Cannabis Research –Legal and Policy Issues

COGR Meeting

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An association of research institutions

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Panel

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Today's Focus

State Legalization Spurring Increased Research Interest

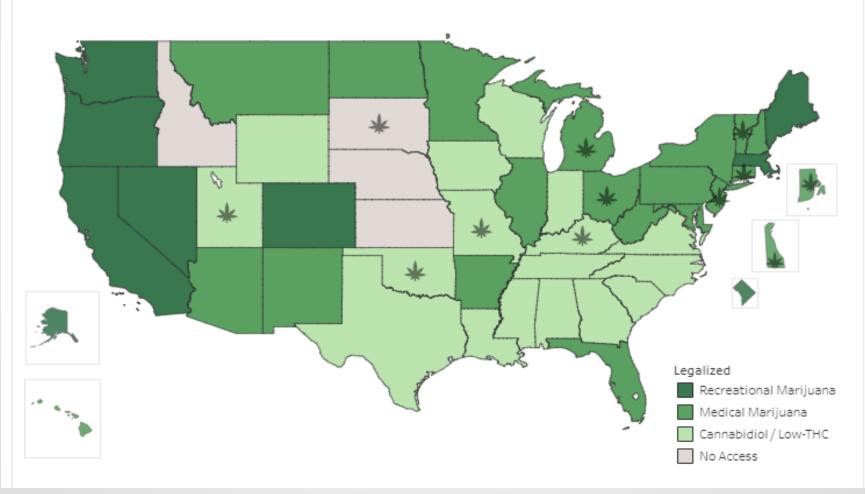
- Overview of Federal Legal Landscape:
 - What IS and ISN'T allowed?
 - GRAY AREAS
 - LEGAL RISKS
 - EVOLVING FEDERAL LANDSCAPE
- State-specific Considerations, Funding Opportunities
- National Academies Report
- What's Happening Globally
- Advocacy
 - COGR Working Group on Research Barriers in Cannabis and Hemp Research
 - Next Steps



Evolving State Cannabis Laws...(Catalyst For Increased Research Interest)



\star 2018 Initiatives



Examples of Research Areas Of Interest

Medical Research

- Medical efficacy
 - o E.g., Pain management, anti-seizure, anti-nausea
 - o Appetite stimulation, glaucoma, sleep disorders
- Health risks/impacts
 - E.g., Cancer, lung disease, psychological effects, impairment

Agricultural/Environmental

- Cultivation issues Marijuana and Industrial Hemp
- Water and Energy Management
- Pest/Weed Control, Erosion, Environmental Impact

Genetic research, basic science

• Molecular structure, different strains

Social science, Policy, Economics/Business

Demographics, marketing, economic impact, legal

Testing (e.g., THC content; pesticides, contaminants)











Overview of the Federal Legal Landscape

- I. Notwithstanding STATE laws, most cannabis possession, distribution, cultivation is still illegal (criminal) under FEDERAL law (the Controlled Substances Act of 1970).
- II. There are LIMITED EXCEPTIONS that allow certain research involving cannabis possession, distribution or cultivation (e.g., research conducted under a DEA Schedule I license, certain industrial hemp research).
- **III.** This is a still-evolving area (we hope!):
 - Still some "gray" re: details of how Federal rules apply in certain areas.
 - Recent Administration statements/memos (e.g., rescission of "Cole memo") suggest stricter enforcement, but effect on research is uncertain.
 - Several pending proposals for regulatory/statutory reform as well as legal challenges could change the landscape (though chances for success are uncertain....).



Key Federal Agency Regulatory Roles

- DOJ/Drug Enforcement Agency (DEA) Primary federal agency charged with enforcing Controlled Substances Act. Oversees Pl registration and site licensure to conduct studies w/marijuana.
- NIH/NIDA supports scientific research; designated by DEA as the government agency overseeing cultivation of marijuana for medical research (under contract to University of Mississippi).
- FDA Scientific assessment used for scheduling; regulates research on potential therapeutic uses; enforcement of products containing MJ compounds (health risks, illegal claims in labeling)



Definitions

"Marihuana" (Controlled Substances Act) 21 U.S.C. § 802(16). (Schedule I).

The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include 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.

"Industrial Hemp" (IH)

Federal Agricultural Act of 2014 (7 U.S. Code § 5940): "industrial hemp" means the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

Multi-agency Statement of Principles on IH (<u>81 Fed. Reg. 53395 (8//12/2016</u>) The term "industrial hemp" includes the plant *Cannabis sativa* L. and any or derivative of such plant, including seeds of such plant, whether growing or not, that is used exclusively for industrial purposes (fiber and seed) with a tetrahydrocannabinols concentration of not more than 0.3 percent on a dry weight basis. The term "tetrahydrocannabinols" includes all isomers, acids, salts, and salts of isomers of tetrahydrocannabinols.

Marijuana Extract (Schedule I) (DEA's "Clarification of the New Drug Code (7350) for Marijuana

Extract"): "does not include materials or products that are excluded from the definition of marijuana set forth in the Controlled Substances Act (CSA)."

Cannabis -- used here, colloquially, as a catch-all-term....



The Controlled Substances Act of 1970 (CSA) prohibits most "marihuana" (*Cannabis sativa*) possession, distribution, cultivation, and provides for criminal and civil penalties for violations.

- The CSA is how U.S. has implemented the international <u>Single</u> <u>Convention on Narcotic Drugs</u> (1961, amended 1970), under which participating countries agreed to restrict production, possession, distribution of marijuana except for medical/scientific purposes.
- Marijuana is classified as Schedule I (same as heroin, LSD, ecstasy!) The most restrictive category under the CSA, for drugs with no currently accepted medical use and high abuse potential. Repeated efforts to have DEA re-schedule marijuana to a lower classification have been unsucçessful.
- The CSA does allow research on Schedule I drugs but with significant controls (e.g., registration, background checks, inspections, source limitations)
- Note that DEA also lists marijuana "extracts" (like Cannabadiol or CBD) as Schedule I (more on that later....)



The Exceptions: What Research IS Allowed Under Fed'I Law?

I. <u>RESEARCH INVOLVING CANNABIS POSSESSION, DISTRIBUTION, CULTIVATION MAY</u> <u>BE DONE IF IT IS</u>:

- A. <u>Conducted under a Schedule I DEA registration, using (only) product obtained</u> <u>via NIDA process (currently, that means obtaining cannabis from the University of</u> Mississippi thru NIDA), and in compliance with all applicable DEA, FDA (and state) rules.
- B. Industrial Hemp research compliant with the Fed'l Farm Bill and state law: Under the Agricultural Appropriations Act 0f 2014 ("Farm Bill"), Section 7606, "notwithstanding the CSA," institutions of higher ed (and state depts. of ag under state pilot programs) may grow low-THC (less than 0.3%) industrial hemp for agricultural or academic research in states that allow it.
 - Caveat: A DEA license may still be needed in connection with obtaining the industrial hemp seed/cultivars for such use (e.g., a DEA import license for importing from abroad).
- II. RESEARCH ABOUT CANNABIS THAT DOES NOT INVOLVE POSSESSION, CULTIVATION, ETC. IS OK! Not all research involves actual contact with cannabis or cannabis extracts! (Caveat: Accepting funding from or providing assistance to cannabis entities may still raise legal concerns....)



The Exceptions: (Permissible under Federal Law):

Research Conducted under a Schedule I DEA registration

- <u>Researchers apply for a Schedule I DEA registration via DEA Form 225</u>
 - PI's must provide info re: protocol, PI qualifications, security measures, criminal CS convictions
 - Registrants must comply with all applicable requirements re: security, inspections, record-keeping, renewals, etc.
- <u>Researchers working under a Schedule I may use only marijuana obtained through</u> the National Institute on Drug Abuse (NIDA) drug supply program.
 - Currently, U. Mississippi is the only entity with a NIDA license to grow/supply MJ for research.
 - Many researchers have obtained cannabis for research through this program, but some have argued for expanded sources to provide more variety and to provide for study of "real world" cannabis closer to what is actually being used (to facilitate research on health effects).
 - <u>DEA announced in August 2016 a new policy designed to increase the number of entities</u> registered to grow (manufacture) marijuana to supply researchers; although dozens of entities have since applied, none has been granted a registration thus far.
- If the research involves human subjects, NIH/FDA review is required; all requests are subject to review for scientific validity and ethical soundness (see: https://www.drugabuse.gov/researchers/research-resources/nida-drug-supply-program)



The Exceptions: (Permissible under Federal Law):

Industrial Hemp Cultivation for Research

Agricultural Appropriations Act of 2014 ("Farm Bill"), Section 7606 (7 U.S. Code § 5940 – "Legitimacy of Industrial Hemp Research"):

- "Notwithstanding the CSA...or any other Federal law," an institution of higher ed or a state dept. of agriculture may grow or cultivate industrial hemp IF:
 - 1) the IH is grown for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; AND
 - 2) the cultivation of IH is allowed under the laws of the state in which the IHE/dept. of ag is located and such research occurs
- Defines IH as "the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.
- Caveat: A DEA license still needed in connection with obtaining the industrial hemp seed/cultivars for such use (e.g., a DEA import license for importing from abroad). No clear guidance re: legality or licensure requirements for obtaining IH intra- or inter-state.



Gray Areas (So What's the Problem)?

UNCERTAINTY RELATED TO INDUSTRIAL HEMP RESEARCH

- LEGAL SOURCES OF INDUSTRIAL HEMP SEED/CULTIVARS FOR RESEARCH. USDA/DEA/DOJ/FDA/HHS "Joint <u>Statement of Principles</u>" on IH noted a DEA import license is still required in order to import viable cannabis seeds from abroad. But no clear guidance re: legality/license requirements for other sources of IH. (Can institutions obtain IH from other entities intra- or inter-state, with or without a license? Would suppliers be restricted to IHEs or State Depts. Of Ag in states with Farm Bill compliant pilot programs?).
- SCOPE OF RESEARCH ACTIVITIES AUTHORIZED BY FARM BILL. The Farm bill authorized IHEs and state depts. of ag (only) to "grow or cultivate" IH for agricultural or academic research. What if on IHE does not wish to cultivate IH, but wishes to conduct research on IH grown by another entity? That seems like it *should* be OK, yet it is not explicitly authorized by the Farm Bill.
- EXTENT TO WHICH IH-DERIVED MATERIALS ARE EXCLUDED FROM SCHEDULE I RESTRICTIONS, Because of confusing and possibly inconsistent definitions of "marihuana," "marihuana extracts," and "industrial hemp" in the CSA, the multi-agency Statement of Principles on IH, and DEA CSA Schedules, it is unclear whether Sch. I Registration restrictions apply to research that involves extracts or derivatives from IH plants.



Gray Areas (So What's the Problem)? (cont.)

UNCERTAINTY RELATED TO MARIJUANA RESEARCH

- Lack of Clarity re: LEGAL/SCHEDULING STATUS OF CERTAIN MATERIALS. Because of confusing and apparently inconsistent definitions of regulated products in the CSA, the multi-agency Statement of Principles on IH, and DEA CSA Schedules, it is unclear whether Schedule I restrictions apply to certain substances, e.g:
 - Extracts or derivatives of mature stalks of the cannabis plant ("Mature stalks" are exempt from the CSA definition of marihuana, but DEA lists all "marihuana extracts" generally as Schedule I)
 - Extracts or derivatives (like Cannabadiol) that might be obtained from sources (e.g., yeast) other than a cannabis plant.
 - Non-psychoactive extracts or derivatives (e.g., DNA) from a cannabis plant?
- Lack of Clarity re: When/Under What Circumstances DEA will approve additional sources of research marihuana
- Prospects for Additional Funding?



Gray Areas (So What's the Problem)?

UNCERTAINTY (POTENTIAL PITFALLS): ACCEPTING FUNDS FROM/CONDUCTING WORK TO AID CANNABIS INDUSTRY

Sale, distribution, manufacture of marijuana is still a crime under Federal law (outside of activities carried out under a Schedule I license or conducted by an IHE or state Dept. of agriculture in compliance with the Farm Bill), SO, POTENTIAL RISKS:



 Money Laundering – Anyone accepting money with the knowledge the funds are derived from the sale of cannabis in violation of federal law is subject to fines and imprisonment and having those funds confiscated by federal authorities.

This is why Banks and Landlords have concerns about working with that industry.

That is also one reason why many Colleges and Universities won't take research or gift funds from that industry.

Note -- this concern may not apply to accepting funding from HEMP industry entities IF those entities are operating under a state dept. of agriculture research pilot program that complies with the Federal Farm Bill (Caveat: Not all hemp industry entities will meet that criterion).



Gray Areas (So What's the Problem)? (cont.) POTENTIAL PITFALLS (CONTINUED):

CONSPIRACY

"Persons who are in the business of cultivating, selling or distributing marijuana, and those that knowingly facilitate such activities, are in violation of the Controlled Substances Act, regardless of state law." From the Cole Memo, June 2011



- This is of concern for those who do business with the cannabis industry and certainly limits that industry's access to needed services.
- This is another reason some Colleges and Universities are unwilling to work with that industry especially if their actions could be seen as promoting the cultivation of cannabis.
- Note, this does not apply to hemp and the hemp industry IF those hemp industry entities are operating under a state dept. of agriculture research pilot program that complies with the Federal Farm Bill (Caveat: Not all hemp industry entities will meet that criterion).



My State says I can use marijuana, why is that not good enough?

"The Federal Government may neither issue directives requiring the States to address particular problems, nor command the State's officers, or those of their political subdivision, to administer or enforce a federal regulatory program." Printz v. United States, 521 US 144, 166 (1997)

In 2006, state and local police made 1,889,810 drug arrests, the Feds made 29,800.

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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.



But wait, what?

The decision noted that the facts in the case were troubling and if credible evidence was found of the efficacy of medical use, it would cast serious doubt on the finding that marijuana be listed as schedule 1.



Criteria for Scheduling and Schedules under the Controlled Substance Act (CSA)

| C R I T E R I A | Abuse Potential | | Low relative | Low relative | Low relative |
|-------------------|--|--|--|--|---|
| | High | High | to CII | to CIII | to CIV |
| | No Medical Use | Medical Use | | | |
| | Lack of accepted safety under medical supervision | Psychological or Physiological Dependence | | | |
| | | Severe Psych or Physical | High Psych or Moderate to low Physical | Ltd Psych or Physical relative to CIII | Ltd Psych or Physical relative to CIV |
| S C H E D U L E S | SCHEDULE I | SCHEDULE II | SCHEDULE III | SCHEDULE IV | SCHEDULE V |
| | Heroin Hallucinogens Marijuana Others | Opioids Barbiturates Cocaine Amphetamine Methylphenidate Methamphetamine PCP | Opioids (Codeine combinations, Buprenorphine) Barbiturates (combinations and products) Ketamine GHB Marinol Anabolic Steroids | Benzodiazepines and other depressants (Zaleplon, Zolpidem, Eszoplicone) Fenfluramine Modafinil Butorphanol Tramadol | Opioids in limited quantities and in combinations (Codeine, Dihydrocodeine, Difenoxin) Pregabalin Lacosamide |

Petition to Reschedule:

Have to prove that cannabis has an accepted medical use in the US, is safe for use under medical supervision and has a relatively low abuse potential compared to other Schedule II drugs.

Five part test for "currently accepted medical use:

- 1. The drug chemistry must be known and reproducible;
- 2. There must be adequate safety studies;
- 3. There must be adequate and well-controlled studies proving efficacy;
- 4. The drug must be accepted by qualified experts;
- 5. The scientific evidence must be widely available.

Rescheduling seems unlikely.

Why re-scheduling is unlikely to happen

1. There are too many barriers to research:

- Schedule 1 and associated security costs;
- Marijuana is the only Schedule 1 drug that non-DEA licensed labs and researchers are not allowed to produce in a scientific study environment; and
- As a cultivated "drug" it does not lend itself to the clinical trials required by the FDA as it is not uniform in quality or potency



Why re-scheduling is unlikely to happen cont.

- 2. Re-scheduling and legalization discussions focus on political considerations and scientific evidence is effectively ignored.
 - A study published in 2016 found that the medical doctors, lobbyist and government officials were in general agreement that scientific evidence played a limited role in the development of medical cannabis policies;
 - That it was not a main motivator of policy change; and
 - The scientific community is not effectively communicating their findings to policy makers.

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.



Marin Alliance for Medical Marijuana

- Operating in violation of an injunction since 2011
- With passage of the 2015 Appropriations Act, MAMM sought to have injunction dissolved
- They won and government did not pursue an appeal

"...as long as Congress precludes the Department of Justice from expending funds in the manner proscribed by Section 538, the permanent injunction will only be enforced against MAMM insofar as that organization is in violation of California 'State laws that authorize the use, distribution, possession, or cultivation of medical marijuana.'"



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.



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 "<u>non-psychoactive</u> <u>hemp</u>" which are excluded from the definition of marijuana by Congress.



The Farm Bill, 2014

- This bill in effect expanded the prior "nonpsychoactive 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 Hemp "work around" or cannabis is cannabis is cannabis

With the enactment of the Farm Bill and its loosening of regulations of cannabis having a THC level of less than .3%, Colorado quickly put into place a program to license the cultivation of low THC cannabis (aka Industrial Hemp).

The Colorado Department of Agriculture obtained a modified schedule 1 to allow them to bring viable hemp seeds into Colorado.



Hemp Work around continued:

Colorado created an Industrial Hemp pilot program and licensed individuals, companies and universities to grow low THC cannabis and possess viable seed.

Suddenly, CSU researchers had legal access to cannabis plants and products – Industrial Hemp.

This has allowed researchers to conduct research on the plant itself but more interestingly, the components parts of the plant – cannabinoids -- derived from the low THC cannabis plant.



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.



Not helping....

In March of 2017, the DEA "clarified" their position saying that the new drug code "...does not include materials or products that are excluded from the definition of marijuana set forth in the Controlled Substances Act."

What about the Farm Bill and Industrial Hemp?



The DEA's Reply Brief:

The guidance cited scientific literature supporting the conclusion that the new code number does not apply to substances outside the CSA definition of "marijuana." See Clarification. As noted above, the rule defines "marijuana extract" as "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." ER 13. DEA's guidance explained that cannabinoids, which are chemicals in the cannabis plant, "are found in the parts of the cannabis plant that fall within the CSA definition of marijuana, such as the flowering tops, resin, and leaves."

Citing to: Molleken & Husmann, Cannabinoids in Seed Extracts of Cannabis Sativa Cultivars, 4 J. Int'l Hemp Ass'n 73 →1997

The DEA's Reply Brief

- "The rule does not obligate anyone to register with the DEA who was not already required to do so."
- "Petitioners also do not need to use the code number if they engage in activities involving 'industrial hemp' that falls within the parameters of [the Farm Bill.]"
- To the extent that a product consisting solely of exempt parts of the cannabis plant contains trace amounts of cannabinoids, 'such product would not be included in the new drug code."
- "...code number applies only to extracts derived from a 'plant of the genus Cannabis.'" -- For example, does not apply if derived from coneflower, electric daisy and liverwort.



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.



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.



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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.



There are lots of legislative fixes being discussed on the Hill:

- The Marijuana Justice Act legalize cannabis and retroactively expunge criminal records.
- Respect State Marijuana Laws Act of 2017 amend CSA to apply enforcement only to those not in compliance with State law.
- Ending Marijuana Prohibition Act of 2017- remove cannabis from CSA and only enforce interstate transport to states where not legal.
- Medical Marijuana Research Act of 2017 make cannabis accessible to researchers.
- Etc.....



Summary

- Research can be done, but there are limitations & restrictions. Researchers & administrators must be aware of the legal landscape and the need to comply with both state and federal law
- When in doubt, consult campus legal counsel
- Work closely with your program officer
- Be mindful of both state and Federal requirements



Our state is LEGAL – now what?

o WSU:

- Created committee of broad University representation
- Created Faculty Guidelines and FAQs
- Worked with state agencies on cannabis: LCB (marijuana) and WSDA (industrial hemp)
- Hosted workshops (WSU, UW, others)
- Find policy gaps, work with industry, creating a Center, be a resource, creating collaborations
- o CSU:
 - Created committee with broad representation
 - Created website: University Guidelines on Marijuana Use and Hemp Research, including CSU Health Network Resource, Student Conduct Code, additional resources
 - FAQ about Hemp and Marijuana Research
 - CSU-Pueblo, Institute of Cannabis Research (ICR)
 - ICR Steering Committee, Annual Conference, Cannabis Journal/Conference Proceedings, Working Group
- o UC:
 - New kids on the block: sale for recreational use legal January, 2018
 - Initial systemwide guidance for researchers issued January, 2017; FAQs in process
 - Systemwide work group exploring issues and policy gaps, including discussions with state agencies, other institutions, experienced researchers
 - Systemwide policy/legal workshop will take place in March
 - Will be exploring risk tolerance with senior leadership

Look at all this money! Revenue and Tax Comparison

- Washington
 - Total sales in FY17 nearly \$1.4B
 - Over \$300M in tax revenue
- Oregon
 - Total sales Jan 2016 August 2017 \$638M (based on a 17% sales tax)
 - Tax revenue \$108.6M
- Colorado
 - Total sales CY17 \$1.37B (\$384M medical, \$995M recreational)
 - Tax revenue \$247M
- California (expected)
 - 2018 sales \$3.7B
 - 2018 tax revenue \$1B



State investments in research

Washington

- Dedicated Marijuana Account—Four-tenths of one percent to Washington State University for research on the short- and long-term effects of marijuana use, to include but not limited to formal and informal methods for estimating and measuring intoxication and impairment, and for the dissemination of such research
- o \$268,000 in 2016 and 2017
- Colorado
 - o Research funded through the Co. Dept. of Public Health and Environment
 - o \$9M 2015-2017
- Oregon
 - o Not clear
- California
 - o \$10M/year of proceeds will be used for research (for 10 years)



But look at all these headlines

- "VA says it won't study medical marijuana's effect on veterans." <u>https://www.washingtonpost.com/news/post-nation/wp/2018/01/16/va-says-it-wont-study-medical-marijuanas-effect-on-veterans/?utm_term=.74f94963de63</u>
- "Is Big Pharma for or Against Legalizing Medical Marijuana? Maybe Both." <u>https://www.entrepreneur.com/article/297984</u>
- "Republican lawmakers optimistic about passing cannabis legislation in 2018" <u>http://thehill.com/video/lawmaker-interviews/371854-</u> republican-lawmakers-optimistic-about-passing-cannabis-legislation
- "Marijuana Research Catch 22" PTSD, ailment focused (marijuana manufacturer/DEA approval) <u>https://www.cato.org/blog/marijuana-research-catch-22</u>



Current Funding Opportunities

(Pivot keywords-cannabis, marijuana, industrial hemp)

o Federal—12 Opportunities

- 11 from HHS/NIH
- 1 from DOJ
- o Industry
 - Professional society or association— National Council of State Boards of Nursing
 - State
 - Nation

o Amounts vary from \$100k to \$2.5M



Working with and Obtaining Funding from Industry

• Working with:

- o Often a broad range of growers, processors, and retailers
- o Very new, so flying blind
- o BIG numbers but doesn't equate to thriving industry
- o Cannabis Commission?
- o WSU Industry Engagement Statement

• Funding from:

- o Can we accept?
- WSU waiting for Cannabis Commission check-off funds



National Academy Report

- "The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research"
- Four main recommendations:
 - Address Research Gaps
 - Improve Research Quality
 - Improve Surveillance Capacity
 - Address Research Barriers



National Academy Report

- Very little has changed since the report was written last year;
- Recommendations have been ignored for the most part;
- Many companies looking at different delivery systems, mostly synthetics since you can't patent the plant and can only acquire from one source.
- Companies must acquire Schedule 1 license to do research so they do it abroad. US to fall behind.



What's happening globally?

- Israel—research in Israel "pioneered the medical marijuana industry," one of first countries to legalize medical marijuana (recreational illegal), and has government-sponsored research program
- Canada—government-sponsored research program; including \$1.4M to research effects of legalizing recreational marijuana in 2018
- Mexico—research showing decline in exports of marijuana from south of the border
- According to a report by AmeriResearch Inc., the global legal cannabis market was valued at \$14.3 billion in 2016 and is estimated to grow at a CAGR of 21.1% between 2017 to 2024 or culminating to \$63.5 billion by 2024



Our advice

- Marijuana: If your state does not yet have approved medical or recreational marijuana, consider proposing a substantive annual research fund in your state legislation (lump sums are not sustainable)
 - Make legislation broad to cover all your research needs.
 Here is the State of Washington's wording:

"Up to six-tenths of one percent to the University of Washington and four-tenths of one percent to Washington State University for research on the short and long-term effects of marijuana use, to include but not be limited to formal and informal methods for estimating and measuring intoxication and impairment, and for the dissemination of such research."



Our advice

- Industrial Hemp: If your state does not have an approved Industrial Hemp Agricultural Pilot program within your state law, Oregon and Kentucky have good models of legislation and implementation
 - The Farm Bill allows a broad interpretation. Push for the legislation beneficial to your institution, and ensure sustainable funding



COGR next steps

- COGR to send Industrial Hemp letter to AG Committee members with cc to Sessions, Rosenstein, Perdue;
- COGR to focus efforts on cannabis and develop position;
- COGR to post FAQ's on website;
- COGR to meet with Deputy AG staff and hill staffers



Questions?

