

Lessons Learned in Regulating Cannabis for Public Health and Safety

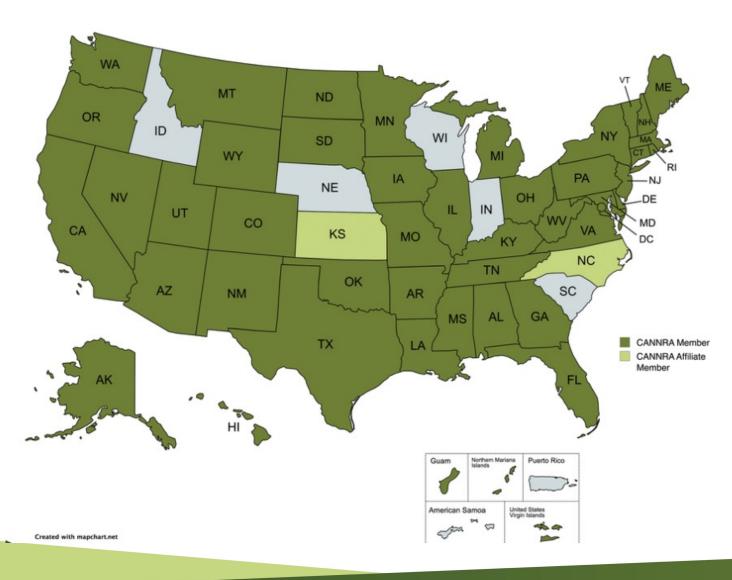
Gillian L. Schauer, PhD, MPH Executive Director, CANNRA Presentation to the North Carolina Advisory Council on Cannabis July 29, 2025

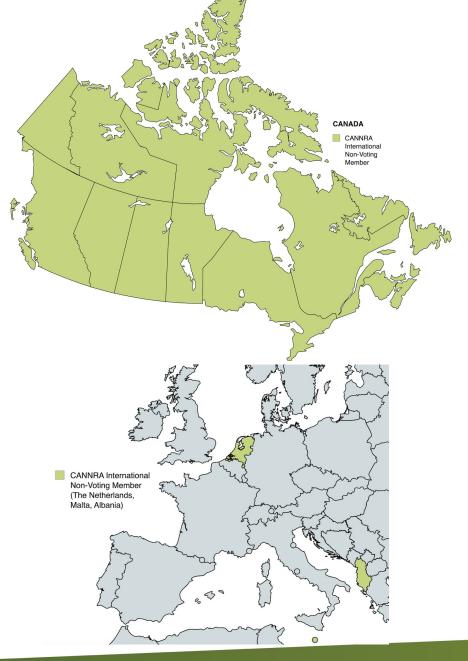
Disclosures

I do not have any external funding sources to disclose and do not take funding from the pharmaceutical, alcohol, tobacco, or cannabis industries.

While this presentation highlights some of the current regulatory work happening across states, the findings in this presentation do not represent an official position of CANNRA or of any of our individual member states or territories.

CANNRA Members

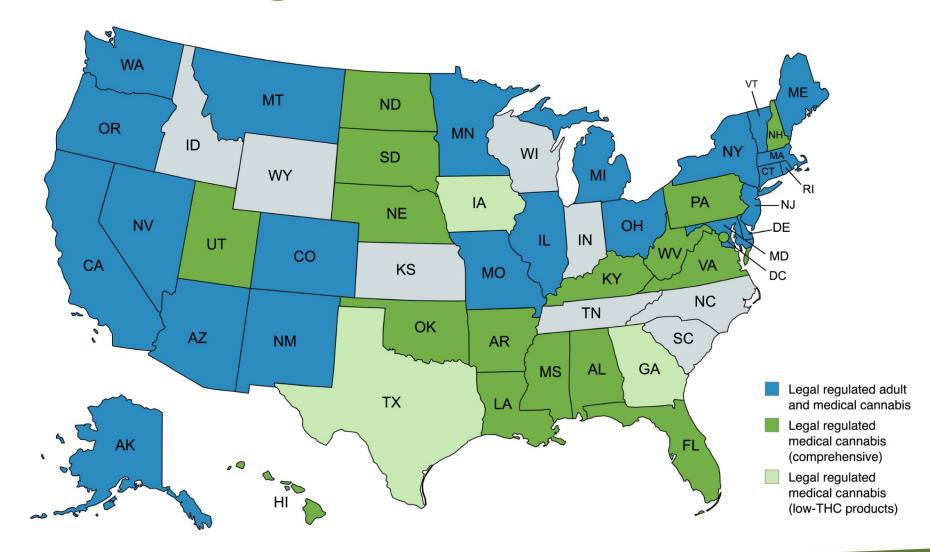




Overview

- Context and Evolution of Legalization
- What do regulated marijuana markets look like?
- Best practices and suggestions for regulating cannabinoids
- Conclusions and next steps
- Q&A

State cannabis legalization



Context in which state-based legalization has occurred

- Marijuana is coming out of almost 100 years of prohibition
- Marijuana (cannabis) is still federally illegal
- Markets must be confined within a particular state (seed to sale)
- The industry is innovative and fast moving (faster than science)
- State regulatory agencies have been limited in their resources given the needs
- Federal agencies have limited to no engagement in state regulated markets



Evolution of the state-regulated cannabis landscape

U.S. Donortment of Justice

Office of the Deputy Attorney General

The Design Lawrence Comm

Washington, D.C. 20530

August 29, 2013

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

ROM: Jan

James M. Cole Deputy Attorney General

SUBJECT: Guidance Regarding Marijuana Enforcement

In October 2009 and June 2011, the Department issued guidance to federal prosecutors concerning marijuana enforcement under the Controlled Substances Act (CSA). This memorandum updates that guidance in light of state ballot initiatives that legalize under state law the possession of small amounts of marijuana and provide for the regulation of marijuana production, processing, and sale. The guidance set forth herein applies to all federal enforcement activity, including evil enforcement and criminal investigations and prosecutions, concerning marijuana in all states.

As the Department noted in its previous guidance, Congress has determined that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal enterprises, gangs, and carels. The Department of Justice is committed to enforcement of the CSA consistent with those determinations. The Department is also committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational way. In furtherance of those objectives, as several states enacted laws relating to the use of marijuana for medical purposes, the Department in recent years has focused its efforts on certain enforcement priorities that are particularly important to the federal government:

- · Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels:
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;

















Guiding principles for cannabis regulatory agencies (generally)



What do regulated marijuana 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, and sell cannabis
 - For adult use, adult-only retail stores that sell cannabis and cannabis products
- Regulations for:
 - Product safety, ingredients, and product testing
 - Packaging and labeling
 - Advertising
 - Point of sale environment
 - Inspections and compliance
- Public education and stakeholder engagement approaches
- Data monitoring and analyses
- Frequent changes to policy and procedures even in established states

Are there best practices for regulating marijuana?



CANNABIS REGULATORS ASSOCIATION

BEST PRACTICES AND GUIDANCE FOR REGULATING CANNABINOIDS FOR SAFETY

OVERVIEW & PURPOSE

The Cannabis Regulators Association (CANNRA) convenes government agencies regulating cannabis and cannabinoids across more than 45 states and U.S. territories, Canada, and the Netherlands. As a body of government regulatory agencies, CANNRA members have unique insight and experience regulating cannabinoids for consumer safety and public health. While individual government jurisdictions take their own approaches to cannabis and cannabinoid regulation, this document aggregates and distills the regulatory approaches that CANNRA members collectively have identified as best practices to protect consumer

METHODS

CANNRA convened discussions with members to identify areas representing the minimum requirements for regulating cannabinoids to protect consumer safety. Members were asked to engage in discussions based on their expertise and experience, not based on the specific policies their state or jurisdiction had implemented in their regulatory scheme. These best practices were discussed, debated, and refined by members and represent a general position, and not the individual perspectives of any one regulatory agency or government jurisdiction.

BEST PRACTICES IN REGULATING CANNABINOIDS FOR SAFETY

CANNRA members identified seven major categories that are important for regulating cannabinoids for safety, each of which include a number of elements and best practices:

LICENSING AND/OR REGISTRATION OF CANNABINOID PROCESSORS, MANUFACTURERS, AND RETAILERS

As in other regulated industries, licensing and registration requirements:

- Allow for consistent application of minimum standards to operate
- Support transparency by enabling the public to identify approved operators
- Define the scope of regulatory enforcement authority in cases of non-compliance

PROCESSING AND MANUFACTURING STANDARDS

Processing and manufacturing standards encompass a range of elements to promote safety, including:

- Compliance with general jurisdictional requirements related to worker safety, energy and environment codes. building codes, fire codes, waste disposal, and other specialty codes
- Use of cannabinoid ingredients from approved source(s), as determined by the regulating jurisdiction
- Use of other non-cannabinoid ingredients that comply with regulatory requirements and safety data
- Standards that establish allowable use of solvents, reagents, and media for extraction, purification, and chemical conversion or synthesis, as permitted by the regulating jurisdiction
- Quality control and quality assurance procedures and systems (e.g., cGMP) to support proper monitoring and control of manufacturing and processing facilities and equipment, including appropriate record keeping systems (e.g., for standard operating procedures, equipment calibration and maintenance, employee training, etc.)
- Testing of cannabinoids and cannabinoid products in final form and, as appropriate, in input or intermediate form to identify contaminants, byproducts, and purity
 - Testing should include a certificate of analysis (COA)
 - o Post market testing should be conducted as needed to ensure the product continues to meet required

 Mechanisms to facilitate recalls, including labeling and record-keeping requirements to allow for the identification of all affected products

AGE-GATING FOR CANNABINOID PRODUCTS

- Particularly products that could be intoxicating
- · Preferably in adult-only or primarily adult retail environments, with strict requirements for age verification in ecommerce or in-person delivery

PRODUCT FORM, DOSE, AND CONTENT REGULATIONS

These practices are aimed at reducing the risk of accidental overconsumption, unintended consumption, and adverse events, and include:

- Limits or restrictions on cannabinoids based on safety data and scientific knowledge about their use in humans
- Limits on cannabinoids per serving and servings per container
- Restrictions on allowable product forms based on safety and risk
- Restrictions on additives, excipients, diluents, and other non-cannabinoid ingredients that may have health and safety implications for the specific mode of consumption

PACKAGING AND LABELING REGULATIONS

These practices are focused on fully informing the consumer and avoiding appeal to children, and include:

- . Labeling that fully informs the consumer about the active ingredients in the product, including the recommended serving size, active ingredients per serving (in milligrams), and servings per container
- Methods to communicate product test results and other safety information to consumers (e.g., through QR codes,
- . Relevant warnings displayed prominently on the label in legible font, using easy to understand language
- Labeling that does not make false or unsupported claims
- · Packaging and labeling that does not appeal to children
- Packaging and labeling that does not mimic non cannabinoid commercial items
- Packaging that is child-resistant as appropriate for product forms and intoxication potential

ADVERTISING REGULATIONS

- Advertising that is not designed or implemented in a way that targets or appeals to children
- Advertising that is not misleading and does not make false or unsupported claims
- · Advertising that includes any relevant warnings

EDUCATION, COMPLIANCE, AND ENFORCEMENT PROGRAMS

• To ensure compliance with minimum standards and regulations in place in the jurisdiction

CONCLUSION

In conclusion, based on the experience and expertise of CANNRA members, there are a range of cannabinoid and cannabinoid product regulations that are warranted to protect consumers and public health. These include licensing and registration. processing and manufacturing standards, age-gating, product form, dose, and content regulations, packaging and labeling regulations, advertising regulations, and education, compliance, and enforcement programs. Because the cannabinoid industry is dynamic and each of these regulatory areas is complex, statutes should provide for regulatory flexibility, allowing regulators to respond appropriately to protect consumer safety in the evolving marketplace

CANNRA is a national, nonpartisan, nonprofit 501(c)(4) association of government agencies involved in cannabis and cannabinoid regulation across more than 45 states and US territories, Canada, and the Netherlands. This guidance document is intended to provide educational information and is not a formal policy position of CANNRA or of any of the CANNRA member jurisdictions

www.cann-ra.org | info@cann-ra.org

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- The timeline for implementation matters a lot

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- Consider a single agency for regulation of any cannabinoids
- Cross agency collaboration is essential

Commentary

Experimenting with Pot: The State of Colorado's Legalization of Marijuana

GOVERNOR JOHN W. HICKENLOOPER

State of Colorado

N NOVEMBER 6, 2012, VOTERS IN COLORADO AND Washington moved to legalize the use and sale of marijuana by adults 21 and older. The passage of Amendment 64, which amended the Colorado constitution, and Initiative 502, which amended the Revised Code of Washington, marked "an electoral first not only for America but the world." In response to the legalization of recreational marijuana, Colorado is taking a proactive approach. We are working as a convener for all interested parties and experts to shape public policy that utilizes the decades of public health lessons gained from regulating alcohol and tobacco. We have applied these lessons to marijuana and are making every effort in our laws, regulations, and revenue allocations to address public health and safety concerns, prevent young people's use of marijuana, and educate parents and children about the risks of its use.

While Colorado and Washington are the first states to legalize marijuana for recreational purposes, since the 1970s, the national trend has moved toward decriminalization, increased social acceptance, and legalization for medical use. Today, more than half the states in the United States have decriminalized the possession of small amounts of marijuana, approved it for medical use, or legalized it completely. Numerous other states—both liberal and conservative—are considering legalization, indicating that the recreational use of marijuana is no longer a partisan issue. Colorado and Washington are at the forefront of these national trends, and the establishment of rules, regulations, and a policy framework that protects the public's health and safety and prevents underage use will set a baseline for other states' marijuana laws.

Colorado voters passed Amendment 64 with 55% of the vote. Although our administration opposed the legalization of adult-use marijuana, we are committed to fulfilling the will of the voters and directing the responsible regulation of this nascent industry. One of our first steps

The Milbank Quarterly, Vol. 92, No. 2, 2014 (pp. 243-249) © 2014 Milbank Memorial Fund. Published by Wiley Periodicals Inc

2/2

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ILLINOIS

LET'S TALK CANNABIS

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- Consider consumer education campaigns that have a harm reduction approach













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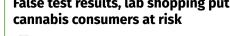


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Which policies are essential for consumer safety and public health?

- Product type and forms do you want to provide regulated access to everything? What are the implications if you do not?
- Ingredient regulation (with final form product in focus)
- Lab testing (and challenges in current lab structure; benefits of reference labs)
- Packaging and labeling that:
 - Includes universal symbol
 - Includes relevant warnings (consider rotating warnings)
 - Includes QR code to Certificate of Analysis
 - Properly labels ingredients, allergens, etc.
 - Does not appeal to kids, risk accidental ingestion
 - Does not include false or unproven information
- Advertising and marketing considerations
- Consumer education

















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- Consider other markets....and it is ESSENTIAL to address cannabinoid hemp

Cannabinoid Markets in the U.S.

Legacy/Illicit

- Interstate commerce
- Not taxed or regulated
- Federally illegal
- Many different markets

Hemp

- Interstate commerce
- Generally, finished products are not taxed or regulated
- Federally legal

State-Regulated "Marijuana"

- No interstate commerce
- Heavily Taxed and Regulated
- Federally illegal

Federal Status of Cannabis Sativa L. in the United States

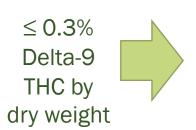
CANNABIS

- Federally illegal
- Regulated by states that have policies in place



>0.3% Delta-9 THC by dry weight





HEMP

- Federally Legal
- Regulated federally by USDA as an agricultural plant



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

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."

The Act did not name a regulator for finished cannabinoid products.

It noted that "nothing in this subtitle shall affect or modify the Federal Food, Drug, & Cosmetics Act," or the authority of the Commissioner of Food and Drugs and the Secretary of HHS but did not specifically and clearly name a regulator for hemp-derived products (processing, retail, etc.).

What are we seeing on the market?



























★★★★ 29 reviews
No questions
MSRP: \$40.00
\$19.99



★★★★↑1 review | No questions

\$29.99

Three main regulatory gaps

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

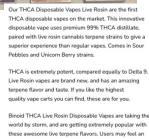


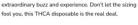
binoid

PREMIUM THCA

LIVE ROSIN







- · Live Rosin Terpenes
- Hemp-derived
- Premium 99% THCA Distillate
- Half Gram Sizing







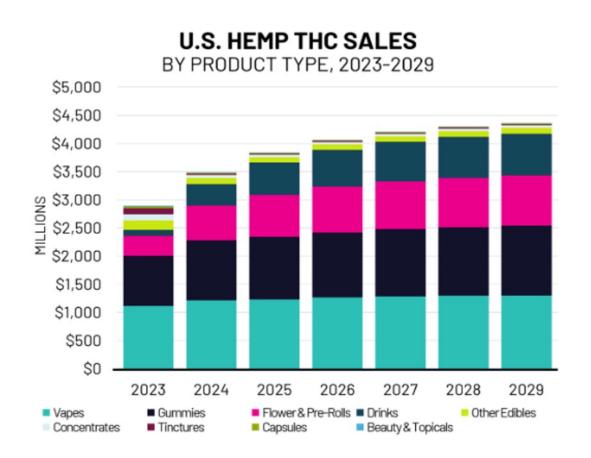


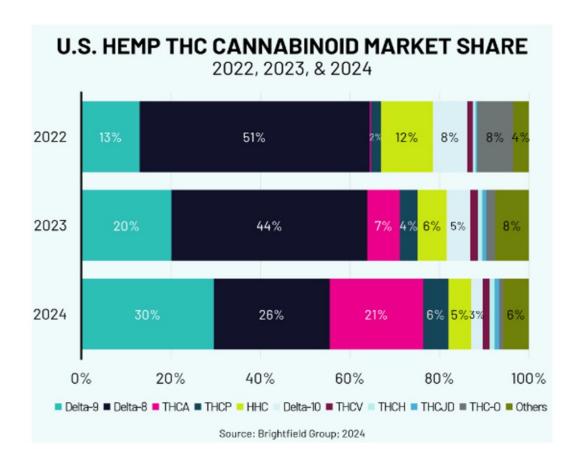




Hemp-Derived/Intoxicating Marketplace







Slide publicly available from FDA

Source: Brightfield Group 2024

Consumer Safety Concerns

- Consumer confusion
- Molecules that are new and unknown
- Lack of product testing and oversight
- No federal regulation over finished products for safety
- Medical claims that are not approved by the FDA and/or supported by research
- Potency, serving sizes and package limits that far exceed the regulated marijuana market



Pain Relief Hemp Gummies to Kick Pain in the Butt

Pain, meet your match with these hemp gummies for pain, formulated with a spicy combination of hemp and adaptogens. This hemp for pain formulation is a full-strength combination of full-spectrum hemp and Ginger Extract, an anti-inflammatory, to help you give pain the kick in the butt it needs.





Vinoid

DELTA 8 V DELTA 9 THCA HHC-P V THC-P V THC-B

HHC-P PRODUCTS

Buy HHC-P products online including vape cartridges, disposables, tinctures, and more below.

HHC-P is a new legal category that is hemp-derived, Made In The USA, and 100% Natural. HHC-P is a lot stronger than other THC cannabinoids and equal strength to THC-P as the HHC equivalent. It is not to be confused with Delta 9 THC.

Youth Appeal and Access











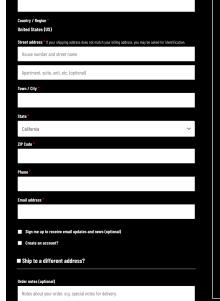


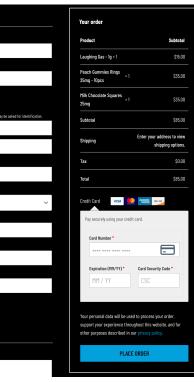






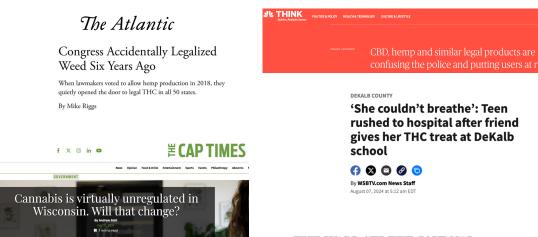
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State Regulatory Challenges from the Current Landscape

- No or limited state regulatory authority over cannabinoid hemp products
- Lack of research to help guide regulatory decisions on many of these molecules; insufficient surveillance for current landscape
- Increased challenges understanding data on safety and adverse events
- Enforcement challenges
- Increasingly blurred lines with the illicit market; increased cartel activity
- Diversion and inversion



THE WALL STREET JOURNAL.

Hemp Gummies Are Sending Hundreds of Kids to Hospitals

Surge of THC products, vapes has states struggling to regulate the booming market



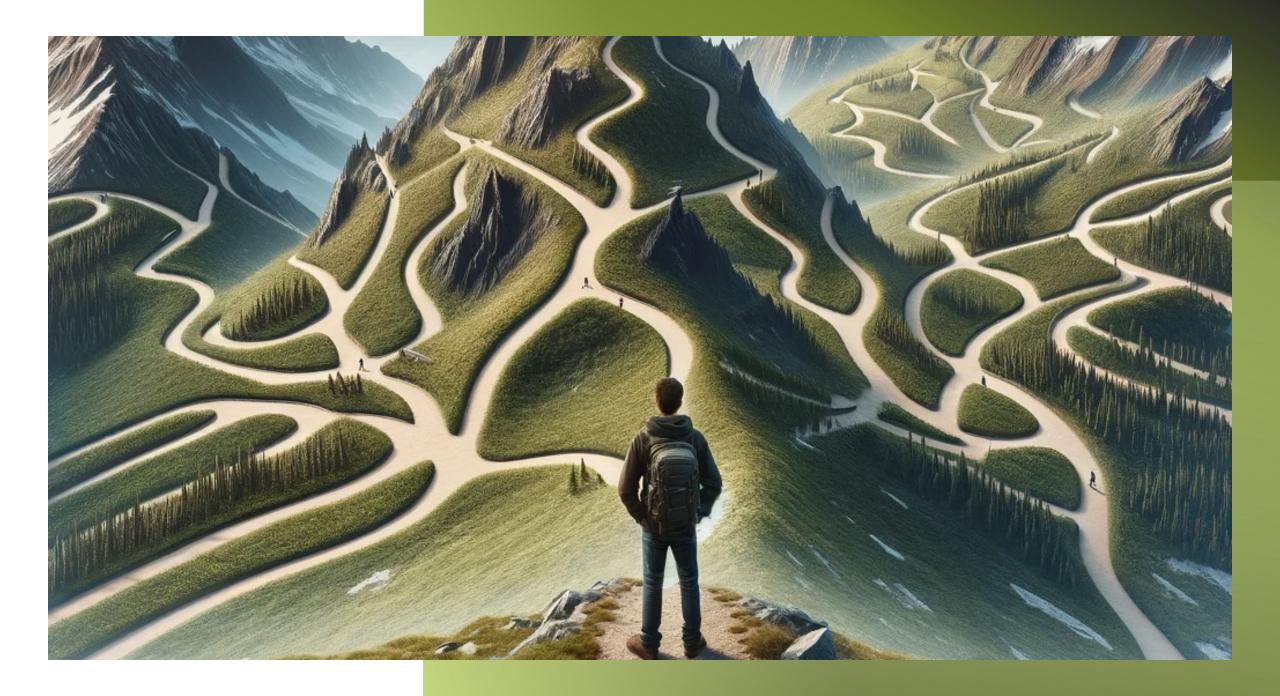
By Rhyma Castillo, Staff writer Dec 23, 2024

To residents of Cave Junction, the legacy of legal weed is a pattern of extraction and

exploitation that recalls the boom years of the timber industry. But this time, the

and 'no one's gonna stop them,' ag commish says





Isn't cannabis just like...

Commercial Tobacco



Similarities:

- Populations
- Mode of use/products
- Industry
- Policy overlap

Differences:

- No accepted medical uses for commercial tobacco
- Not intoxicating
- > Addiction potential
- > Morbidity and Mortality

Alcohol



Similarities:

- Prohibition → Legality
- Policy overlap
- Industry
- Impairing
- Addiction potential

Differences:

- Mode of use
- > Morbidity and Mortality



Opioids



Similarities:

- Medical uses
- Produced by our bodies
- Impairing
- Industry

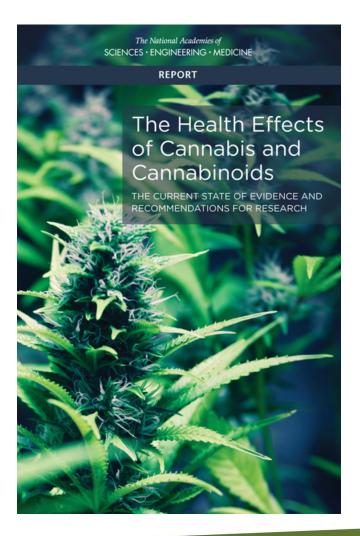
Differences:

- Respiratory depression
- > Addiction potential
- > Morbidity and Mortality

Scientific support for medical cannabis



The health and social effects of nonmedical cannabis use







Policies - Products, Place, Promotion

















Research finds that cannabis smoke contains many of the same carcinogens as tobacco smoke

Chem. Res. Toxicol. 2008, 21, 494-502

A Comparison of Mainstream and Sidestream Marijuana and Tobacco Cigarette Smoke Produced under Two Machine Smoking Conditions

David Moir,*,† William S. Rickert,‡ Genevieve Levasseur,§ Yolande Larose,^
Rebecca Maertens,† Paul White,† and Suzanne Desjardins^

Safe Environments Programme, Tobacco Control Programme, and Drug Strategy and Controlled Substances
Programme, Health Canada, Ottawa, ON, Canada K1A 0K9, and Labstat International Inc.,
Kitchener, ON, Canada N2C 1L3

Received July 31, 2007

Table 3. Various Analytes Including Tobacco-Specific Compounds and Heavy Metals Determined in Mainstream Smoke from Tobacco and Marijuana under Two Smoking Conditions^a

	ISO		extreme	
	tobacco	marijuana	tobacco	marijuana
tar (mg/cig)	38.2 ± 2.2	37.4 ± 4.5	80.3 ± 5.6	$103 \pm 11*$
pH	5.5 ± 0.05	$7.21 \pm 0.17*$	5.47 ± 0.04	$7.73 \pm 0.10*$
NO (μg/cig)	65.7 ± 8.9	$296 \pm 33*$	151 ± 10	$685 \pm 58*$
NOx (µg/cig)	68.2 ± 9.2	$302 \pm 33*$	158 ± 10	$693 \pm 58*$
CO (mg/cig)	20.8 ± 1.9	$13.4 \pm 1.6*$	41.5 ± 4	$35.3 \pm 2.9*$
nicotine (mg/cig)	2.44 ± 0.18	$0.005 \pm 0.011*$	5.2 ± 0.39	0.002-0.007*
ammonia (µg/cig)	35.5 ± 2.4	$720 \pm 84*$	67 ± 9.9	$1315 \pm 106*$
HCN (µg/cig)	208 ± 24	$526 \pm 46*$	320 ± 29	$1668 \pm 159*$
NNN	87.6 ± 4.4	<1.49*	160 ± 15	<1.49*
NAT	71 ± 3.4	<1.87*	125 ± 9	<1.87*
NAB	5.68 ± 0.42	<0.063*	8.26 ± 0.47	0.063-2.00*
NNK	86.7 ± 5.2	<3.72*	158 ± 15	<3.72*
mercury	3.17 ± 0.32	<1.10*	5.35 ± 0.52	$3.51 \pm 0.31*$
cadmium	145 ± 8	$6.91 \pm 1.34*$	284 ± 7	$14.6 \pm 1.2*$
lead	21.1 ± 1.1	3.85-12.8*	43.8 ± 2.9	7.7-25.7*
chromium	5.94 - 19.8	5.94 - 19.8	11.9 - 39.6	11.9-39.6
nickel	6.47 - 21.6	6.47 - 21.6	12.9 - 43.1	<12.9
arsenic	5.49 ± 0.33	1.13-3.75*	12.7 ± 0.9	2.25-7.49*
selenium	2.21 - 7.37	2.21 - 7.37	4.42 - 14.7	4.42 - 14.7

UCSF Dr. Suzaynn Schick's "combo plate approach" to PM_{2.5} Control (at least one item from each column)

Reduce

- 1. Limit capacity
- 2. Non-combustible methods only

Contain

- Separate consumers from <u>all</u> other customers and employees
- Exhaust hood over consumer
- 2. Enclosed one-person booths

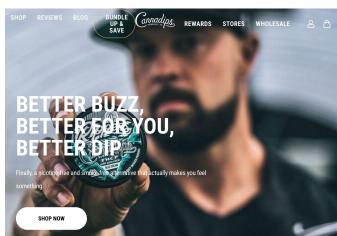
Remove

- 1. Ventilate
- 2. Take it outdoors

Devices and products















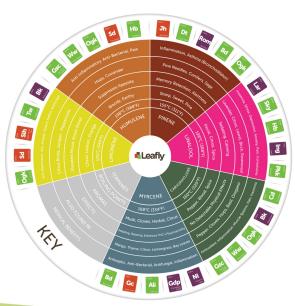


Important differences between nicotine & cannabis vaping

- Nicotine is liquid soluble, THC is fat soluble
 - Temperature differences for aerosolization
- Additives differ
 - Excipients/diluents
 - Flavors need to be approached differently







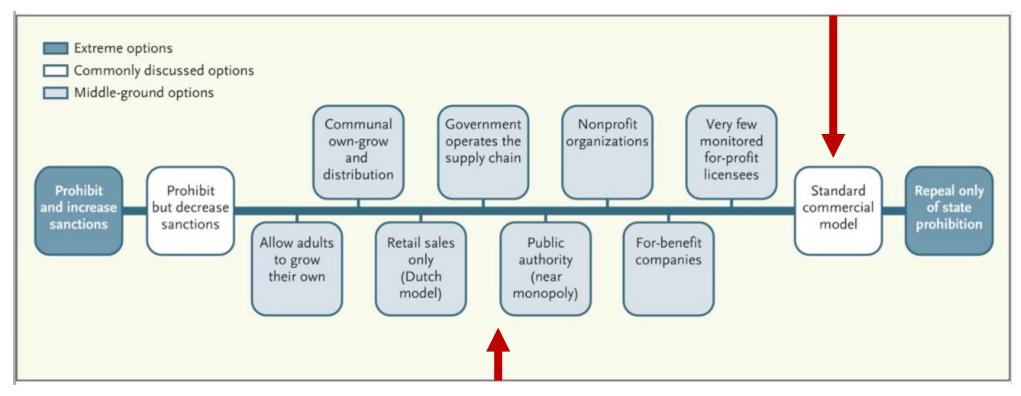








A range of cannabis legalization frameworks...



Citation: Kilmer, B. Recreational Cannabis – Minimizing the Health Risks from Legalization (2017) New England Journal of Medicine; 376 (8): 705-707

What can you do now?

- Identify the core things North Carolina wants as part of any regulatory mission (e.g., consumer safety, public health, equity, small business promotion, etc.)
- Think strategically about the market you want to have and how it might change over time
- Research different regulatory models and recognize that no two are the same (and no one has gotten it perfect)
- Listen to a diverse array of stakeholder groups – identify areas of overlap
- Collect baseline data and support research where you can (we don't have enough!)



Contact me:

info@cann-ra.org