

The State of Edibles Address

Presented By:

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Oregon Responsible Edibles Council, Chair

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David McNicoll: Edible Processor

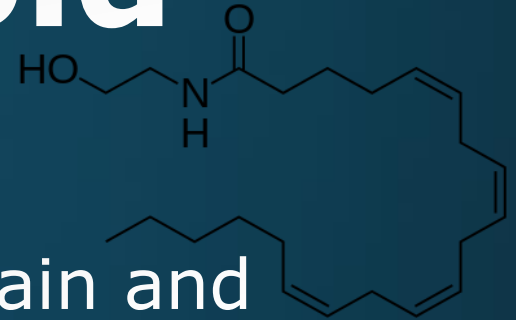
- 9 years experience as OMMP grower/edible maker
- Given edible products to thousands of people and worked with many to teach about dosage
- Began Dave's Space Cakes in March 2014
 - Worked with over 100+ dispensaries
 - Brought over 20+ products to market
- OLCC RAC Sub-Committee for Edibles, Topicals and Other Infused Products member
- Formed OREC in May of 2015
- Current OHA RAC Member



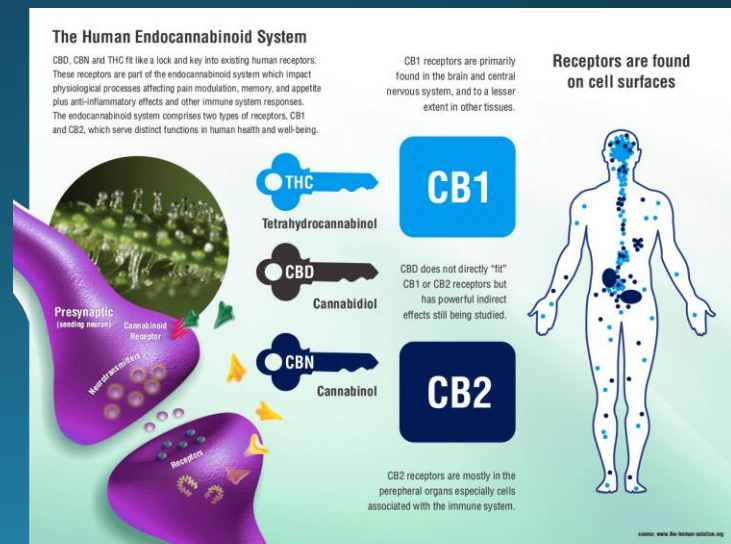
Presentation Overview

- Complete The Story on marijuana exposure & harm to children
- Why 5mg per single dose is bad?
- Why 10mg per single dose is good?
- Stop-gap issue: Fix by June 1st
- Educational solutions

Endocannabinoid System



- Cannabinoid receptors throughout brain and nervous system interact with natural cannabinoids produced within the human body (Anandamide) and help regulate mood, appetite & sleep.
- Same system interacts with cannabinoids from marijuana ingestion
- Only "rec drug" to have its own system pre-built into human anatomy



The Complete Story...

- We must talk about the full & complete story when discussing childhood marijuana exposure
- Cases are incredibly rare. Data is limited due to scarcity of actual cases
- Full recovery with no long term effects
- Undue harm from misdiagnosis
- 0 deaths from marijuana exposure

The Complete Story: 100% Full Recovery Within 48-72 hours

- Data reflects a 100% full recovery rate within 48-72 hours:
- (Doc. A) "toxicology screening showed the presence of cannabinoids in all children and all of them recovered without any sequelae and were discharged from PICU within 48 h"
- (Doc. B) "the child gradually became more responsive over the next 12 hours and made a full, uneventful recovery."

The Complete Story: **100% Full Recovery Within 48-72 hrs**

- (Doc. B) "children should be observed for at least 6 h after ingestion"
- (Doc. C) "the majority of patients exhibited clinical effects lasting fewer than 24 hours"
- (Doc. F) "most symptoms 2-24 hrs."
- All data I have looked at over the past 2 months includes information on full recovery within 48-72 hours of ingestion

The Complete Story: 100% Full Recovery Within 48-72 hrs

Table 1 Characteristics of children admitted to the PICU after an accidental cannabis ingestion

Age (months)	15.62 (11.85–33.23)
Sex (n)	
Male	2
Female	5
Weight (kg)	10.54 (7.32–18)
Significant symptoms (n)	
Glasgow coma scale ≤ 8	5
Bilateral reactive mydriasis	6
Respiratory rate < 12 breaths/min	1
Heart rate < 70 beats/min	1
Systolic blood pressure < 75 mmHg	2
Laboratory findings	
Glucose (mmol/l)	5.7 (5–6.6)
pH	7.34 (7.30–7.43)
PCO ₂ (mmHg)	39 (35–45)
Na (mmol/l)	137 (134–140)
CRP (mg/l)	< 10
Brain imaging (n)	
Computed tomography (with contrast)	5 (3)
Magnetic resonance imaging	2
Lumbar puncture (n)	4
Need for intubation (n)	3
Duration of mechanical ventilation (h)	18 (4–24)
Need for fluids ≥ 40 ml/kg (n)	2
Administration of IV aciclovir (n)	4
Administration of IV antibiotics (n)	3
Duration of PICU stay (h)	19 (11–48)

Data are absolute values and medians (minimum value–maximum value)
IV intravenous, PICU paediatric intensive care unit

Wang et al

Table 2. Symptoms and duration of symptoms of unintentional pediatric exposures (2005 to 2011).

Symptoms*	Nonlegal States (n=496)	Transitional States (n=93)	Decriminalized States (n=396)
Nervous system			
Drowsiness/lethargy (%)	97 (20)	28 (30)	147 (37)
Ataxia (%)	29 (6)	3 (3)	14 (4)
Agitated/irritable (%)	16 (3)	2 (2)	14 (4)
Confused (%)	7 (1)	3 (3)	17 (4)
Other (%) [†]	10 (2)	7 (8)	19 (5)
Total	159 (32)	43 (46)	211 (53)
Gastrointestinal system			
Nausea/vomiting (%)	9 (2)	2 (2)	19 (5)
Cardiovascular and respiratory systems			
Respiratory depression, bradycardia, hypotension (%)	3 (<1)	2 (2)	5 (1)
Duration of symptoms			
≤ 2 h (%)	9 (2)	4 (4)	12 (3)
> 2 h, ≤ 8 h (%)	55 (11)	12 (13)	63 (16)
> 8 h, ≤ 24 h (%)	58 (12)	16 (17)	63 (16)
> 24 h, ≤ 3 days (%)	5 (1)	3 (3)	16 (4)
> 3 days, ≤ 1 wk (%)	1 (<1)	1 (1)	1 (<1)

*Not all patients had symptoms, type of symptom, or duration of symptoms documented. Some patients had more than 1 symptom.

[†]*Other* includes tremor, coma, hallucinations, nystagmus, muscle weakness, slurred speech, and seizures.

The Complete Story: Undue harm was not caused by marijuana

- Medical reports detail harmful invasive procedures were only performed by health care providers because marijuana exposure was not considered or a known suspected cause.
- (Doc A)"As cannabis is one of the most commonly abused drugs worldwide, paediatric intensivists must be aware of the various symptoms caused by cannabis ingestion in children...Prompt urine screening for the presence of cannabinoids with rapid reporting of results, may avoid unnecessary additional investigations, such as brain imaging and lumbar puncture."

The Complete Story: **Undue harm was not caused by marijuana**

- (Doc. B) "THC can be detected in urine and rapid screening for this and other toxic substances in the child with unexplained coma may reduce the need for invasive procedures or treatments."
- (Doc. C) "most patients with exposures did not have documentation of receiving therapeutic interventions. Aggressive interventions were rare. There were no deaths."

The Complete Story: **Undue harm was not caused by marijuana**

- Education of healthcare providers on signs of marijuana exposure and treatment recommendations are essential to preventing use of unnecessary invasive treatments

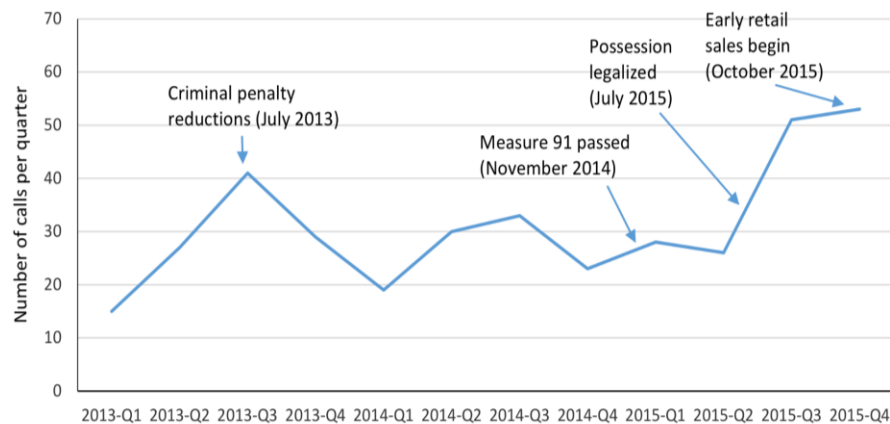


The Complete Story: Data

- National Data-
- 2011: 1.28 million total cases of exposures to any toxic substance age 12 and under
- 2005-2011: 985 total reported cases of pediatric exposure to marijuana nation wide age 9 and under
- Oregon Data- Exposure age 13 & under:
- 2013-13 calls 2014-18 calls 2015-31 calls
- 2015: 158 total calls all ages . Same number for children and 20-29 yr olds

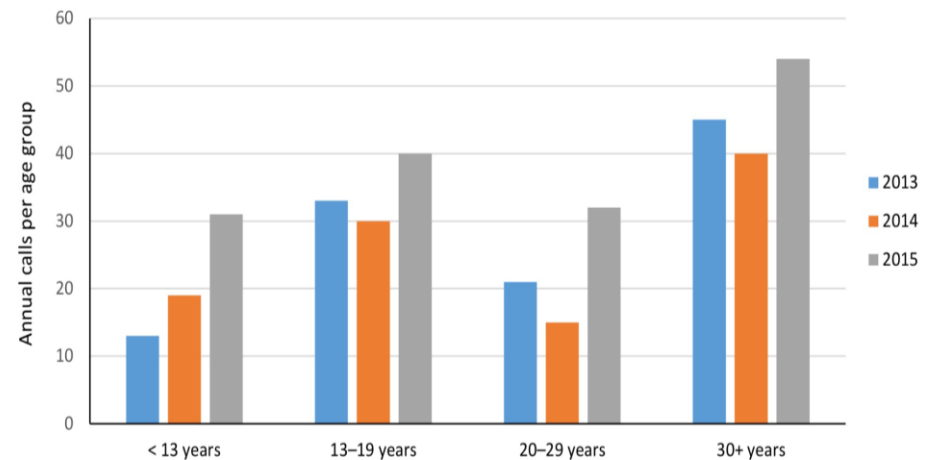
The Complete Story: Data/Graphs

Figure 37. Marijuana-related calls to the Oregon Poison Center, quarterly, 2013–2015



Data source: Toxic Exposure Surveillance System. Oregon Poison Center, Oregon Health & Science University, 2013–2015

Figure 38. Annual marijuana-related calls to Oregon Poison Center, by age group, 2013–2015



Data source: Toxic Exposure Surveillance System. Oregon Poison Center, Oregon Health & Science University, 2013–2015

The Complete Story: Data Comparisons

- Oregon: 2015 data shows same number of calls for kids as 20-29 year olds. Shows proportion of childhood cases is not more significant than adults.
- Fig. 37: Steady decline of 50% from 2013-Q3 thru 2014-Q1
 - Reduction was maintained thru 2015-Q2
 - Current level only 12 calls more than previous peak of 40 calls in 2013-Q3

The Complete Story: Colorado Governor Hickenlooper

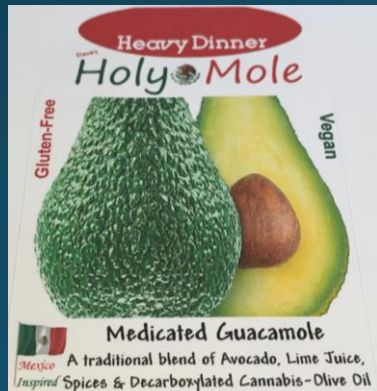
- Colorado Gov. John Hickenlooper quote:

In response to articles about Levy Thamba Pongi, the 19 yr old who fell to his death in 2014, "people read about one failure of the system-a tragic accident- and they don't see the context. There are tragic accidents everyday, everywhere: accidental deaths, prescription drugs-over 1,000 people died from that last year. No one cared...It would serve people better to have a sense of proportion."



Edible Use Patterns

- 45%-55% of recreational marijuana sales are in the form of edibles
- A safer alternative to smoking
- Allows Recreational consumers who do not want to smoke or vaporize to experiment with cannabinoids and interact with their own endocannabinoid system



Current Market Analysis



- \$1.66 Million worth of products on Oregon shelves right now. Estimate of 166,000 units @ \$10 each
- Products only available to 77,000 medical patients
- Hard to predict recreational projections, potential to easily double or triple current figures.

- Equation:

$$\begin{array}{r} 333 \text{ stores} \times \frac{(25 \text{ products})}{(20 \text{ units per product})} \times 500 \text{ units} = \\ 166,500 \text{ units} \quad @\$10 \text{ each} = \$1.66 \text{ mil} \end{array}$$

Dosage



- Serving size not same as dosage
- Serving size refers to Nutrition Facts
- Dosage has no relation to body weight & one single dose will affect people in great variation
- Individualized dosage is based on metabolism and endocannabinoid system and cannot be predicted

Nutrition Facts

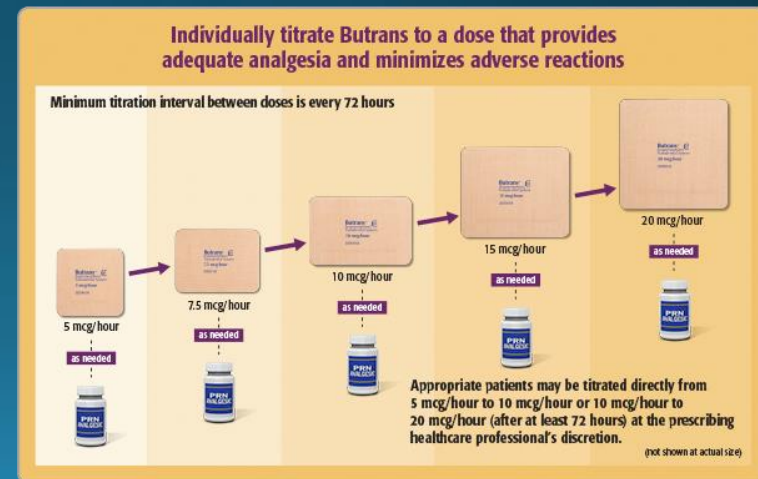
Serving Size 2/3 cup (55g)
Servings Per Container About 8

Nutrition Facts

8 servings per container
Serving size 2/3 cup (55g)

Importance of Individual Dosage

- One person's effects from edibles will vary greatly from others
- Personal THC tolerance level and metabolic rates determine efficacy
- Delta-9 THC processed through liver turns into Delta-11 THC causing differing effects from smoking
- Experimentation or proper Titration are only ways to determine individual dose



5mg Activated THC per Dose: Why it's Bad?

- Encourages at home edibles: no labels, packages, or dosing. Adding extracts or concentrates can be dangerous.
- Pics of current products
- Multi-use alcohol comparison does not apply because of delayed reaction time. Multiple servings encourages accidental over-ingestion



5mg Activated THC per Dose: Why it's Bad?



Baker Bros. Sugar Kookies
Getting High never tasted so good. Kick off the good times with a delicious bite then have a couple more bites when you are ready.

Enjoy a little at a time!
Be Cautious! Baker Bros kookies can take 30 minutes to 90 minutes to take full effect. We suggest that eating a half (5mg THC) or whole (10mg THC) to start, then eat more when you are comfortable. Overindulging can harsh your mellow.

FOR MEDICAL USE ONLY
CONTAINS 1.42 grams CANNABIS
IN COMPLIANCE WITH ORS 475.348

THC 180 mg CBD .4mg per package
1oz cookie serving
10 mg THC .02 mg CBD
18 one ounce servings per container

Tested By 3B Analytical TX #31104 12/11/15
Net Wgt 16.5 oz / 1.03 lbs
Processed by Wild West Growers
1/4/16 Eugene, Oregon

1. Preheat oven to 375F
2. ADD 1/4 Cup warm water
3. Bake for 12-14 minutes

Nutrition Facts
Serving size 1oz (amount for one cookie)
Serving per container 17

Amount per serving	
Calories	120
Calories from Fat	30

Directions:
Mix contents of package with 1/4 Cup water until dough forms. Portion into 1oz pieces and bake at 375F for 10-12 minutes. Enjoy!

5mg: Sub-Intoxicating Dose

- Dosage of intoxicating substance designed to give less than an intoxicating effect
- Promotes "stacking" of individual doses
- When one dose doesn't work, credibility of single dose is compromised, leading user to try 3-4 more doses rather than just one more
- Leads to more accidental over-ingestions



5mg: Environmental Impact



- Tremendous impact on waste production and usage of non-recyclable plastic material
- Incongruent with state in which I can't even go to the grocery store and request a plastic bag
- Double fuel costs and CO₂ emissions as twice as many products would need transported
- Twice as many products on the market would lead to twice as many packages for kids to potentially get their hands on

5mg: Production Difficulties

- Very difficult to produce micro-products containing only 5 mg
- 30% Homogeneity Requirement: Margin of only 1.5mg unrealistic from production stand-point. Batches will be deemed unsellable causing undue hardship on small businesses.



5mg: Promoting Obesity



- Products not strong enough to affect average or even moderate consumers
- Requiring customers to consume more products to ingest the desired THC level means requiring them to consume the extra sugar, sodium, fat, etc.
- 100mg of THC from chocolate bar edibles 2-3 times a week would be equivalent to an extra 8-16 chocolate bars per month, averaging 144 extra chocolate bars per year

10mg Activated THC per Dose: Why it's Good?



- Enough flexibility in dosage to satisfy consumer access; reducing need for at-home or black market edibles
- Cautious approach still not enough to cause undue harm to children if accidental exposure occurs
- Reduces environmental impact and eliminates undue burden on processors and consumers
- Provides easy way for consumers to learn about and control dosage

**The Fiver-
Double Chocolate**
Total
THC:10mg
(4.76mg per cake)
CBD: <0.01mg

10mg: Caution and Access

- 10mg per single dose is on the very edge of the spectrum for an intoxicating dose
- This number was chosen for the safety of the first time or infrequent user to attempt and avoid over-ingestion for inexperienced consumers
- Access to 10mg doses and 100mg packages allows for a robust market-place capable of satisfying varied customer needs while eliminating risk of at-home products



10 mg: Colorado, Washington & California

- 10mg per dose/100mg per unit has become the national standard
- Colo. & Wash. Have 10mg servings/100mg package
- California is proposing 10mg/100mg also
- It is important for Oregon to band with the other pioneer legalization states and support the same edible potency standards as we help set the example of the National Standard as the country moves toward further legalization



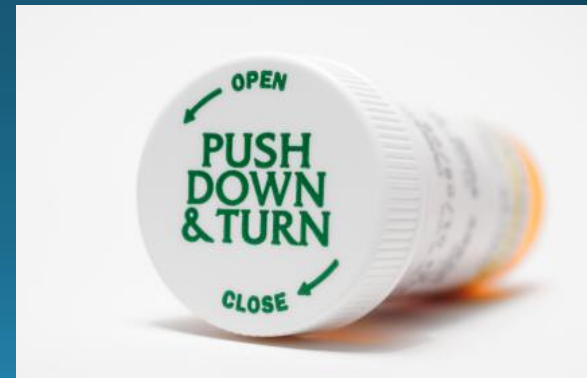
10mg: Legislative Intention

- SB 1511: Expanded definition of Limited Marijuana Retail Sales to include single-serving, low dose edible, one per customer per day
- 10mg THC per package limit would teach consumers about how to dose before full package products become available thru OLCC stores
- Essential step needed for smoothest possible legalization roll-out



Child-Resistant Containers

- ASTM standard containers with additional tamper-proof seal
- Limited Options: Current options make form-fitting necessary, however companies are positioning to open this market and make more packaging options available
- Poison Prevention Packaging Act of 1970:
 - Led to 46% drop in overall cases of exposure



Exit Bags



- An extra layer of child-protective packaging
- Adds safety to all packaging regardless of type of product
- Minimal one-time cost passed to consumers
- Re-usable: Bring back to store with you for re-use

Negligence & Child Endangerment Laws

- Child Negligence & Reckless Endangerment of a Child laws
- Mandatory reporting requirements
- Mechanisms to protect children on all fronts
- Change OHA handout cards
- The last line of defense is the parent, again, highlighting the importance of education on every level.



Stop-Gap Issue

- Emergency Rules required by 5/31/16
- OHA has pledged to make changes
- OHA RAC was not able to discuss rules before temporary rules were passed
- No financial impact report was provided
- Environmental impact was not considered
- Industry stakeholders were not consulted
- 10 weeks of discovery and discussion has led to greater understanding of the complex multi-layered issues and logical changes considering all issues must be made.

Educational Solutions

- Healthcare community
- Parents
- Teens
- Children
- Dispensaries
- Consumers



Educational Solutions: **OREC**

- The Oregon Responsible Edibles Council
- Purpose: Create Public Education campaigns funded from within the cannabis industry
- Proactive approach to eliminate these problems before they exist
- Members: Oregon cannabis related businesses
- Fundraising Campaign: Major fundraising campaign in final planning stages



Educational Solutions: Public Education Campaigns



- Know Your Dose: Encourages first time/new edible consumers to start with a low dosage.
- Marijuana Exposure Pamphlet: Work with health care professionals to develop and distribute pamphlet about marijuana exposure in children to parents, counseling centers, ER's, and regional public health departments.
- Develop effective youth prevention campaigns

Educational Solutions: Public Education Campaigns (cont.)

- Parental Education campaigns: Information on useful at-home storage techniques and reminders of other sources- grandparents, babysitters, other family members or friends...
- Marijuana Handler Certification: Provide classes on how to quickly educate consumers on safe edible consumption in a fast paced retail environment
- Universal Symbol: Promote the symbol so children know to stay away from it !!!



Educational Solutions: Youth Prevention Pilot Program

- Proposed in HB 4014:
- \$1,000,000.00 budget from general fund
- State provided youth prevention program mandated by m91 committee



Citations:

- Sources: ¹Wang, George S. "Association of Unintentional Pediatric Exposures With Decriminalization of Marijuana in the United States." *Annals of Emergency Medicine* 63.6 (2012): 684-89. Print. ²Oregon Public Health Division. Marijuana Report: Marijuana use. Attitudes and health effects in Oregon. Oregon Health Authority. Portland, OR. 2016 January. ³Garrec, Sophie Le. "Cannabis Poisoning in Children." *Intensive Care Medicine* 40.9 (2014): 1394-396. Print. ⁴Appelboam, Andrew, and Patrick J. Oades. "Coma Due to Cannabis Toxicity in an Infant." *European Journal of Emergency Medicine* 13.3 (2006): 177-79. Print. ⁵Onders, B. "Marijuana Exposure Among Children Younger Than Six Years in the United States." *Clinical Pediatrics* (2015). Print