Redman.John.CADFY

FDA Public Hearing

Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds

May 31, 2019



Presenter

John Redman Chief Executive Officer Community Alliances for Drug Free Youth 501(c)3 founded in late 1970's as a grassroots parentled anti-drug movement

Substance abuse prevention organization that works at the state, national and international levels to encourage multi-stakeholder collaborations that drive policies and actions that:

- Target illicit drug usage and related problems
- Promote research-based prevention strategies and programs
- Create initiatives that support community-based drug awareness and education

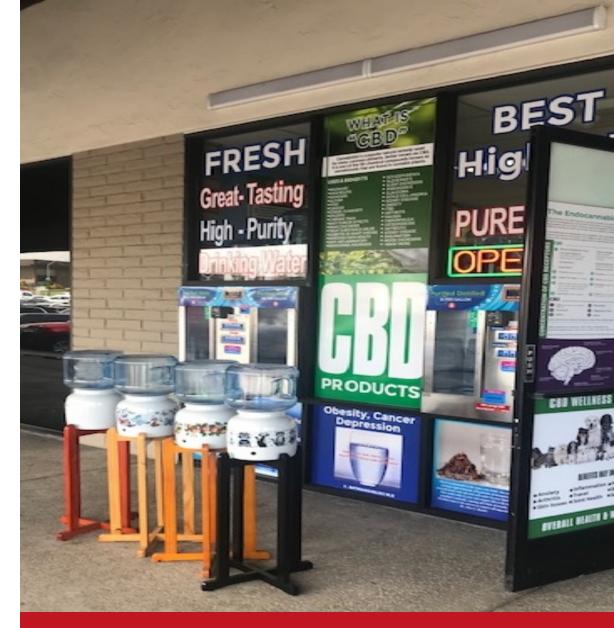


"We have a profound responsibility to support sound drug policy that will explicitly protect our youth"

CADFY's concerns:

Despite scientific evidence that THC (tetrahydrocannabinol) is a public health threat, especially among children and adolescents:

- Availability and consumption of products containing THC is steadily rising
- Illicit, recreational and therapeutic usage
- At higher concentrations and doses shown to induce dependence and addiction
- Without the public's awareness of health concerns or amounts contained in products consumed
- Rampant promotional activities for both regulated and unregulated products, some targeted at vulnerable populations
- Regulation is lax, at best



We're treating THC as a Commodity

CADFY's Request for Action:

The FDA should proceed with extreme caution and treat any levels of THC as unsafe, especially for vulnerable populations.

To protect the public's health and safety, we urge the FDA to prohibit THC in CBD-containing consumer goods.

CADFY's concerns: THC's harmful effects

What we **CAN** say with certainty



THC consumption can result in dependence/addiction
Amount of consumption matters, as does potency



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THC use associated with structural and functional brain changes, particularly in those under 25y

- Dramatically lower IQ scores (6-10 point drop)
- Diminished ability to compete academically
- Lower median income
- Increased likelihood of requiring public aid

THC is associated with serious mental illness

• Psychosis, schizophrenia, bipolar disorder, anxiety

4 Mate

Maternal consumption of THC during pregnancy may cause developmental changes to fetal brain

Vulnerable populations cannot be protected by age-related restrictions on marketing and sales

What we **CANNOT** say with certainty



- The amount of THC use that may contribute and/or cause adverse health effects
 - Dose, chronic use, genetic make-up?



Stopping marijuana/THC use for long periods of time (e.g., periods over a year) restored IQ levels



There is a minimal safe level of exposure, especially for chronic users



The amount and dose of THC contained in unregulated products is within the "legal limit" (by percentage)

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Whether product is mislabeled as to content

CADFY's concern: How much THC is too much

Human health impact?

- THC amount (%/wt) consumed that causes dependence and/or addiction
- THC amount that causes first-episode psychosis, other chronic adverse health effects



CADFY's concern: How much THC is too much

Legal/regulatory basis



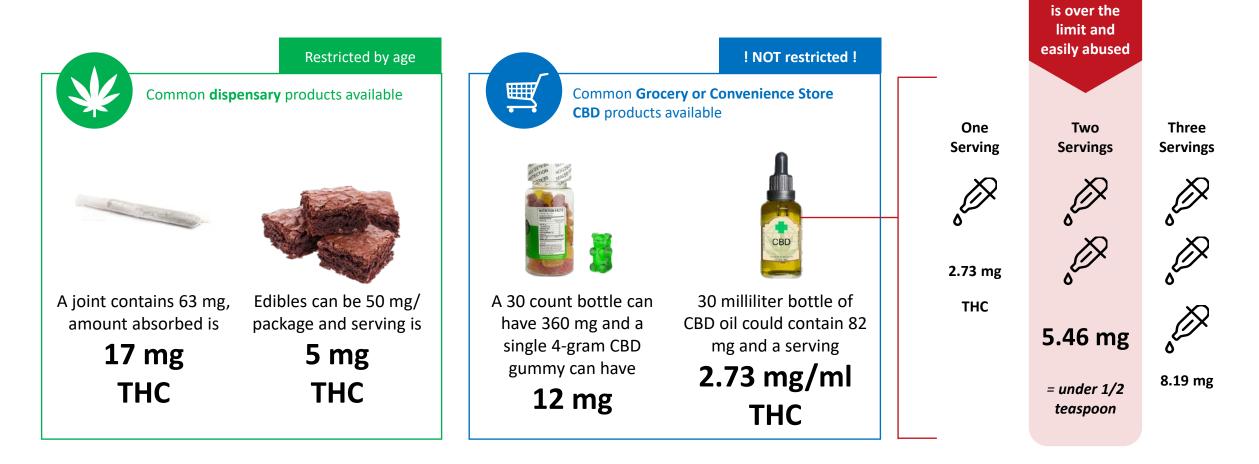
Oregon – **5mg THC produces psychoactivity**; THC-edible \leq 5mg THC/serving



Agricultural Improvement Act of 2018 (*Farm Bill*) – **CBD from hemp** –*MAC* THC \leq 0.3% by dry weight

One dropper, two dropper, three...

Oregon – **5mg THC produces psychoactivity**; THC-edible ≤ 5mg THC/serving



Two servings

Available at a store near you...



PROVER

1/11/2019

GREEN REMED

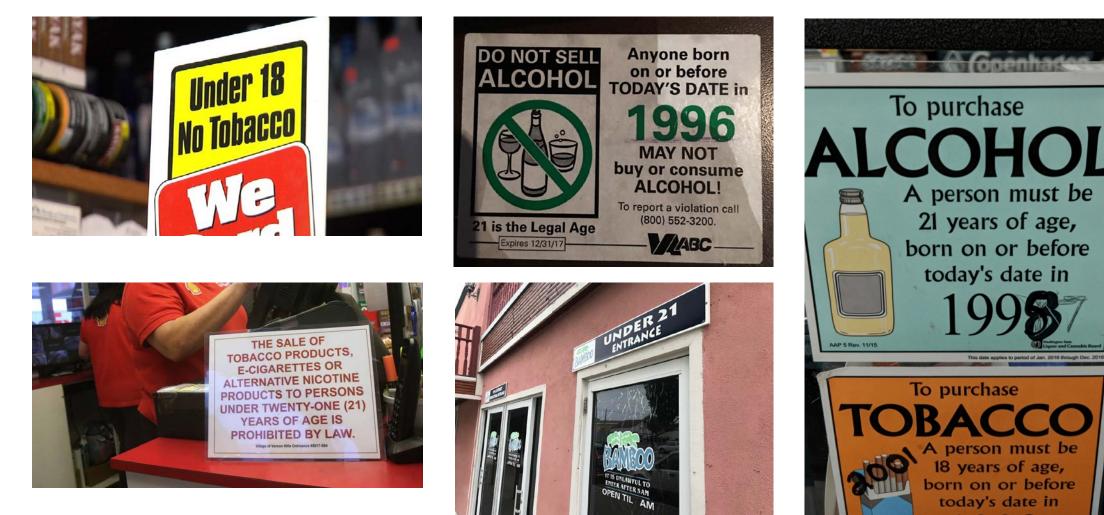
FULL SPECTRUN HEMP EXTRACT

NATURAL

500mg CBD 1 FL oz. (29m)

Age Restricted Sales Don't Work





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