Slide 1

Cannabis Regulation in the U.S. – challenges for policy research

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1

Slide 2

Disclosures and Disclaimers

I do not have anything to disclose. I do not take funding from the cannabis, tobacco, alcohol, or pharmaceutical industries.

The findings and conclusions in this presentation are my own and do not necessarily represent an official position of CANNRA or any of the agencies with whom I work.

2

Slide 3

Brief Overview of CANNRA

- A **national nonpartisan nonprofit association of government agencies involved in cannabis regulation** across 43 states, DC, 2 U.S. territories, and Canada.
- Not an advocacy group; **takes no formal position for or against cannabis legalization** – we focus on implementation.
- Mission and goals are to:
  - To identify and share best practices that safeguard public health and safety, promote equity, and promote regulatory certainty for industry participants.
  - To harmonize policy across jurisdictions where possible.
  - Equip policymakers with unbiased information from current state, territorial, and international regulators.
- More than a dozen committees spanning the breadth of cannabis policy topics.
- Funded primarily by member agencies; no non-governmental membership.

www.cann-ra.org

3

Slide 4

Agenda

- Brief cannabis regulatory overview
- Major Challenges for U.S. policy research related to cannabis
  - Binary approaches and oversimplification of policy
  - Timeline errors
  - Oversimplified units of measure
  - Failure to acknowledge hemp as major confounder
- Conclusions

4

Slide 5

Cannabis legalization policy, by state, November 2023

Legend:
- Legal Adult & Medical Cannabis
- Legal Medical Cannabis Program
- Low THC/CBD Program

Created with mapchart.net

5

Slide 6

Dearth of policy research to help guide cannabis regulatory policy

Called for specific research related to regulatory policy and the following topic areas:

- Medicinal use of cannabis
- Cannabis product safety
- Cannabis consumer behaviors
- Policies to promote equity and reduce disparities
- Policies to prevent youth consumption and promote public health and safety
- Policies to reduce the illicit market and associated harms

6

What do regulated cannabis markets look like?

- Regulation through: Departments of health, revenue, consumer protection, alcohol/beverage control boards, or stand-alone regulatory agencies

7

Guiding principles for cannabis regulatory agencies (generally)

- Consumer safety
- Public health and safety
- Equity
- Market stability
- Economic growth

8

What do regulated cannabis markets look like?

- Regulation through: Departments of health, revenue, consumer protection, alcohol/beverage control boards, or stand-alone regulatory agencies
- Licensed entities that grow, process, deliver, and sell cannabis
  - For adult use, adult-only retail stores that sell cannabis and cannabis products
- Regulations for:
  - Licensing
    - Small/craft business, equity operated business
  - Allowable products
  - Product safety, ingredients and additives, and product testing
  - Packaging and labeling
  - Advertising
  - Point of sale environment
  - Seed to sale tracking systems, monitoring
  - Inspections and compliance
- Public education and stakeholder engagement process

9

Cannabis Legalization 3.0 (and beyond)

- Shift from ballot measures to legislative measures
- Broader focus than Cole Memo era
- Increased focus on:
  - Public health & consumer safety
  - Social equity and restorative justice
  - Parity in regulations across cannabis (medical, adult use, hemp)

Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products

The Washington Post — As more states legalize marijuana, more children accidentally ingest THC-laced edibles

THE DENVER POST — Despite legalization, people of color still disproportionately targeted for marijuana, new studies say

Forbes — How Hemp And The Farm Bill May Change Life As You Know It

10

Policies to protect public health are those that:

1. Promote equity
2. Promote consumer safety
3. Prevent youth access

11

Policies to Promote Social and Economic Equity

- EQUITY IN THE MARKETPLACE
- EXPUNGEMENT AND RECORD CLEARANCE
- COMMUNITY REINVESTMENT

12

Slide 13
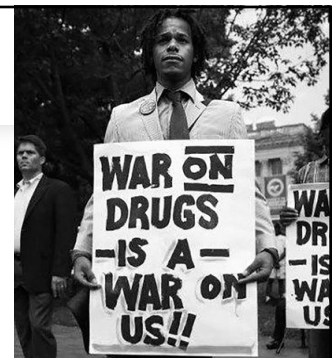
Policies to Promote Consumer Safety and Prevent Youth Access

PRODUCT COMPOSITION AND SAFETY

PRODUCT PACKAGING, LABELING AND ADVERTISING

THE RETAIL AND CONSUMPTION ENVIRONMENT

13

Slide 14
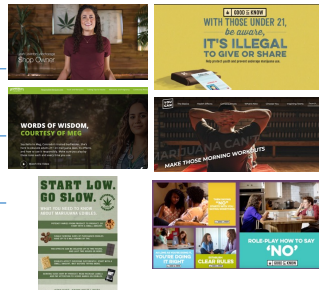
Policy Research Challenges

14

Slide 15

Challenge #1:
Legalization is not binary

15

Slide 16

Legalization is usually measured as binary

- Policy research often models cannabis policy as:
  - Not legal
  - Legal for medical only
  - Legal for medical and adult use

- What's needed are strength level variables or indices to measure deeper constructs that may impact the outcome. For example:
  - **Access** (e.g, limited licensing? # retail stores/capita? proximity to stores?)
  - **Consumer safety** (e.g., testing requirements, warning labels, serving sizes)
  - **Youth prevention focused policies** (e.g., packaging, advertising, access, point of sale)

16

Slide 17

Example of the complexity & variation in policy

Variables likely to impact "Access"

- License caps or limits on licenses
  - e.g, Arizona, California (localities), Colorado (localities), Connecticut, Illinois, Massachusetts, Maryland, Montana, Nevada
- Zoning laws and opt-outs
  - e.g., opt outs in California, Massachusetts, New Jersey, New York
  - Most municipalities can change state zoning requirements
- Types of products allowed
  - e.g., caps on concentrates in Connecticut and Vermont (and potential implications)
- Delivery (for adult use)
  - e.g., not allowed in: Washington, New Jersey, Montana, Illinois, Arizona, Alaska
- Home grow (for adult use)
  - e.g., not allowed in: Washington, New Jersey, Illinois, Connecticut

Map of Local Zoning Ordinances for State-Licensed Cannabis Businesses in Washington State
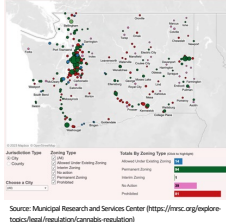
Source: Municipal Research and Services Center (https://mrsc.org/explore-topics/legal/regulation/cannabis-regulation)

17

Slide 18

Example of the complexity & variation in policy

Variables likely to impact "Consumer Safety":

- Ingredients and additives
  - e.g., State bans on additives/excipients/diluents
  - A quick note about terpenes (NV Guidance)
- Testing requirements
  - What contaminants are tested? At which thresholds? What is the testing scheme?
- Warning labels
  - Every state has a different warning
- Serving size
  - 5mg or 10mg/serving, 50mg or 100mg/package

18

Slide 19

Example of the complexity & variation in policy

Variables likely to impact youth prevention

Cannabis packaging requirements in adult use states:
- Plain or uniform packaging
  - Connecticut, Massachusetts, New Jersey, Maryland, Missouri
    - "plain and opaque" vs. "uniform"
- Should not appeal to kids or people under age 21
  - "no bright colors" "no cartoons" "no bubble font" "cannot mimic existing commercial food product"
  - Wide variety in interpretation and implementation

Advertising requirements in adult use states
- Audience requirements:
  - Prohibited except in electronic advertising → Montana
  - Prohibited unless subscription service for adults only → New Mexico
  - Prohibited if likely to reach person under 21 → Maine
  - >90% audience 21+ → Connecticut, New York
  - >85% audience 21+ → Maryland,
  - >71.6% audience 21+ → most other states

19

Slide 20

Challenge #2:
Implementation timeline matters!

20

Slide 21

Timeline of Adult Use Cannabis Legalization, by State

State	Year adult use legalization passed	Ballot measure (% support) OR legislative passage	Date retail marketplace opened
CO	2012	Ballot measure (55%)	January 2014
WA	2012	Ballot measure (56%)	July 2014
OR	2014	Ballot measure (56%)	October 2015 (through medical dispensaries)
AK	2014	Ballot measure (53%)	October 2016
DC	2014	Ballot measure (65%)	No retail marketplace approved
CA	2016	Ballot measure (56%)	January 2018
ME	2016	Ballot measure (50%)	October 2020 (through medical dispensaries)
MA	2016	Ballot measure (54%)	November 2018
NV	2016	Ballot measure (54%)	July 2017 (through medical dispensaries)
VT	2018	Legislative	October 2022
MI	2018	Ballot measure (56%)	December 2019
IL	2019	Legislative	January 2020 (through medical dispensaries)
AZ	2020	Ballot measure (60%)	January 2021 (through medical dispensaries)
MT	2020	Ballot measure (57%)	January 2022 (through medical dispensaries)
NJ	2020	Ballot measure (67%)	April 2022
NY	2021	Legislative	December 2022
VA	2021	Legislative	No retail marketplace approved
NM	2021	Legislative	April 2022
CT	2021	Legislative	January 2023 (through hybrid dispensaries)
RI	2022	Legislative	December 2022 (through medical dispensaries)
MO	2022	Ballot measure (53%)	February 2023
MD	2022	Ballot measure (67%)	July 2023
DE	2023	Legislative	Expected late 2024
OH	2023	Ballot measure (57%)	Expected late 2024

Legalization ≠ legal retail

Delayed market opening
(2 months to 2+ years)

Illicit sources may increase after legalization but before market opening

21

Slide 22

A good example of why this matters

Am J Public Health. 2019 September; 109(9): 1294–1301.
Published online 2019 September. doi: 10.2105/AJPH.2019.305191   PMCID: PMC6687243   PMID: 31316668

Post-Legalization Opening of Retail Cannabis Stores and Adult Cannabis Use in

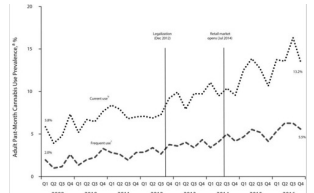Abstract   Go to: +

Objectives. To assess the relationship between adult cannabis use and time-varying local measures of retail cannabis market presence before and after legalization (2012) and market opening (2014) in Washington State.

Methods. We used 2009 to 2016 data on 85 135 adults' current (any) and frequent (20 or more days) past-month cannabis use from the Washington Behavioral Risk Factor Surveillance System linked to local retailer proximity and density. Multilevel models predicted use over time, accounting for nesting within communities.

Results. Current and frequent cannabis use grew significantly between 2009 and 2016; use did not significantly change immediately after legalization but increased subsequently with greater access to cannabis retailers. Specifically, current use increased among adults in areas within 18 miles of a retailer and, especially, within 0.8 miles (odds ratio [OR] = 1.45; 95% confidence interval [CI] = 1.24, 1.69). Frequent use increased among adults living within 0.8 miles of a retailer (OR = 1.43; 95% CI = 1.15, 1.77). Results related to geospatial retailer density were consistent.

Conclusions. Increasing cannabis retail access was associated with increased current and frequent use.

Public Health Implications. Policymakers might consider density limits as a strategy for preventing heavy cannabis use among adults.

Figure 1 displays Washington statewide adult cannabis use prevalence over time. Quarterly current use prevalence more than doubled over the course of our study, increasing from 5.8% in quarter 1 of 2009 to 13.2% in quarter 4 of 2016; frequent use increased over that period as well, from 2.0% to 5.5%.

22

Slide 23

Policy changes frequently, so timeline for policy implementation matters, too!

23

Slide 24

Policy changes frequently, so timeline for policy implementation matters, too!
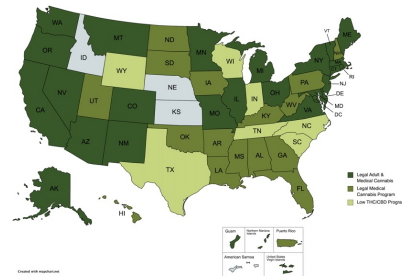

24

Challenge #3:
Unit of Measure

25

Cannabis legalization policy, by state, November 2023

26

But local opt-out is common

Allow: 44%
Cities and counties allow at least one cannabis business type.

Prohibit: 56%
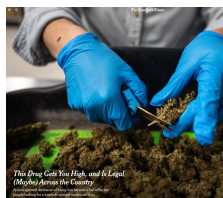Cities and counties prohibit all cannabis business types.
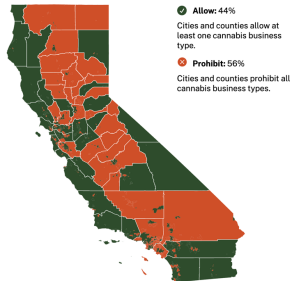
27

And local regulations can vary from state

- Time, place, manner
- Zoning and land use
- Business license costs and requirements
- Number of businesses (caps)
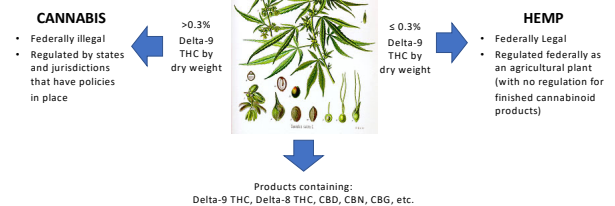- Hours of operation
- Onsite consumption

28

Challenge #4:
Hemp-Derived Cannabinoids

29

Federal Status of *Cannabis Sativa L.* in the United States

CANNABIS
- Federally illegal
- Regulated by states and jurisdictions that have policies in place

>0.3% Delta-9 THC by dry weight

≤ 0.3% Delta-9 THC by dry weight

HEMP
- Federally Legal
- Regulated federally as an agricultural plant (with no regulation for finished cannabinoid products)

Products containing:
Delta-9 THC, Delta-8 THC, CBD, CBN, CBG, etc.

30

2018 Farm Bill

2018 Farm Bill Legalized:

"The plant species 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 THC concentration** of not more than 0.3% on a dry weight basis."

Named USDA as the regulator of hemp crops and regulation of farming; did not specifically and clearly name a regulator for hemp-derived products (processing, retail, etc.).

31

What are we seeing on the market?

32

Three main loopholes

1) **Derivatives loophole -** Chemically derived impairing cannabinoids (Delta-8, Delta-10, HHC, THCO, etc.)
2) **TCHA loophole –** Products being marketed with high levels of THCA that are indistinguishable from cannabis products.
3) **0.3% loophole -** Impairing amounts of Delta-9 THC in products that meet the legal definition of "hemp" per the 2018 farm bill.
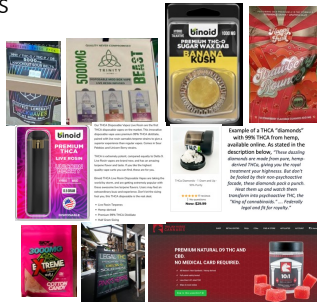
33

## Consumer safety and youth access issues

- Not subjected to the same packaging, labeling requirements
- Not subjected to the same testing requirements
  - Some new cannabinoid products have no data from use in humans
  - Potentially dangerous manufacturing
  - Unknown byproducts
- Widely available in retail outlets and online → widely available to youth

34

Youth access

- Available in general population stores (gas stations, drug stores, grocery stores, coffee shops, etc.)
- Widely available online with no or limited age-gates
- Further blurs the line with illicit market products
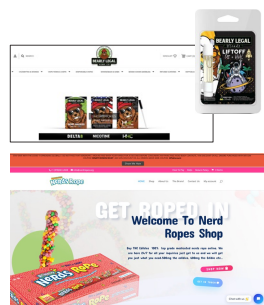
35

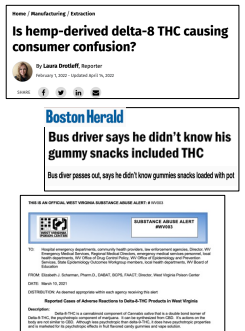## Updated adverse event data from CDC/FDA

- National Poison Center Data between Jan 1, 2021 and Feb 28, 2022:
  - 2,362 exposure cases
  - 41% involved pediatric patients less than 18 years of age
  - 40% involved unintentional exposure to Delta-8 (and 82% of these unintentional exposures impacted pediatric patients)
  - 70% of cases required health care facility evaluation, 8% of those resulted in admission to critical care (45% of patients requiring evaluation were pediatric patients)
  - One pediatric case was coded with a medical outcome of death

Source: U.S. FDA "5 Things to Know about Delta-8 Tetrahydrocannabinol". Available from: https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc

36

Confounds policy data

- Consumers may not know what they are consuming to report accurately on state and federal data monitoring and surveillance.
  - No requirement to list cannabinoids in product
  - Increasing trend for online sales to just list "hemp" (e.g., 1000mg hemp)
- Adverse events reporting may not be granular enough to know what caused the effect.
- Major policy and regulatory differences.

Home / Manufacturing / Extraction

Is hemp-derived delta-8 THC causing consumer confusion?

By Laura Drotleff, Reporter
February 1, 2022 - Updated April 14, 2022

Boston Herald

Bus driver says he didn't know his gummy snacks included THC

Bus diver passes out, says he didn't know gummies snacks loaded with pot

37

State legislation to protect consumer safety and public health has been met with lawsuits

Alaska Beacon

Hemp growers sue Alaska agriculture officials in attempt to keep hemp products legal

Home / Legal

Hemp companies sue to overturn Arkansas ban on delta THC products

By MJBizDaily Staff
August 2, 2023

VIRGINIA MERCURY

Hemp businesses sue governor, administration over new law

Lawsuit seeks to block Virginia's stricter hemp laws

Suit alleges state 'THC limits' putting it out of business

SunSentinel

Fort Lauderdale

Louisiana's largest CBD manufacturer sues state to keep products on shelf. Here's why.

Greg Hilburn
Lafayette Daily Advertiser

Courthouse News Service

Hemp advocacy group, extract producer seek clarity on status of low-THC products in Indiana

38

Conclusions

- Policy data and regulatory science is urgent and needed
- Policy in the US is complex, heterogeneous, and constantly changing
- Many current studies are subject to major limitations, biases, and confounding because of this nuanced landscape
- Failure to account for these major limitations could lead to false and invalid conclusions that future policy will be based on
- Best practices for how to conduct through cannabis and hemp-related policy studies is urgently needed
- A robust, longitudinal, policy tracking system is urgently needed – and ideally one that extends beyond state level variables
- Validated scales and indices are needed to better model cannabis policy variables

39

Thank you!

40