What if Marijuana Were NOT a Schedule I Drug: Legal & Policy Implications

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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
Agenda

- Cannabis Conundrum & Catch-22
- Our Government at Work
- A Menu of Options
  - Maintain Status Quo – “Let It Be!”
  - Cooperative Federalism – “Let’s Get Real!”
  - Deschedule – “Let’s Get Radical!”
  - Reschedule – “Let’s Get Creative!”
- Where Does This Leave Us?
Cannabis Conundrum

Marijuana is illegal under federal law.

Federal law PREEMPTS local law. . . .

YET . . . .

33 states, DC, Guam, & Puerto Rico have passed laws broadly legalizing medical marijuana in some forms &

10 states & DC permit recreational marijuana use.
Cannabis Catch-22

- “Difficult situation or problem whose seemingly alternative solutions are logically invalid.”
To become a legal substance under federal law, clinical trials need to show marijuana has a medical use.

This would move it from Schedule 1.

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

Thus, there’s no evidence to move it from Schedule 1.
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

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

The Infuriating Catch-22 Of Federal Marijuana Scheduling
Controlled Substances Act (1970)
Factors in Drug Classification

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
Type of Drug Schedules

- **Schedule 1**: 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 1

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.”
Scheduling Controlled Substances

- Congress created original listing
- DEA and FDA determine which substances are added to or removed from the various schedules
- Scheduling can be changed via:
  - Congressional action (either new marijuana legislation or CSA amendments)
  - Administrative action
Food & 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.
The FDA has recently approved a few cannabinoids as drugs:

  - First FDA-approved drug derived from an extract of the cannabis plant
  - Accepted medical use

- Synthetic cannabinoids *dronabinol* and *nabilone* to treat nausea and vomiting associated with chemotherapy & loss of appetite in people with AIDS
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 Opiates

- 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
Marijuana Policy Taxonomy

- Product control
  - Agency with authority to regulate
  - Cultivation and distribution
  - Product testing, specification and certification
  - Packing, warning labels, methods of distribution
  - Licensing of retail sales outlets
  - Retail sales transactions,
  - Local authority

- Taxation, fees, and pricing

- Advertising, marketing, and mass media

- Transportation, crime, and public safety

- Health care services and financing

- Education

- Public services, functions, and programs

- Employment and workplace issues

- Other marijuana policy areas (not otherwise categorized)

Klitzner et al., The New Cannabis Policy Taxonomy on APIS, 38 J. PRIMARY PREVENTION 295 (2017)
U.N. Single Convention on Narcotic Drugs, 1961

- Aims to combat drug abuse by coordinated international action
  - Limits the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes.
  - Combats drug trafficking through international cooperation to deter and discourage drug traffickers.
“Government is at best but an expedient; but most governments are usually, and all governments are sometimes, inexpedient.”

Thoreau, *Civil Disobedience* (1849)
A Menu of Options

- Maintain Status Quo ("Let It Be!")
- Collaborative Federalism (or "Let’s Get Real!")
- Deregulate ("Let’s Get Radical!")
- 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 of the United States showing states where marijuana is legal]
2 Out of 3 U.S. Adults Favor Marijuana Legalization

Support for Legalizing Marijuana Continues to Edge Up

Do you think the use of marijuana should be made legal, or not?

% Yes, legal

GALLUP

2019 North American Cannabis Summit
Benefits of Status Quo

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

- Tobacco industry staying out for now

- Ensures compliance with U.S. obligations under international drug treaties/conventions
Drawbacks of Status Quo

- Inconsistent state and federal laws
- Unpredictable & unfair legal enforcement
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

• Development of Big Weed industry

• Limited collaboration among federal agencies –
  • In understanding and preventing current harms & forecasting industrialization effects
  • FDA, National Institutes of Health, SAMHSA, the National Highway Traffic Safety Administration & others
Drawbacks of Status Quo

- Significant impact on –
  - Criminal justice system / health equity
  - Social normalization
  - Black market

- Lack of funding to invest in –
  - Proactive regulatory planning & research
  - Balanced thorough assessments of local/state regulatory systems
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?

Marijuana Legalization
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
**Drawbacks of Cooperative Federalism**

- Still would NOT –
  - 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 international treaty obligations
  - Solve other problems resulting from status quo approach, including impact on social justice, etc.
Lack of scientific and safety data, controlled studies, epidemiologic research, evidence-based findings from states that have legalized cannabis

Limited experience of state and local governments in developing and implementing effective regulatory policies – scatter-shot state-by-state regulation

Trend to pass marijuana laws via ballot initiatives

Tendency of some states to “borrow” regulatory language from other states

Bandwagon effect & focus on “pay-off” (tax revenue)

Ongoing challenges posed by federal prohibition and need to align dual regulatory systems for medical & recreational marijuana

State of uncertainty re. federal position on marijuana; sense that “something’s coming”; likelihood of major marijuana industry in future (similar to Big Tobacco, Big Pharma, Big Alcohol)

Normalization of marijuana use by youth
3. Deregulation

Deregulation?
Deregulation

Deregulation?

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

- 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…
Deregulation

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

- EPA has duty under FIFRA to regulate pesticides on crops:
  - Instead of long approval process, EPA has already begun allowing some special uses of pesticides on hemp, and could probably temporarily extend similar pesticide regulation to marijuana as a crop.

*Hemp could be a feed crop for animals but does not appear to be regulated as such yet*
Deregulation

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.
- No existing EPA-recognized studies of pesticides on marijuana as a food.
- 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.
Deregulation

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.
Deregulation

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 is likely to GROW (and consolidate).
Deregulation

Industry structure and power

- Two current issues under *status quo*:
  - Diversion to other states.
  - Diversion to black market (e.g. to minors or outside of tracking and taxation).
Deregulation

Industry structure and power

- If CSA drops marijuana:
  - Diversion to other states.
  - Diversion to black market (e.g. to minors or outside of tracking and taxation).
Deregulation

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
Deregulation

- **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)

Deregulation

- 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)

Deregulation

- 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
Deregulation

Addressing black-market diversion post-CSA

- Under *status quo*:
  - Diversion to other states.
  - Diversion to black market (e.g. to minors or outside of tracking and taxation).
Deregulation

Addressing black-market diversion post-CSA

- If CSA drops marijuana:
  - Diversion to black market is not new.

This is the plot of notable cautionary tale…
Addressing black-market diversion

- If CSA drops marijuana:
  - Diversion to black 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
Deregulation

Addressing black-market diversion post-CSA

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

Addressing black-market diversion post-CSA

- 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.
Deregulation

Addressing black-market diversion post-CSA

- 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?
Deregulation

Addressing black-market diversion post-CSA

- RAND take on “standard commercial model”:
  - Public health agency would likely focus on (1) killing the black 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.
**Deregulation**

- **RAND position:**

From: *Considering Marijuana Legalization: Insights for Vermont and Other Jurisdictions*

Available at: [https://www.rand.org/pubs/research_reports/RR864.html](https://www.rand.org/pubs/research_reports/RR864.html)
Deregulation

Addressing black-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 black market.”
  - Options include: no legal sales but allow individual/group grow; limited licenses; non-profit/for-benefit/government sales only; strong local control.
Deregulation

Addressing black-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.
Deregulation

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.
Free speech post-CSA

- If marijuana is removed from CSA:
  - Marijuana is not 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.
Deregulation

Free speech post-CSA

- If marijuana is removed from 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.

- Incidentally: There will be a gold rush of trademark registrations at federal level.
Deregulation 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 sue over existing controls.
4. Rescheduling

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

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

*Nothing, but…*
Rescheduling

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.
Rescheduling

One medicine already approved and rescheduled:

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

- Note: Epidolex is made abroad, avoiding the current CSA issues around sourcing, and allowing sufficient clinical trials to meet FDA standards.
If marijuana were rescheduled:

- Smoked marijuana may never be approved by FDA as a drug.
- But closing all recreational 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 now, state medical marijuana on a different track from FDA.

Drawbacks

- Does not resolve most issues in Status Quo.
- Similar to opioid crisis: making something Schedule II or lower is not a panacea for health.
Where Does This Leave Us?
“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the precautionary principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.”

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
TOKING, SMOKING, & PUBLIC HEALTH
Lessons from Tobacco Control for Marijuana Regulation

A Law Synopsis by
the Tobacco Control
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