

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 parent-led 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

- 1 **THC consumption can result in dependence/addiction**
 - Amount of consumption matters, as does potency
- 2 **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
- 3 **THC is associated with serious mental illness**
 - Psychosis, schizophrenia, bipolar disorder, anxiety
- 4 **Maternal consumption of THC during pregnancy may cause developmental changes to fetal brain**
- 5 **Vulnerable populations cannot be protected by age-related restrictions on marketing and sales**

What we **CANNOT** say with certainty

- 1 **The amount of THC use that may contribute and/or cause adverse health effects**
 - Dose, chronic use, genetic make-up?
- 2 **Stopping marijuana/THC use for long periods of time (e.g., periods over a year) restored IQ levels**
- 3 **There is a minimal safe level of exposure, especially for chronic users**
- 4 **The amount and dose of THC contained in unregulated products is within the "legal limit" (by percentage)**
- 5 **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



Restricted by age

Common dispensary products available



A joint contains 63 mg, amount absorbed is

**17 mg
THC**



Edibles can be 50 mg/ package and serving is

**5 mg
THC**



! NOT restricted !

Common Grocery or Convenience Store CBD products available



A 30 count bottle can have 360 mg and a single 4-gram CBD gummy can have

12 mg



30 milliliter bottle of CBD oil could contain 82 mg and a serving

**2.73 mg/ml
THC**

One Serving



2.73 mg

THC

Two Servings



5.46 mg

= under 1/2 teaspoon

Three Servings



8.19 mg

Two servings is over the limit and easily abused

Available at a store near you...



CHARLOTTE'S WEB
STANLEY BROTHERS Boulder, CO 80301 • 719-419-8169

CERTIFICATE OF ANALYSIS

Product Name: Charlotte's Web Hemp Extract Oil Maximum Strength Mint Chocolate 30mL
 Product Batch: A00700
 Product Code: 910.069
 Best By: July 2020

Parameter	Result
Cannabinoids <small>Testing performed by Eurofins Food Chemistry Testing - Boulder, CO</small>	
THC	2.8 mg/mL
THC-A	0.033 mg/mL
THC-V	None Detected
CBD	64.3 mg/mL
CBD-A	0.44 mg/mL
CBD-V	0.31 mg/mL
CBG	0.32 mg/mL
CBG-A	None Detected
CBN	0.23 mg/mL
CBC	2.3 mg/mL
Total THC per Bottle	84 mg
Total THC per Serving	1.4 mg

Manufactured By: Charlotte's Web Inc.
 Manufacture Date: 16JAN19, 18JAN19 - 20JAN19
 Batch Size: 297,540 mL
 Units Manufactured: 9,773



THC 2.8 mg/ml

THC 2.89 mg/ml



Test Certificate

Certificate ID: 45017
 Client Sample ID: GR121218 50mg/ml
 Lot Number:
 Matrix: Tincture - MCT Oil

Received: 12/18/18
 Scan QR Code for authenticity
 Green Remedy Inc.
 4104 Bishop Lane
 Louisville, KY 40218
 Attn: Chris Smith

Authorization: Jon Podgorni, Lab Manager
 Signature: *Jon Podgorni*
 Date: 1/11/2019



PJLA Testing
Accreditation # 80585

The data contained within this report was collected in accordance with the requirements of ISO/IEC17025:2005. I attest that the information contained within the report has been reviewed for accuracy and checked against the quality control requirements for each method. These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety.

CN: Cannabinoid Profile & Potency [W1-10-17 & W1-10-17-01]
 Analyst: LG
 Test Date: 1/9/2019

The client sample was analyzed for plant-based cannabinoids by Liquid Chromatography (LC). The collected data was compared to data collected for certified reference standards at known concentrations.

ID	Weight %	Conc.
D9-THC	0.30 wt %	2.89 mg/mL
THCV	ND	ND
CBD	5.58 wt %	53.63 mg/mL
CBDV	0.04 wt %	0.34 mg/mL
CBG	0.05 wt %	0.50 mg/mL
CBC	0.15 wt %	1.47 mg/mL
THCA	ND	ND
CBDA	ND	ND
CBGA	ND	ND
Total	6.12 wt%	58.83 mg/mL
Max THC	0.30 wt%	2.89 mg/mL
Max CBD	5.58 wt%	53.63 mg/mL

Ratio of Total CBD to THC: 18.5:1

Max THC (and Max CBD) are calculated values for total cannabinoids after heating, assuming complete decarboxylation of the acid to the form. It is calculated based on the weight loss of the acid group during decarboxylation: Max THC = (0.877 x THCA) + THC. ND = Not detected above the limits of detection (LLD)

FM-10-05, Rev. 1, DCN:14-0001
 420 Fortune Blvd • Milford, MA 01757 • 617-221-3356
 www.ProVerdeLabs.com



Age Restricted Sales Don't Work



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.