VERMONT MEDICAL SOCIETY THIRD THURSDAY WEBINAR SERIES



Date: March 12, 2020

Title of Talk: CBD Oil: Fact vs. Fiction

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CME credit must be claimed within 30 days of participating in the event.

VMS Third Thursday Webinar Series "CBD Oil: Fact vs. Fiction"

Speakers:

Alan J. Budney, PhD

Planning Committee Members:

Jessa Barnard, ESQ, Stephen Leffler, M.D.& Stephanie Winters

Purpose Statement/Goal of This Activity:

To discuss what is *actually known* about cannabinoids, particularly when addressing medical issues.

Learning Objectives:

To educate participants further on the many facets of cannabinoids and THC today.

Disclosures:

Is there anything to Disclose? Yes No

Did this activity receive any commercial support? Yes No



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CBD Oil: Fact vs. Fiction

(and related Cannabis/Cannabinoid Issues)

Alan J. Budney, PhD

Dartmouth College, Geisel School of Medicine

Center for Technology and Behavioral Health

Vermont Medical Society
Webinar Series
March 2020

Disclosures

- Training and Research: funded for ~ 30 years by *NIH-NIDA*
- National Advisory Council / Scientific Advisory Board: Center for Medical Cannabis Research (UCSD), State of CA
- Tilray Pharmaceuticals DSMB: THC/CBD trial
- DSM-5 Substance Use Working Group / Revision Panel

** Developing a strong bias against "Medical Marijuana" Laws

Today – Provide Info, Generate Thought and Discussion, Encourage Caution and Action

- 1. Ongoing science and scientific reports on CBD and other Cannabis / Cannabinoids, and how it can impact Public Health intentionally and inadvertently. [General Primer]
- 2. Mitigating harm and maximizing benefit (practitioners /scientists)
- 3. The challenge and importance of learning how to communicate effectively about what is known and not known to best serve the public health particularly the vulnerable

AGENDA

- CBD, THC, Cannabinoids --- Differentiation
- "Evidence" related to use of CBD for "therapeutic" conditions
- Interpreting Evidence; Advising Patients, Families, Friends
- Public Perception
- Call to Action

Operationalize "Medical Marijuana"?

There is no such thing as "Medical Marijuana"!

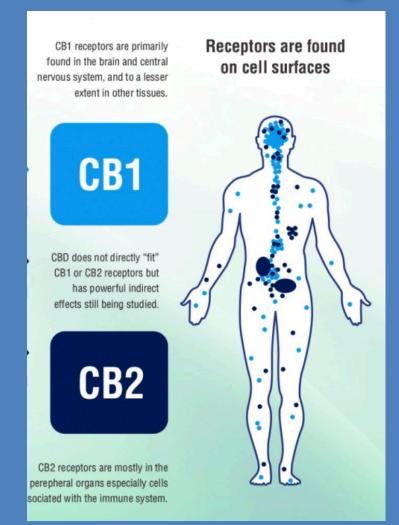
- Same plant and compounds as "Recreational" Marijuana

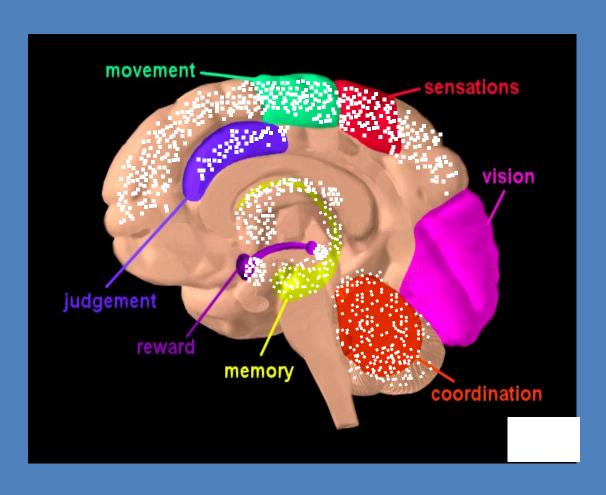
We do have FDA approved cannabinoid-based medicines:

- Dronabinol (synthetic THC); Nabilone (synthetic "thc-like)
- Epidiolex (CBD oral solution plant extract)

Other countries have: Sativex (CBD/THC oromucosal spray)

Biological Plausibility: Cannabinoid Receptors Are Located Throughout the Brain and Body



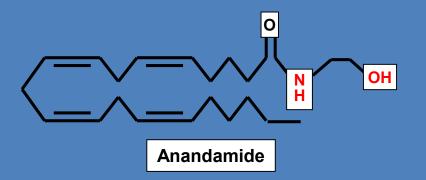


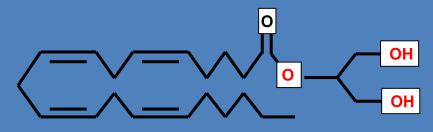
Biological Plausibility: Cannabinoid Receptors / eCB system

- Brain Development
- Memory and Cognition
- Motivational Systems & Reward
- Appetite
- Immunological Function
- Reproduction
- Movement, Coordination
- Pain Regulation. & Analgesia

BIOLOGICAL PLAUSIBILITY

Endogenous Cannabinoid System (eCB)





2-Arachidonoylglycerol (2-AG)

Cannabinoid Receptors
CB1
CB2

Endogenous Cannabinoid
Ligands
Anandamide
2-Arachidonoylglycerol

Phytocannabinoids

✓ Cannabis: Hemp Plant >100 phytocannabinoids, (terpenes, flavonoids)

✓ ∆9-tetrohydrocannabinol (THC): Primary psychoactive component. Defines cannabis potency

1979: 1-4% THC in flower

2014 : 12-19% in flower, 80-90% in concentrates

✓ Cannabidiol (CBD): Not intoxicating; very low concentrations (<0.7%) in most typical cannabis flower products

What is "active" in the Cannabis Plant?

- THCA (Δ⁹-tetrahydrocannabinolic acid)
- CBDA (Cannabidiolic acid)
- CBGA (Cannabigerolic acid)
- CBCA (Cannabichromenenic acid)
- CBGVA (Cannabigerovarinic acid)
- THCVA (Tetrahydrocanabivarinic acid)
- CBDVA (Cannabidivarinic acid)
- CBCVA (Cannabichromevarinic acid)
- Terpenes: essential oils, smells, flavor

Entourage Effect: Mixture or Ratio of Compounds

Cannabis plants / products have varying amounts of each of these compounds.

How much does each contribute to various effects?

Logically, combinations should have some effect, but these have not been well studied clinically.

Addiction / Therapeutics Data: Starting Point

Cannabis (THC-laden) is addictive in every accepted meaning of that concept

Science / evidence for this is strong / unambiguous

Therapeutic "potential" of compounds in the cannabis plant (THC, CBD and others) is plausible.

For <u>a very few *medical* conditions</u>, the evidence is supportive of recommending as a treatment

SUMMARY

To make sense of cannabis research findings To have an intelligent conversation about cannabis To be smart about what you choose to use or recommend -

Requires that you are aware and understand:

All Cannabinoids are not the same!

- THC \neq CBD \neq CBG \neq THC+CBD
- Dose / strength of THC and CBD matters
- Their ratio may matter
- Other cannabinoids and terpenes likely also matter

1. Cannabidiol (CBD)



► Low affinity for CB1 and CB2 receptors, 5HT1a agonist, TRPV1 and TRPV2 agonist, inhibits anandamide uptake and hydrolysis Gotenhermen et al., 2005; Izzo et al., 2009; Pertwee et al., 2010



CBD



1oz Tincture \$55.00 Tincture \$30.00

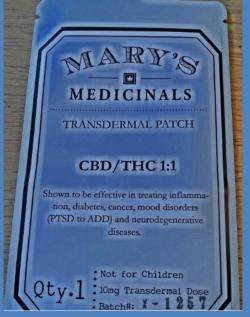




Lotions / Cremes / Salves / Patches











CBD?

What is High CBD?



By: SVW/CVD

FLOWER · HYBRID

The famous Blue Dream, crossed with CBD-rich California Orange by Humboldt Seed Organization to create a very special, terpenerich 1:1 strain. Strong berry aromas from Blue Dream harmonize with citrus and pine from Cali-O. Ideal for daytime pain relief.



CBD Rich Craft Cartridge

By: O.penVAPE

VAPE · CBD

No description available

Cannabinoids

No information provided

Terpenes

No information provided

Link to CBD 101 website (Misleading)

https://cvdvt.org/resources/
https://www.projectcbd.org/

- CBD: THE MULTIPURPOSE MOLECULE
- Many people are seeking alternatives to pharmaceuticals with harsh side effects medicine more in synch with natural processes. By tapping into how we function biologically on a deep level, CBD can provide relief for chronic gain, anxiety, inflammation, depression and many other conditions.
- Extensive scientific research (NOT) much of it sponsored by the U.S. government and mounting anecdotal accounts from patients and physicians highlight CBD's *potential* as a treatment for a wide range of maladies, including (but not limited to):

Link to CBD 101 website (continued) MISLEADING

- Autoimmune diseases (inflammation, rheumatoid arthritis)
- Neurological conditions (<u>Alzheimer's</u>, dementia, <u>Parkinson's</u>, <u>multiple</u> sclerosis, <u>epilepsy</u>, <u>Huntington's chorea</u>, stroke, <u>traumatic brain injury</u>)
- Metabolic syndrome (<u>diabetes</u>, <u>obesity</u>)
- Neuropsychiatric illness (<u>autism</u>, <u>ADHD</u>, <u>PTSD</u>, <u>alcoholism</u>)
- Gut disorders (colitis, Crohn's)
- Cardiovascular dysfunction (<u>atherosclerosis</u>, arrhythmia)
- <u>Skin disease</u> (acne, dermatitis, psoriasis)
- CBD has proven <u>neuroprotective</u> effects and its <u>anti-cancer</u> properties are being investigated at several academic research centers in the United States and elsewhere. A 2010 brain cancer <u>study</u> by California scientists found that CBD "enhances the inhibitory effects of THC on human glioblastoma cell proliferation and survival." This means that CBD makes THC even more potent as an anticancer substance. Also in 2010, German researchers reported that <u>CBD stimulates neurogenesis</u>, the growth of new brain cells, in adult mammals.



FDA Update Report (March 2020)

https://www.fda.gov/news-events/press-announcements/fda-advances-work-related-cannabidiol-products-focus-protecting-publichealth-providing-

market?utm_campaign=030520_PR_FDA%20Advances%20Work%20Related%20to%20Cannabidiol%20Products&utm_medium=em_ail&utm_source=Eloqua

- We're seeing CBD being marketed in a number of different products, such as oil drops, capsules, syrups, food products, such as chocolate bars and teas, cosmetics and other topical lotions and creams, as well as products marketed for pets and other animals and we understand consumers are seeking out these novel products for a variety of perceived health-related or other reasons.
- But as the agency has stated before, we are concerned that some people wrongly think that the myriad of CBD products on the market have been evaluated by the FDA and determined to be safe, or that using CBD 'can't hurt.' Aside from one prescription drug approved to treat two rare, severe pediatric epilepsy disorders, no other CBD products have been evaluated or approved by the FDA.

FDA Update

- There may be risks that need to be considered before using CBD products outside of the monitored setting of a prescription from your health care provider.
- In particular, the agency recently <u>updated the public</u> on concerns about potential harm from CBD products, including potential liver injury, interactions with other drugs and male reproductive toxicity, as well as side effects such as drowsiness. In addition, there is still much we do not know about other potential risks. For example, other than the approved prescription drug, we know little about the potential effects of sustained and/or cumulative use of CBD, co-administration with other medicines, or the risks to vulnerable populations like children, pregnant and lactating women, the elderly, unborn children and certain animal populations. This does not mean that we know CBD is unsafe to these populations or under these circumstances, but given the gaps in our current knowledge, and the known risks that have been identified, we also are not at a point where we can conclude that unapproved CBD products are safe for use.

Therapeutic Effects of Cannabis ("Medical Marijuana")

"Potential" is there:

biological plausibility -	yes
laboratory models -	yes
pre-clinical demos -	yes
case reports /open label	yes
controlled clinical data -	777

What Do We Know from Scientific Studies? National Academy of Sciences

The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research (NAS, 2017)

https://www.nap.edu/catalog/24625/the-health-effects-of-cannabis-and-cannabinoids-the-current-state

** Mixes Cannabinoids, including CBD with THC

National Academy's Findings

There is conclusive or substantial evidence that cannabis or cannabinoids are effective:

- For the treatment for chronic pain in adults (cannabis) NOT?
- Antiemetics in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids)
- For improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids)

Pain and CBD

Uberall et al (2020). Cumulative evidence from clinical trials and an exploratory analysis of the German Pain e-Registry suggests that add-on THC:CBD oromucosal spray (nabiximols) may have a role in managing chronic neuropathic pain, although further precise clinical trials are required to draw definitive conclusions.

Boyaji et al (2020). Since there are currently no approved pharmaceutical products that contain CBD alone for the management of pain, this review focused on nabiximols (which is a combined product of THC/CBD in a 1:1 ratio) as the only pharmaceutical product available that contains CBD and is being used for the management of pain. Based on the available literature, it is difficult to make a recommendation for the use of CBD in chronic pain management. It is also important to note that there are many CBD products currently available as supplements, but these products are non-pharmaceuticals and lack the appropriate clinical studies to support their efficacy claims.

Pain and CBD

Lynch et al., (2015). This review adds further support that currently available cannabinoids are safe, modestly effective analgesics that provide a reasonable therapeutic option in the management of chronic non-cancer pain. None of these studies were of CBD.

e.g., Social Anxiety and CBD

Cannabis use does not appear to increase the likelihood of developing depression, anxiety, and posttraumatic stress disorder.

Regular cannabis use is likely to increase the risk for developing social anxiety disorder.

** There is <u>limited evidence</u> that cannabis or cannabinoids are effective for: improving anxiety symptoms, as assessed by a public speaking test, in individuals with social anxiety disorders (cannabidiol)

LIMITED Evidence for Therapeutic Effects: There is weak evidence to support the conclusion that cannabis or cannabinoids are an effective or ineffective treatment for the health endpoint of interest. For this level of evidence, there are supportive findings from fair-quality studies or mixed findings with most favoring one conclusion. A conclusion can be made, but there is significant uncertainty due to chance, bias, and confounding factors.

e.g., Social Anxiety and CBD: Dose Matters?

... identified one randomized trial with a high risk of bias that compared a single 600 mg dose of CBD to a placebo in 24 participants (undergraduates) with "generalized social anxiety disorder"

CBD was associated with a greater improvement on the anxiety factor of a 100-point visual analogue mood scale (mean difference from baseline -16.52, p = 0.01) compared with a placebo during a simulated public speaking test. (Bergamaschi et al., 2011)

DOSE: single 600mg CBD

CBD Dosing

Social Anxiety Study. single dose: 600mg CBD

Epidiolex Trial: 10-20mg/kg

100lbs (45kg):

Hurd et al. lab testing

450-900mg CBD

400-600mg CBD

What is being sold:

20mg CBD Capsules. \$80 pack of 10

CBD-Rich Tincture 400mg per bottle *1 drop=1mg \$90

CBD Dosing?



1oz Tincture \$55.00 Tincture \$30.00





CBD / THC - watchout

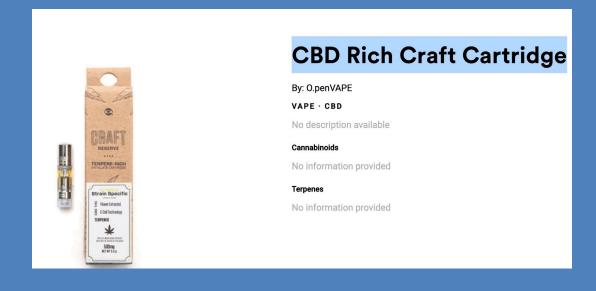
What is High CBD?



By: SVW/CVD

FLOWER · HYBRID

The famous Blue Dream, crossed with CBD-rich California Orange by Humboldt Seed Organization to create a very special, terpenerich 1:1 strain. Strong berry aromas from Blue Dream harmonize with citrus and pine from Cali-O. Ideal for daytime pain relief.



CBD Unknowns

What is High CBD product?

What is a dose?

What is in the product being sold?

- CBD, THC,

120 mg CBD USA Grown Hemp

Full Spectrum Extract

Web advertising

• What Is CBD Ointment Used For?

- CBD contains anti-inflammatory and anti-spasmodic properties, kills pain, enhances circulation and regenerates cellular activity. There are a wide variety of conditions that can be treated by using CBD ointments and other CBD infused topicals. The list is long, but a few of the most commonly treated are:
- Skin conditions: eczema, dermatitis, psoriasis, rashes, fungal infections, dry skin, blisters, etc.
- Localized joint pain, arthritis pain, inflammation muscle soreness, sprains and other mild injuries.
- Faster healing of wounds, cuts, scrapes and bruises.
- Chronic pain
- Multiple sclerosis
- Nerve pain/sciatica
- Seizures
- Muscle spasms
- Earaches
- Migraines
- Menstrual cramps
- Hemorrhoids
- Mental disorders (anxiety, depression, PTSD)

Web advertising

- Top 10 CBD Topicals: Lotions, Creams, and Salves
- Medically reviewed by <u>Debra Rose Wilson, PhD, MSN, RN, IBCLC, AHN-BC, CHT</u> on Septem
- ber 27, 2019 Written by Carly Werner
- BEST for PAIN: This cream packs 1,000 milligrams (mg) of CBD into a mere 8 ounces. That means it's highly concentrated, which may make it more effective. The CBD used is isolate rather than full-or broad-spectrum CBD, making this product a good choice for people who want to avoid THC altogether. Good for sore joints and pain, this cream has added benefits from feel-good oils like organic jojoba oil, camphor oil, and peppermint oil.
- Repair Remedy Salve 200 MG CBD: The combination of ingredients like willow bark, Helichrysum, and arnica work in tandem with full-spectrum CBD to provide relief for sore, achy muscles. Organic Coconut Oil*, Full Spectrum CBD, Willow Bark*, Chamomile*, Arnica*, Peppermint*, Lavender*, Aloe*, Helichrysum*, Bees Wax* (* indicates Organic)

Vermont Dispensary CBD cream

• CBD Salve: By: Ceres Natural Remedies (2oz, \$40)

- TOPICAL · CBD
- Extra-strength CBD salve made with 500mg Vermont-grown hemp and companion herbs. Ingredients: Coconut oil, hemp seed oil, beeswax, hemp extract, St. John's Wort, arnica, chamomile, vitamin E oil and essential oils of birch, blue chamomile and helichry

Vermont Dispensary CBD topicals

- Muscle Freeze. By: Mary's
- TOPICAL · CBD
- Combines hemp oil, aloe vera, camphor, <u>menthol</u> and tea tree oil with vitamins and <u>other natural plant extracts</u> to cool and soothe sore muscles and joints.

• CBD Medic Arthritis Deep Joint Rub >200mg CBD/40g

• Menthol, beeswax, clove oil, cottonseed oil, emulsifying wax, eucalyptus oil, hemp extract (THC-free), jojoba seed oil, peppermint oil, purified water, shea butter, sorbic acid, tea tree oil.

• Use instructions: massage in a small amount on your elbows, feet, hands, hips, knees or torso. Apply to affected area no more than 3-4 times daily.

Vermont

The Committee recommends relieving the Department from providing educational and safety information developed by Vermont Department of Health to each registered patient and caregiver upon registration, as contained in 18 V.S.A. § 4474m. The Committee advocates transitioning this responsibility from the Department of Public Safety and Vermont Department of Health to the registered <u>dispensaries</u>. The required educational material should include the following topics to effectively serve the needs of registered patients: a) Safe storage b) Dosing information (tolerance) c) Routes of administration d) Edibles consumption (start low and go slow). This recommendation is proposed due to the inadequacy of the educational and safety information developed by the Vermont Department of Health. The current document does not provide practical information suitable for the needs of registered patients and his or her caregiver.

Dispensaries

Individual responses to cannabis strains and methods of consumption vary. Currently, no scientific consensus exists that indicates any one cannabis strain is more effective than another for relieving specific symptoms or conditions. Each consumer must determine, through their own use of can which strains and products are most effective for their needs.

• Points-based rewards program that offers free cannabis products + accessories,

Vermont Dispensary Welcome Packet

CBN (CANNABINOL) is very similar to THC but has fewer psychological effects. It is produced as THC breaks down within the medical cannabis plant. High THC will make CBN's effects stronger, and very high CBN concentrations can produce undesirably strong head highs. A strain with high CBN levels can be particularly helpful for:

• lowering eye pressure

• analgesic

• anti-seizure

Vermont Dispensary Welcome Packet

THC (DELTA-9-TETRAHYDROCANNABINOL) acts as a muscle relaxant, an anti-inflammatory, and as a psychological stimulant. A cannabis strain high in THC is a good choice for a patient who wishes to remain alert and active. THC in medical cannabis acts in the following ways:

- anti-epileptic.
- anti-depressant

- anti-inflammatory
- appetite stimulant
- reducing blood pressure

CBD (CANNABIDIOL) tends to reduce the psychological effects of medical cannabis. A strain that has high THC and high CBD will have fewer "mental" effects and more physical ones. High CBD strains are especially effective for illnesses with strong physical symptoms.

- reduced pain
- reduced nausea.
- anti-convulsive.
- reduced anxiety
- sedative effects
- anti-schizophrenic

CBC (CANNABICHROMENE) tends to enhance the effects of THC. High CBC levels will increase the potency of a high-THC medical cannabis strain. CBC working together with THC is known to be a:

• sedative • analgesic • anti-inflammatory

CBG (CANNABIGEROL) has no psychological effects on its own and is not usually found in high amounts in most medical cannabis. It has anti-microbial properties. CBG has physical effects such as:

- lowering pressure in the eye
- sedative

- anti-inflammatory
- sleep assistance

Vermont Dispensary

CBN (CANNABINOL) is very similar to THC but has fewer psychological effects. It is produced as THC breaks down within the medical cannabis plant. High THC will make CBN's effects stronger, and very high CBN concentrations can produce undesirably strong head highs. A strain with high CBN levels can be particularly helpful for:

- lowering eye pressure
- analgesic

• anti-seizure

"These five major cannabinoids are most effective when they work together. Professional medical cannabis growers can analyze their strains to breed and grow medication for patients with the desired range of levels of each major cannabinoid. With an understanding of what each compound does, medical cannabis pharmacists can find the right combination for patients to treat specific conditions and find maximum relief."

Standards of Evidence? Status of Evidence?
Terminology for Communicating about Evidence?
Potential for Adverse Effects? Placebo Effects?
Specificity: Compound, Dose, Route of Administration?
Magnitude of Effects?
Symptom Relief vs. "Cure" vs. Treatment
Recommendations?

Arthritis Foundation: https://arthritis.org/health-wellness/healthy-living/managing-pain/pain-relief-solutions/cbd-for-arthritis-pain?_ga=2.147898743.136757213.1569864954-1933996502.1569428824

Does CBD work for arthritis? Animal studies have suggested that CBD has pain-relieving and anti-inflammatory properties, but these effects have not been validated in quality studies in humans. Anecdotally, some people with arthritis who have tried CBD, but not all, report noticeable pain relief, sleep improvement and/or anxiety reduction.

Is CBD safe to use? Research evaluating the safety of CBD is underway. At this point very little is known.

Should I give CBD a try? Without quality clinical studies on CBD and arthritis, doctors have not been able to say who might benefit from CBD, at what dose and in which form, who likely won't benefit and who should avoid it. Still, there is agreement on several points:

CBD is not a substitute for disease-modifying treatment for inflammatory arthritis. Patients who are interested in trying CBD should first talk to the health care provider who treats their arthritis before trying CBD. Together, they can review what has worked or not worked in the past, whether there are other options to try first, how to do a trial run, what to watch for and when to return for a follow-up visit to evaluate the results. Keep a symptom and dose diary to track effects.

Quality CBD products can be expensive, especially when used for prolonged periods. To avoid wasting money, be completely sure that the product is truly having a positive effect on symptoms.

Whether these products deliver CBD below the skin is unknown. Topical products may also include common over-the-counter ingredients such as menthol, capsaicin or camphor, making it difficult to determine if a positive effect is due to the CBD or another ingredient.

How much CBD should I use? While there are no established clinical guidelines, the medical experts consulted by the Arthritis Foundation recommend the following for adults:

Most Vulnerable Populations for the Development of Cannabis Use Disorder and Experiencing other Adverse Consequences

- Poverty --- Disadvantaged minorities, low SES
 - Reduction/Deprivation of Prosocial Reward
 - Increased Stress
- Psychiatric Disorders perceived benefits, symptom relief
- Physical Disorders perceived benefits, symptom relief

What Can Practitioners and Scientists Do? (other than conduct science)

Speak Up: Inform Regulations and Educate the Public

- Differences among Cannabinoids
- Safe / Low Risk Use
- High Risk / Problematic Use
- Therapeutic / Evidence
- Addictive / Adverse Consequences

<u>Audiences</u>: legislators, physicians, healthcare workers, school personnel, prevention specialists, middle or high school, college-aged youth, community groups, parents

Lobby for Change: FDA / DEA: Controlled Substances Act

Cannabis / cannabinoids are still Schedule I

- Exceptions: Epidiolex (CBD plant-based product)

Marinol, Dronabinol (FDA approved)

IMPEDES research!

Need easier research access to diverse, higher potency THC/CBD and other cannabinoid products

Increase funding for research

De-Medicalize Cannabis / Marijuana?

What's the Problem?

Legalization and approved medical indications for cannabis influence:

Public Perception, Behavior, Availability which can increases the probability of developing problems related to cannabis use?

Cannabis Industry Impact

The Cannabis Lobby

The Cannabis Trade Federation (CTF) has hired 15 lobbyists to push the Strengthening the Tenth Amendment Through Entrusting States Act



Joint effort: cannabis lobby heads to Washington to woo US lawmakers

Industry leaders descended on the capital this week amid hopes the country at large is slowly embracing legalization





\$3,771,500

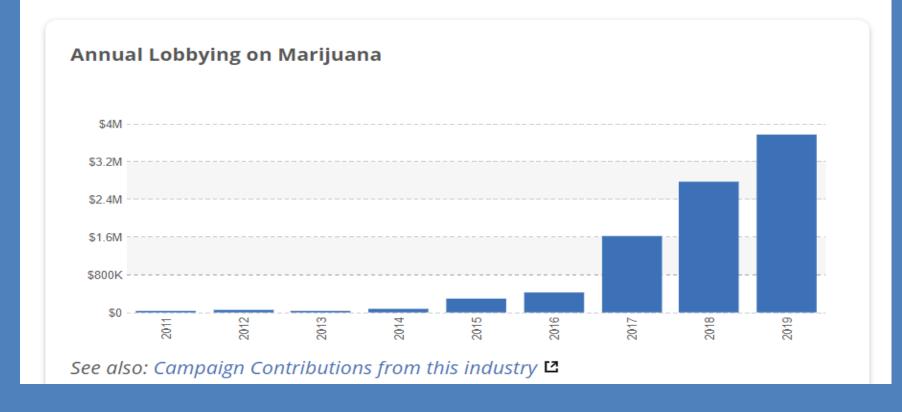
Total Spent on Marijuana, 2019

Number of Clients

80 (71.25%)

Number of Lobbyists/Percent of Former Government Employees ②





Science is Needed at All Levels Cannabis Research / Policy Priorities

- Regulatory Science: mitigate harm
 - Industry/marketing, dose/content control, access
- Protect those Vulnerable to Addiction and Consequences
 - disadvantaged/poor, mental and physical health disorders, youth
- Communication Science
 - How do we best communicate about potential positive effects and potential harmful effects?
- Develop Cannabis Use Guidelines
 - What level of use is low risk (safe)? High risk?
 - Help everyone make informed and safe choices

Science is a Slow Process



Extrapolate from What is Known and Use Commons Sense

Thanks for Listening