WHAT IF MARIJUANA WERE NOT A SCHEDULE I DRUG?
LEGAL & POLICY IMPLICATIONS
PRESENTERS

Kerry Cork
Senior Staff Attorney

Hudson B. Kingston
Staff Attorney
LEGAL TECHNICAL ASSISTANCE

- Legal Research
- Policy Development, Implementation, Defense
- Publications
- Trainings
- Direct Representation
- Lobby
FOCUSING ON EQUITY AND INCLUSION
WHEN WE WORK ON PUBLIC HEALTH LAWS

Introduction
Law and policy are essentials tool for improving public health and addressing the social determinants of health. Laws, in the form of statutes or codes, ordinances, and administrative or agency rules, are a particularly potent type of policy because they have the power of government behind them. Laws are also powerful because they reflect and help to shape and reinforce social norms.

Law impacts our health and our opportunities to lead healthy lives in multi-layered ways. It regulates our access to healthcare services, which directly affects our health. Law also impacts our health in less

There are many helpful ways to explain what equity means. PolicyLink provides this concise and inspiring definition: “This is equity: just and fair inclusion into a society in which all can participate, prosper, and reach their full potential. Unlocking the promise of the nation by unleashing the promise in us all.” In turn,

Law is a key force for equity and health equity, both for good and for ill.
OVERVIEW

• Controlled Substances Act (CSA) Overview
• Cannabis Conundrum
• A Menu of Options
  1. Maintain Status Quo – “Let It Be!”
  2. Cooperative Federalism – “Let’s Get Real!”
  4. Reschedule – “Let’s Get Creative!”

• Where Does This Leave Us?
CONTROLLED SUBSTANCES ACT (1970)
FACTORS IN DRUG CLASSIFICATION
BY THE DEA AND FDA

1. Drug’s actual or relative potential for abuse
2. Scientific evidence of its pharmacological effect, if known
3. The state of current scientific knowledge regarding the drug or other substance
4. Its history and current pattern of abuse
5. The scope, duration, and significance of abuse
6. What, if any, risk there is to public health
7. Its psychic or physiological dependence liability
8. Whether the substance is an immediate precursor of a substance already controlled under the CSA
TYPES OF DRUG SCHEDULES

- **Schedule I**: Heroin, LSD, “Ecstasy,” peyote, cannabis
- **Schedule II**: Methadone, OxyContin, Percocet
- **Schedule III**: Cocaine, morphine, hydrocodone (Vicodin)
- **Schedule IV**: Ativan, Ambien, Lunesta, Valium, Xanax
- **Schedule V**: Cough preparations w/ <200 mg codeine per 100 grams (Robitussin AC)
THE MOST DANGEROUS – SCHEDULE I

1. A “high potential for abuse”

2. No “currently accepted medical use” in the U.S.

3. Lack “accepted safety for use ... under medical supervision.”

21 U.S.C. § 812(b)(1)
SCHEDULING CONTROLLED SUBSTANCES

• Congress created original listing
• Scheduling can be changed via:
  1. **Congressional action** (either new marijuana legislation or CSA amendments)
  2. **Administrative action** through the Department of Justice:
     • U.S. Attorney General in consultation with other federal agencies
     • Petition by interested party to U.S. Attorney General
The Single Convention on Narcotic Drugs of 1961

- Imposes restrictions on the manufacturing, distribution, and trade in narcotic drugs
- Administration resides at UN Office on Drugs and Crime
- Authority to delist in WHO and UN Commission on Narcotic Drugs
- UN is in the process of delisting cannabis and derivatives

A Cannabis Conundrum:

- The CSA obligates the AG to put restrictions on cannabis consistent with the international treaties
- The U.S. has historically led the way in putting cannabis prohibitions into international treaties
FOOD AND DRUG ADMINISTRATION

- Protects public health by assuring safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices.

- Also responsible for safety and security of U.S. food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.
CANNABIS CONUNDRUM: MEDICAL RESEARCH

To become a legal substance under federal law, clinical trials need to show marijuana has a medical use.

This would move it from Schedule I . . .

BUT because marijuana is illegal under federal law, doing clinical trials to show it has a medical use is nearly impossible.

Thus there’s little evidence to move it from Schedule I.
CANNABIS CONUNDRUM
MEDICAL RESEARCH

Cannabis Catch-22

How The 'Cannabis Catch-22' Keeps Marijuana Classified As A Harmful Drug

The U.S. Has a Marijuana Legalization Catch-22 on Its Hands

Medical Marijuana’s 'Catch-22': Limits On Research Hinder Patient Relief


Cannabis catch-22: PTSD patients could be dropped from state's medical program

The Infuriating Catch-22 Of Federal Marijuana Scheduling

Cannabis catch-22: Utah research on medical pot hamstrung by drug's federal status

PUBLIC HEALTH LAW CENTER
at Mitchell Hamline School of Law

6/6/2019
The FDA has recently approved one natural (i.e. from the cannabis plant) cannabinoid as a “drug:”

- First FDA-approved drug derived from an extract of the cannabis plant
- Accepted medical use
A FEW FEDERAL AGENCIES REGULATING ALCOHOL

- U.S. Department of Treasury
  - Alcohol and Tobacco Tax and Trade Bureau (TTB)
- U.S. Department of Justice (DOJ)
  - Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)
- U.S. Department of Labor
  - Occupational Safety and Health Administration (OSHA)
- U.S. Environmental Protection Agency (EPA)
- U.S. Department of Transportation (DOT)
- U.S. Postal Service
A FEW FEDERAL AGENCIES REGULATING OPIOIDS

- U.S. Department of Health and Human Services (HHS)
  - Food and Drug Administration (FDA)
  - Centers for Disease Control and Prevention (CDC)
  - Substance Abuse and Mental Health Services Admin. (SAMHSA)
  - Centers for Medicare and Medicaid (CMS)
- U.S. Department of Justice
  - Drug Enforcement Administration (DEA)
- U.S. Department of Labor
  - Occupational Safety and Health Administration (OSHA)
- U.S. Environmental Protection Agency (EPA)
- U.S. Department of Transportation (DOT)
- U.S. Postal Service
A FEW FEDERAL AGENCIES REGULATING TOBACCO

- U.S. Department of Health and Human Services (HHS)
  - Food and Drug Administration (FDA)
  - Centers for Disease Control and Prevention (CDC)
  - Substance Abuse and Mental Health Services Administration (SAMHSA)
- U.S. Department of Treasury
  - Alcohol and Tobacco Tax and Trade Bureau (TTB)
- U.S. Department of Justice (DOJ)
  - Federal Communications Commission (FCC)/Federal Trade Commission (FTC)
  - DOJ, Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)
- U.S. Environmental Protection Agency (EPA)
- U.S. Department of Labor
  - Occupational Safety and Health Administration (OSHA)
- U.S. Postal Service
A MENU OF OPTIONS

1. Maintain Status Quo (“Let It Be!”)
2. Cooperative Federalism (or “Let’s Get Real!”)
3. Deschedule (“Let’s Get Radical!”)
4. Reschedule (“Let’s Get Creative!”)


1. **STATUS QUO**

- As Schedule 1 drug under CSA:
  - **Federal offense** to –
    - Cultivate, manufacture, distribute
    - Sell, purchase, possess, or use marijuana

- **Harsh penalties**: $1,000s+ in fines & substantial prison time

- Current “prosecutorial forbearance” (per DOJ’s Cole & Ogden memos) could change at any time
CANNABIS CATCH UP

States where marijuana is legal

- Legalized recreational and medical marijuana
- Legalized medical marijuana

[Map showing states where marijuana is legal]
“BENEFITS” OF THE STATUS QUO

• Depends on who you ask & where you live
  • Recreational marijuana industry & related businesses
  • Some pro-marijuana advocates
  • Some in law enforcement?

• Ensures compliance with U.S. obligations under international drug treaties/conventions

• States are legalizing with “light touch” regulation
DRAWBACKS OF STATUS QUO

• Inconsistent state and federal laws
• Significant impact on –
  • Social normalization
  • Illicit market
• Lack of funding to invest in –
  • Proactive regulatory planning & research
  • Balanced thorough assessments of local/state regulatory systems
• Unpredictable & unfair legal enforcement
  • Selective enforcement of criminal laws oppress segments of the population
THE “WAR ON DRUGS”

TARGETING COMMUNITIES OF COLOR

BLACKS HAVE BEEN NEARLY FOUR TIMES MORE LIKELY THAN WHITES TO BE ARRESTED FOR MARIJUANA POSSESSION

PUBLIC HEALTH LAW CENTER
at Mitchell Hamline School of Law

6/6/2019
DRAWBACKS OF STATUS QUO

• **Insufficient research** on health effect & therapeutic potential of marijuana

• Significantly impedes:
  - Scientific understanding of cannabis
  - Advancement of public policy & overall public health
DRAWBACKS OF STATUS QUO

Lack of federal regulatory oversight over—

• Agriculture & production
• Manufacture
• Advertising
• Sales
• Dissemination
DRAWBACKS OF STATUS QUO

• Limited collaboration among --
  - Federal agencies & states
  - FDA, National Institutes of Health, SAMHSA, the National Highway Traffic Safety Administration & others

• Development of “Big Weed” industry
IMPLICATIONS OF STATUS QUO

- Lack of commercial banking services
  - Many marijuana businesses operate solely in cash
  - Public safety concern from law enforcement perspective
- Disadvantageous federal income tax terms
- Limited access to legal services
- Possible loss of employment for off-site marijuana users
- Role of marijuana use in family law proceedings
HOW’S THAT WORKING OUT FOR YA?
2. COOPERATIVE FEDERALISM

- Respect states’ rights by codifying current approach in Cole Memorandum
- Amend CSA to exempt marijuana activities that are lawful in jurisdictions where they occur
- More permanent than Attorney General guidance or agreements between states and the AG regarding enforcement
- “STATES Act of 2018” – ensures each state has right to determine best approach to marijuana w/in its borders
CANADA, O CANADA!

• Canada’s Cannabis Act took effect **Oct. 17, 2018**
• Legalizes the sale, cultivation, and use of marijuana throughout Canada.
• Sets limit for marijuana possession at 30 grams and 4 marijuana plants.
• Leaves everything else to the provinces—age restrictions, who can sell and distribute marijuana, where you can sell or smoke, police protocol, etc.
BENEFITS OF COOPERATIVE FEDERALISM

• Respects state sovereignty & local control
• Provides consistent legal norms
• Would solve critical conflict-of-law concerns (e.g., unpredictable criminal enforcement)
• Would result in more comprehensive federal regime than current approach (perhaps stepping stone?)
• Would promote stability for medical users and suppliers
BENEFITS OF COOPERATIVE FEDERALISM

Recent Example: SAFE Banking Act
DRAWBACKS OF COOPERATIVE FEDERALISM

Would be unlikely to —

- Ease research into marijuana harms and benefits
- Bring products into FDA purview to ensure safety, quality control, & efficacy
- Reduce likelihood of Big Marijuana Industry
- Prevent tobacco industry appropriation / involvement
- Address potential conflicts with current international treaty obligations
- Solve other problems resulting from status quo approach, including impact on social justice, etc.
3. DESCHEDULING

Deregulation?
H. R. 420

To provide for the regulation of marijuana products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

January 9, 2019

Mr. Boomer introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committees on Energy and Commerce, Ways and Means, Natural Resources, and Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

A BILL

To provide for the regulation of marijuana products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Regulate Marijuana Like Alcohol Act”.

TITLE II—REGULATION

Subtitle A—Amendments To Decriminalize Marijuana At The Federal Level

SEC. 201. DECRIMINALIZATION OF MARIJUANA.

(a) Removal From Schedule Of Controlled Substances.—Notwithstanding any other provision of the Controlled Substances Act (21 U.S.C. 801 et seq.), the Attorney General shall, not later than 60 days after the date of the enactment of this Act, issue a final order that removes marijuana in any form from all schedules under section 202(c) of that Act (21 U.S.C. 812(c)).
DESCEDULING

De-regulation?

Remember: You can’t spell “deregulation” without “regulation”
DESCEDULING

De-regulation

• Removing marijuana from CSA entirely would have significant repercussions, including existing federal regulatory authorities.

• Research on marijuana would be significantly easier to do, a prerequisite for reasoned regulation.
DEREGULATION

For example: pesticides.

- EPA has duty:
  - Under FIFRA to regulate pesticides on crops.
  - Under FFDCA to set pesticide residue limits on foods.

- Currently, because of CSA, marijuana is not a legal crop, medicine, or food. But the moment that it is removed from CSA.....
DESCHEDULING

If marijuana was out of CSA and not a “drug”…

• FDA definition of food is met: edibles.
• EPA has duty under FFDCA to limit pesticide residues on food.
• Only one EPA standard for pesticides on hemp (only hemp seeds and certain derivatives) as a food, none for marijuana.
• Normal process: pesticide makers submit detailed applications, including rigorous studies; and pesticide limits are set through formal rulemaking with publication in the Federal Register. This takes months or years but should improve product safety.
If marijuana was out of CSA and not a “drug”…

• *No pesticide regulation corollary in tobacco control.*
• FDA regulates tobacco under a different/independent authority, and tobacco excepted from many federal laws.
• EPA has no duty under FFDCA to regulate pesticide residues on tobacco. No EPA pesticide residue limits on tobacco leaf.
DESCEDULING

If marijuana was out of CSA and not a “drug”…

• Tobacco industry excepted from many federal laws.
• Alcohol/tobacco highly regulated within industry-specific taxes, but lobbying keeps tax low.
• Will the marijuana industry benefit from similar exceptions or experience robust regulatory scrutiny under deregulation?
  • Depends on political power of the industry.
If marijuana was out of CSA, what would likely happen to industry?

• Ready access to investment and banking.
• Potential change to federal tax projected to make marijuana businesses pay an extra $5 billion/decade.
• Increased certainty in market invites larger investors who are happy to take higher returns at reduced risk.
If marijuana was out of CSA, what would likely happen to industry?

- Ready access to investment and banking.
- Potential change to federal tax projected to make marijuana businesses pay an extra $5 billion/decade.
- Increased certainty in market invites larger investors who are happy to take higher returns at reduced risk.

... so, the industry to likely to GROW (and consolidate)
DESCHEDULING

Industry structure and power

• Two current issues under *status quo*:
  1. **Diversion to other states.**
  2. Diversion to illicit market (e.g., to minors or outside of tracking and taxation).
DESCHEDULING

Industry structure and power

• If CSA drops marijuana:
  • Diversion to other states:
    • In immediate aftermath, still illegal under state laws, but this could be changed to benefit industry (CA and OR overproduction)
  • U.S. Constitution Commerce Clause argument
  • NAFTA argument
Status quo:

- Diversion to/from other states currently not allowed by federal policy because states must stop interstate diversion to avoid DOJ enforcement.

- Authority: Cole memo, (revoked but still apparently status quo)

If CSA drops marijuana:

• Diversion to/from other states no longer opposed by federal law
• Industry is overproducing and needs new markets to stay afloat/expand profit
• States cannot ban interstate trade under the U.S. Constitution Commerce Clause (with caveats)

If CSA drops marijuana:

- Diversion to/from other countries (where marijuana is legal)
- NAFTA doesn’t allow discrimination against foreign avocados, corn syrup, or Coca-Cola … marijuana could be treated the same.
- NAFTA’s Investor-State Dispute Settlement gives companies a way to undo trade obstruction.
If CSA drops marijuana:

- All these arrows suggest a growing market that can now consolidate into (or get purchased by) large corporate businesses:
  - Race to the bottom concern
  - Concentration of power concern
  - Big industry will be ahead of regulation at the outset
Addressing illicit market diversion post-CSA

• Under *status quo*:
  1. Diversion to other states.
  2. **Diversion to illicit market (e.g. to minors or outside of tracking and taxation).**
DESCHEDULING

Addressing illicit market diversion

• If CSA drops marijuana:
  – Diversion to illicit market is not new.

This is the plot of notable cautionary tale:
Addressing illicit market diversion

• If CSA drops marijuana:
  – Diversion to illicit market is not new.

This is the plot of notable cautionary tale: Half Baked (1998)

photo credit: http://eclecticboredom.blogspot.com/2014/01/delayed-movie-reaction-half-baked.html
Descheduling

Addressing illicit market diversion

If CSA drops marijuana:

- Diversion to illicit market:
  - This could grow significantly if chosen methods of enforcement/community education fails to control it.
  - Federal role unclear.
  - Corollary to tobacco and alcohol illicit market sales.
  - Culture of forbearance by those with access (adults/workers) might not be there yet.
DESCHEDULING

Addressing illicit market diversion

• If CSA drops marijuana:
  • States could adopt different market structures to avoid diversion to illegal uses, including ownership and direct control of industry.
  • RAND Corporation’s analysis suggested twelve different structures, where “standard commercial model” was one of many and likely not the best option for public health.
From: Considering Marijuana Legalization: Insights for Vermont and Other Jurisdictions

Available at: https://www.rand.org/pubs/research_reports/RR864.html
Addressing illicit market diversion

- RAND take on “standard commercial model”:
  - Exists to maximize efficient market within some constraints.
  - This is why CO and WA allowed regulation by Revenue/Liquor Board instead of Health Department.
  - But is an efficient market really an optimal goal, or good for public health?
Addressing illicit market diversion

- RAND take on “standard commercial model”:
  - Public health agency would likely focus on (1) killing the illicit market (2) without generally increasing use.
  - But Health Departments aren’t usually in the business of: collecting taxes, issuing licenses, monitoring compliance, and enforcement.
  - So there is a disconnect between abilities and needs if you want to do a public-health-first commercial model.
DESCHEUDLING

“Standard Commercial Model”

https://twitter.com/NLintheUSA/status/571029686949711872?s=21
DESHEDULING

Addressing illicit market diversion post-CSA

RAND position:

• “A state monopoly option is—arguably—the most attractive supply model of legalization for protecting public health while reducing or even eliminating the [illicit] market.”

• Options include: no legal sales but allow individual/group grow; limited licenses; non-profit/for-benefit/government sales only; strong local control.
Addressing illicit market diversion post-CSA

My take on RAND position:

- Tobacco lessons: limiting licenses and strong local control.
- Alcohol lessons: government control of sales, or even more of supply chain.
- Public utility lesson: states can allow legal monopolies and regulate/control every aspect of their business (e.g. prices, safety, standards) without having to own/run the monopoly.
DESCHEDULING

Free speech:
- Under the status quo:
  - Marijuana is illegal, advertising to sell it is illegal.
  - Commercial speech is protected only if speech is not misleading and legal.
- It follows that states may restrict advertising however they want.
- The (limited so far) court cases seem to support this.
DESCHEDULING

Free speech post-CSA:
- Marijuana is no longer illegal at the federal level.
- Commercial speech is protected if truthful.
- States can only control speech that is misleading or burden truthful speech in ways that are:
  - Based on a substantial government interest
  - Directly advanced by the control on speech
  - Without the control being more extensive than necessary
Free speech post-CSA:

• Tobacco lesson: companies have sued to stop point-of-sale controls to eliminate tobacco advertising.
• Junk food lesson: companies have sued to stop warning labels on sugar-sweetened beverages.
• States can still protect youth from exposure to advertising, but will need to carefully calibrate prohibitions. Current broad power will be circumscribed.
DESCHEDULING SCORECARD

Benefits

• Research now much easier.
• States have new options for structuring legal marijuana that might improve health.
• Existing federal health standards (e.g. pesticide regulation) should apply.

Drawbacks

• Industry likely to grow quickly and lobby at federal level.
• Unclear if federal policy will be hands-off or will support state efforts and health.
• Industry could have more power to sue over controls that are currently defensible.
4. RESCHEDULING

What automatically happens if marijuana stays in the CSA but is rescheduled?
What automatically happens if marijuana stays in the CSA but is rescheduled?

Nothing, but…
If marijuana were rescheduled:

- NIH could begin funding research, and researchers might not need to use DEA source.
- The justification for existing federal prosecutorial discretion (Cole memo) would get stronger.
- More marijuana-derived medicines could be submitted to FDA for approval, especially since research on effectiveness would be easier to do.
One medicine already approved and rescheduled:

- In June FDA approved Epidiolex, a drug using CBD to treat rare forms of epilepsy. DEA scheduled Epidiolex as Schedule V.

Note: Epidiolex is made abroad, avoiding the current CSA issues around sourcing, and allowing sufficient clinical trials to meet FDA standards.
RESCHEDULING

If marijuana were rescheduled:

• Smoked marijuana may never be approved by FDA as a drug.
• But closing all existing facilities is likely beyond the power/interest of the federal government.
• Marijuana sold as “medical” could be better tested and proven, but likely to continue as distinct FDA/state tracks.
RESCHEDULING SCORECARD

Benefits

• Research now easier.
• FDA could start vetting more drugs for formal approval.
• State’s efforts likely to be treated similar to federal forbearance now, state medical marijuana on a different track from FDA.

Drawbacks

• Does not resolve most issues in Status Quo.
• Lesson of opioid crisis: making something Schedule II or lower is not a panacea for health.
WHERE DOES THIS LEAVE US?
GUIDING PRINCIPLES

• Use the power of law to improve health for all
  • Reduce health disparities
  • Protect vulnerable populations, such as minors, those with behavioral health/mental illness, other priority groups
• Rely on evidence-based policymaking, including safeguards from corporate interests
• Preserve local control
• Support regulatory environments that protect public health and safety
QUESTIONS
CONTACT US

651.290.7506

publichealthlawcenter@mitchellhamline.edu

www.publichealthlawcenter.org

@phealthlawctr

facebook.com/publichealthlawcenter