate commerce of Hemp and removes Hemp from the CSA which protects growers from criminal enforcement actions and from having their water stopped by the Army Corps.

• Repeals the Farm Bill/7606 one year after Act takes effect.
My Favorite Part

(1) HEMP.—The term ‘hemp’ means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.
This Time it’s the Justice Department

In 2013, US Attorney General James Cole issued guidance to all US attorneys in the DOJ establishing enforcement priorities with respect to state authorized cannabis operations.

It suggested that federal resources not be focused on operations that were in compliance with state cannabis laws.

We all saw this as a signal that if you operated within state guidelines, you were probably safe from arrest and prosecution under Federal law.
Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE
Thursday, January 4, 2018

Justice Department Issues Memo on Marijuana Enforcement

The Department of Justice today issued a memo on federal marijuana enforcement policy announcing a return to the rule of law and the rescission of previous guidance documents. Since the passage of the Controlled Substances Act (CSA) in 1970, Congress has generally prohibited the cultivation, distribution, and possession of marijuana.
Sessions has another bad day

“Late Wednesday, I received a commitment from the President that the Department of Justice’s rescission of the Cole memo will not impact Colorado’s legal marijuana industry. Furthermore, President Trump has assured me that he will support a federalism-based legislative solution to fix this states’ rights issue once and for all.“

Press Release, 4/13/18
Office of Senator Cory Gardner (R-CO)
April 9, 2018
Food and Drug Administration

• Published a notice in the Federal Register seeking comments “concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of five drug substances.”

• Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol; Stereoisomers of Tetrahydrocannabinol; and Cannabidiol.

• Purpose is to prepare responses to WHO Questionnaire on recommending control or decontrol of these substances in an updated Convention on Psychotropic Substances.
WHAT COULD IT MEAN?

I think the possible benefit from this is that studies in the US show that scientific evidence plays a limited role in the development of our medical cannabis policies and that politics is the big driver.

If the WHO recommends easing controls on medical marijuana use – which most states and many countries have done – this would provide some “independent” assessment which might help US law makers and regulators reach similar conclusions.
On the Horizon

• New Psychoactive Substances – aka synthetic marijuana/cannabinoids – (NPS):
  • Increasing focus on those by Feds and others
  • No medical benefit high abuse potential
  • Enforcement is difficult because chemical components are often legal and if become regulated can be swapped out with another.
• FDA approval of GW Pharma cannabis derived CBD oral solution developed in England as an antiepileptic drug would have a significant impact on scheduling discussions.
and, lots of proposed new legislation...

- **Better Drive Act**: HR 1952
- **Ending Federal Marijuana Prohibition Act of 2017**: HR 1227
- **Marijuana Revenue and Regulation Act**: HR 1823
- **Regulate Marijuana Like Alcohol Act**: HR 1841
- **Respect State Marijuana Laws Act**: HR 975
- **SAFE Act of 2017**: HR 2215
- **Small Business Tax Equity Act of 2017**: HR 1810
- **Veterans Equal Access Act**: HR 1820
- **Etc.**
Regulatory Issues

Image credit: https://www.rollingstone.com/politics/news/why-the-gop-is-pushing-for-medical-marijuana-research-w504976
How did we get here?

Hidden in a locked room on New York University's campus in lower Manhattan, a half-tonne steel safe guards hundreds of vials of a drug extracted from marijuana. To the US government, the drug — Epidiolex — is one of the world's most dangerous substances, ripe for abuse. But to Orrin Devinsky, a neurologist at the university, it is a potential treatment for tremors in children with severe epilepsy.

Federal red tape ties up marijuana research

Despite drug's legalization in two US states, biomedical science faces continued restrictions.

Helen Shen
25 March 2014

Image credit: https://www.rollingstone.com/politics/news/why-the-gop-is-pushing-for-medical-marijuana-research-w504976
Regulatory Issues
Regulatory Issues

• **IRB**
  - Most research is observational, which is *de facto* in the absence of a Schedule 1
  - Some examples:
    - MS studies based on self-administration of marijuana
    - Supply chain studies
    - Student use of cannabis (survey research)
    - College student perceptions, legal marijuana, state tourism

• **IACUC**
  - Studies evaluating the impact of CBD products on canine health
    - Treated as a supplement
      - Not intended to prevent, treat, or cure a disease

• **IBC**
  - ???
Regulatory Issues

• But, this doesn’t capture all research or activities within the University.

• How can we facilitate related research and ensure adherence to all laws and regulations?

• Cannabis and hemp research presents new challenges to research oversight professionals
Regulatory Issues

HEMP & MARIJUANA RESEARCH FREQUENTLY ASKED QUESTIONS & GUIDELINES

Within the Controlled Substances Act, there is no current legal delineation between marijuana and hemp – it all falls within the act’s definition of *Cannabis sativa*. The Controlled Substances Act criminalizes the possession, growing and use of *Cannabis sativa* without registration with the Drug Enforcement Administration for a schedule 1 controlled substance. It is also a federal crime for any individual to assist others to violate federal law. This means that if a CSU employee provides advice, which promotes in some way a violation of law, that itself can constitute a violation of law.

That said, the 2014 USDA Farm Bill did contain language providing for cultivation for research purposes of industrial hemp by universities in states that allow cultivation. Colorado has legislation permitting the research and commercial growth of industrial hemp, but requires written registration with the Colorado...
Cannabis and Hemp Research Advisory Committee

Background

• The Cannabis and Hemp Research Advisory Committee (CHRAC) began as a task force
  o Initial planning meeting on May 23, 2017
  o Understand the scope and breadth of related research conducted in affiliation with or under the auspices of CSU
  o No centralized mechanism for understanding these streams of research
    • Not all studies are funded (no OSP involvement); not all studies rely on compliance review for HS, animals, or biosafety concerns
Cannabis and Hemp Research Advisory Committee

Background

- July 2017—Task force transitions to a standing committee

  - Membership is comprised of representatives from across CSU, including administrative, faculty, and community representatives

    - OGC, RICRO, OSP, Risk and Public Safety, Psychology, Health and Exercise Science, Public Affairs, EHS, CSU-Pueblo, OVPR
Mission

- Advise the research community on the complex and rapidly evolving regulatory environment surrounding cannabis and hemp research
  - Facilitation is via an opt-in mechanism for researchers
  - The committee discusses the legal and regulatory issues governing C/H research and relays necessary information to PI(s)
  - Serves as an advisory committee where PI(s) can obtain study-specific guidance
Cannabis and Hemp Research Advisory Committee

Activities

- CSU “Hemp and Marijuana FAQ”
- Developing “information clearing house” website for researchers
  - Will include form for PI(s) to enter their information to be included in database for information dissemination
  - Be available to anyone with an eID
    - Encourage collaboration
  - Include upcoming events for interested parties (e.g., Institute for Cannabis Research annual conference)
- 4 CSU members included among COGR’s Cannabis and Hemp committee
Partnering with a Research University- What to Expect

- Institutions of Higher Education (IHE’s) are large, diverse, and complex organizations with many different touch points and ways to access their broad capabilities.

- To the outside observer is will not always be obvious who to contact and/or where to start a partnership.

- Be prepared to get conflicting information depending on who you are talking to.
  - Faculty member vs. Vice President.

- Most IHE’s have a Industry Liaison Officer, or equivalent to help guide you
  - Start there.
  - At CSU that person is currently me*…

*…
## CSU Interactions with Industry

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<th>Services</th>
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### Colleges, Departments and PI’s

1. **Grad School**
2. **Office of Research**
3. **B&F**
4. **Business & Finance**
5. **Technology Transfer**
6. **Engagement & Outreach**
7. **Advancement / Foundation**
8. **International Programs**

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Farm Bill of 2014

7 U.S. Code § 5940 - Legitimacy of industrial hemp research

(a) In general Notwithstanding the Controlled Substances Act (21 U.S.C. 801 et seq.), chapter 81 of title 41, or any other Federal law, an institution of higher education (as defined in section 1001 of title 20) or a State department of agriculture may grow or cultivate industrial hemp if—

(1) the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and

(2) the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or State department of agriculture is located and such research occurs.

(b) Definitions In this section:

(1) Agricultural pilot program The term “agricultural pilot program” means a pilot program to study the growth, cultivation, or marketing of industrial hemp—

(A) in States that permit the growth or cultivation of industrial hemp under the laws of the State; and

(B) in a manner that—

(i) ensures that only institutions of higher education and State departments of agriculture are used to grow or cultivate industrial hemp;

(ii) requires that sites used for growing or cultivating industrial hemp in a State be certified by, and registered with, the State department of agriculture; and

(iii) authorizes State departments of agriculture to promulgate regulations to carry out the pilot program in the States in accordance with the purposes of this section.
Why should I care?

• Provided the other tests of Section 7606 of the Farm Bill are met.
  o Having a research agreement in place with an IHE, currently helps provide a safe harbor for the growing / cultivation of Industrial Hemp.
  o Having ongoing R&D and publications issued as a result of that work helps to:
    ▪ Dispel the myths associated with Hemp.
    ▪ Rising tide helps to lift all boats.

So what contractual issues do I need to be aware of / ready to discuss when working with a IHE?
Getting a Research Agreement in place with an IHE

Clauses you should be prepared to discuss:

• **Indemnification**
  o Be aware that ALL state supported IHE’s have serious issues around Indemnity / Hold Harmless clauses.
  o Prohibitions for IHE’s to Indemnify will be codified as part of the state constitution or within public law(s) of that State.

• **State Law**
  o If you are dealing with a IHE in Colorado you will not be able to get New York law into the agreement.

• **Research Integrity & Compliance**
  o See Brad’s slides above
Research Agreement Clauses (Cont.)

• **Publications** (Publish or Perish)
  o IHE’s must reserve the right to publish their works.
  o Publication restrictions causes problems on many **many** levels.

• **Intellectual Property** (Who owns what)
  o Bayh-Dole Act of 1984
    ▪ Allows IHE’s to retain title on Federally funded projects.
    ▪ We expect it for non-federally funded projects as well.
  o Universities will perform “Work-made-for-hire” services on a case by case basis. However, will not do so for R&D projects. Remember the safe harbor of R&D…
• **Warranties** (…or more importantly the lack thereof)
  o Inspection & Acceptance of results
    ▪ Inspection of results is fine.
    ▪ Acceptance of R&D, the results of which is not guaranteed is not OK to an IHE.
  o Merchantability and fitness for a particular purpose.
    ▪ IHE’s will not provide such a warranty.
    ▪ In-fact you should expect a Disclaimer of Warranty.
  o FDA, cGMP, GLP, GCP, etc.
    ▪ IHE’s will generally not agree to live up to these standards.
    ▪ Some (like CSU) will but only on a case by case basis.
Research Agreement Clauses (Cont.)

- **Budgets** (Should be a piece of cake right?)
  - Direct Costs, plus
  - Indirect Costs or Facilities and Administrative Costs (F&A)

- What are F&A costs?
  - Costs borne buy the IHE, but are not easily allocated to a particular project or cost center.
  - Include administrative support (HR, Finance, Compliance, Research etc.), Utilities, Equipment and Building Depreciation, Operations Maintenance, G&A.

- Most Universities charge Industry partners their Federally Negotiated rate.
  - Depending on the University, their rate is around 45% - 60% of the Direct Costs of the Project.
  - Because the rate is Negotiated a University’s Actual Indirect Expenses are 5 – 15 % points higher.
Why Should I pay?

- F&A is not: a tax, a fee/profit, or a slush fund.
  - IHE’s are usually non-profit organizations who cannot charge or recover a profit, to do so jeopardizes their tax exempt status.

- Industry have their own version of F&A but is expressed as either G&A, IDC or Both.
  - Industry builds these very same indirect costs into their cost of goods sold / cost of doing business.
  - Just not expressed in a way that is visible to customers.

- No matter how the costs are expressed, they are real to both IHE’s and Industry and should be covered in transactions going in either direction.

- Universities cannot give a better deal to for-profit companies then they can to the Federal government.
Questions?