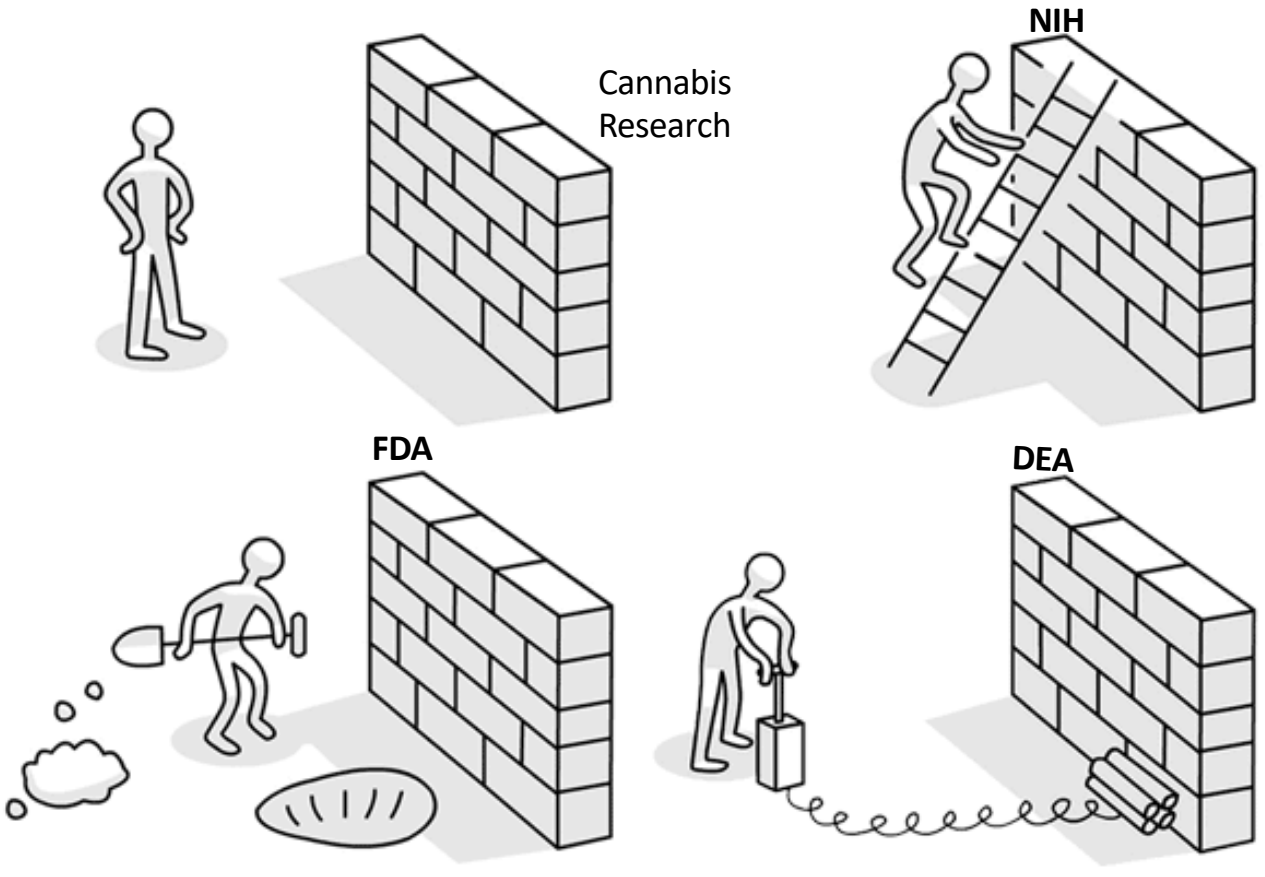
Cannabis and Health

Module 3

Lecture 1: Barriers to Research

Why don’t we know more?



Legal Barriers to Research

- Controlled Substances Act (CSA) of 1970
  - Controls manufacture, importation, possession, use, and distribution of cannabis – schedule I to V

- Schedule I most restrictive
  - high potential for abuse
  - no accepted medical use
  - lack of safety even when medically supervised
  - LSD, Heroin, Cannabis (among others)

HOW DRUGS ARE CLASSIFIED IN THE US

SCHEDULE	DESCRIPTION	EXAMPLES
Schedule 1	Drugs with no currently accepted medical use and a high potential for abuse. They are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence.	- Heroin - Lysergic acid diethylamide (LSD) - Marijuana (Cannabis) - Methylenedioxymethamphetamine (Ecstasy) - Methaqualone - Peyote
Schedule 2	Drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.	- Combination products with less than 15mg of hydrocodone per dosage unit (Vicodin) - Cocaine - methamphetamine - Methadone - Hydromorphone (Dilaudid) - Meperidine (Demerol) - Oxycodone (OxyContin) - Fentanyl - Dexedrine - Adderall - Ritalin
Schedule 3	Drugs with a moderate to low potential for physical and psychological dependence. Schedule 3 drugs abuse potential is less than Schedule 1 and Schedule 2 drugs but more than Schedule 4.	- Products containing less than 90mg of codeine per dosage unit (Tylenol and codeine) - Ketamine - Anabolic steroids - Testosterone
Schedule 4	Drugs with a low potential for abuse and low risk of dependence.	- Xanax - Soma - Darvon - Darvocet - Valium - Ativan - Talwin - Ambien - Tramadol
Schedule 5	Drugs with lower potential for abuse than Schedule 4 and consist of preparations containing limited quantities of certain narcotics. Schedule 5 drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.	- Cough preparations with less than 200mg of codeine per 100ml (Robitussin AC) - Lomotil - Motofen - Lyrica - Parepectolin

SOURCE: Drug Enforcement Administration

BUSINESS INSIDER

CBD as Schedule I – now Schedule 5

- FDA recently approved plant derived cannabidiol made by GW Pharma
- Cannabidiol made by GW Pharma now Schedule V
- Schedule V means
  - Low potential for abuse
  - Has a medical indication
  - But abuse may still lead to dependence
- The federal scheduling of cannabis and CBD has defied logic and common sense
  - Unfortunate because it makes it difficult for the public to see federal agencies as honest brokers of science and information

Drug Free Federal Workplace Act (1988)

- Intended to help employers enforce regulations related to drug use
- Any organization that received $100,000 in a contract or a grant of any size must:
  - Prepare and distribute a formal drug-free workplace policy statement
  - Establish a drug-free awareness program
  - Ensure that all employees working on the federal contract understand their personal reporting obligations
  - Notify the federal contracting agency of any covered violation
  - Take direct action against an employee convicted of a workplace drug violation
- Penalty for violation – you lose your federal money!

Drug Free Schools and Communities Act

- Institutions receiving federal funds must establish drug and alcohol abuse prevention programs
- Must produce biennial report on drug and alcohol infractions
- Must establish drug use prevention programs on campus
- Must certify compliance to the department of education
- Penalty is that federal funds are taken away

Institutional Barriers

- Drug Enforcement Agency (DEA)
  - Job is to enforce CSA and related laws
  - To do research on cannabis, must obtain a Schedule I license
  - Complete application
  - Pass DEA initial site inspection (must have a steel safe inside of locked room inside of a locked building)
  - Subject to periodic inspections
  - Takes a long time - varies from field office to field office
  - Experience suggests this is not an easy way to do research

Food and Drug Administration (FDA)

- Along with DEA, responsible for scheduling drugs
- FDA must approve research protocols for a schedule I license
- Also oversees clinical research more broadly on drugs
- A university IRB will not allow clinical research to move forward unless the FDA approves it
- FDA will only approve cannabis research if you are using federally supplied cannabis

National Institutes of Health

- The biggest funding agency for health related research (actually a collection of institutes) – $39 Billion in FY2019
- Until recently, it was primarily the National Institute of Drug Abuse (~ $1.1 Billion budget) that funded cannabis research and it was mostly on the harms
- Without funding, it is difficult to do high quality research
- With spreading legalization, other institutes have show interest in funding health research
  - National Cancer Institute (NCI) - ~ $5.74 Billion
  - National Institute of Aging (NIA) - ~$3.1 Billion
  - National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
  - National Heart Lung and Blood Institute (NHLBI)
  - National Center for Complementary and Integrative Health (NCCIH)

University Legal Counsel

- Thought it was going to be easy to do cannabis research when CO legalized
- Should be like doing alcohol or nicotine research
- Legal counsel shot us down
- True for all universities – no legal counsel is going to let one faculty member put $400 million of federal funds at risk!!
- However, CU has done a truly impressive job at trying to find ways to help us get the work done
- They do seem to be swayed by arguments about the public health importance and the ”risk” of doing nothing

Emerging Barriers

- Federal authorities (for similar trends see lecture on history) want to dismiss anything that does not conform to a Western definition of medicine
- Case in point –argument that results of big pharma studies on CBD do not generalize to products in state regulated markets
  - Because there are other low level components in these products (e.g., terpenes, THC, etc)
  - Because we “just don’t know what is in those products”
- Note – we have had 50 years of research on the harmful effects of THC based on the notion that THC is THC regardless of terpenes or anything else

Summary

- Nixon administration did an amazing job of raising barriers that persist through today
  - CSA
- Additional legislation in the 1980s built the barriers even higher (Drug Free acts)
- Federal institutions (FDA, NIH) limited by these barriers
- Impossible for Universities to meet public need for research on health effects of cannabis

Discussion Prompt

- What do you think of the argument that we don't know what is in CBD products and CBD in those products may work differently than plant-derived CBD made by GW Pharma?