

Pediatric Intoxication from Ingested Cannabis Products in Colorado, and the Preventive Value of Child-Resistant Packaging

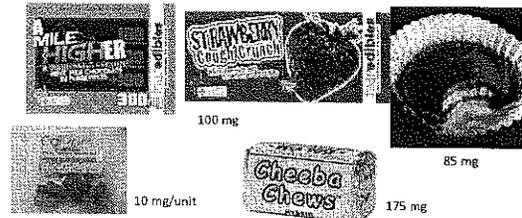
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A diversity of THC-infused food products are sold by medical marijuana dispensaries in Colorado

THC content ranges from a few milligrams to hundreds of milligrams

These highly palatable products are very attractive to young children – far more so than other “medications”



Adverse Health Effects of Pediatric Ingestion of THC and THC Containing Substances

Dronabinol (THC; Marinol®) in clinical trials of anti-emetic efficacy in chemotherapy patients:

Maximum Tolerated Dose (naïve patients) = 7.5 – 15 mg/m²
Assuming body surface area of 0.5 to 0.8 m² in 2 to 4 year olds, this equates to oral THC dose of = 4 to 12 mg

Case reports hospitalized young children who ingested THC containing cookies have noted lethargy and decreased breathing:

- Weinberg D et al. Intoxication from Accidental Marijuana Ingestion. *Pediatrics* 71: 848-850; 1983
- Macnab A et al. Ingestion of cannabis: a cause of coma in children. *Pediatr Emerg Care*;5:238-239; 1989
- Boros CA et al Cannabis cookies: a cause of coma. *J Paediatr Child Health*. 32:194-195; 1996

Pediatric Marijuana Exposures in a Medical Marijuana Legal State [Abstract] Wang GS, Heard K. *Clin Toxicol* 50:679; 2012

Objective: To compare the number of pediatric marijuana exposures presenting to a pediatric emergency department (ED) before (Jan 2005 – Sept 2009) and after (Oct 2009 – Dec 2011) change in federal enforcement activities pertaining to sale of medical marijuana

Methodology:

- Retrospective cohort study; patients ≤ 12 years
- Tertiary care children's hospital ED
- Abstraction of data from ED evaluations with ICD 9 codes pertaining to drug ingestion and/or poisoning

Cannabis Exposures

- 8 months – 12 years, 65% male
- Symptoms: CNS effects (lethargy, somnolence), respiratory insufficiency
- Work up: CBC, CMP, UA, RSV, CT head, CXR, c-spine x-rays, AXR, ECG, LP, APAP/ASA, IV antibiotics, Urine drug screen
- Disposition
 - More than half were admitted, some to ICU
- Source
 - More than half were due to medical marijuana
 - Majority edible products

- 3 yo healthy boy, Parent of Child (POC) put him to bed.
- After 3 hours, parent checked on him - very unbalanced, difficulty keeping his head up. He became less responsive so brought to an emergency department
- ER - very somnolent, only intermittently responsive to voice but responsive to painful stimulus
- Evaluation included many tests, CT scan; spinal tap refused by parents.
- Admitted to Pediatric ICU
- Urine Drug Screen returned positive for THC (confirmed)
- Social work, county social services, child abuse team consultation
- Exposure traced to deceased grandmother's medical marijuana cookies

Grandmother Gave 3-Year-Old Grandson Pot Cookies Boy Rushed To Hospital After Grandmother Couldn't Wake Him Up

Posted: 12/23/2009 - 7news

- ☐ A Denver medical marijuana activist was under investigation after she gave her 3-year-old grandson at least one peanut butter cookie laced with pot and the boy couldn't wake up the next morning.
- ☐ The toddler was rushed to the hospital Dec. 5, where he was treated in intensive care and fully recovered, according to a police report. Medical tests determined the child had THC, the active ingredient in marijuana, in his system.
- ☐ In a tragic twist, the 44-year-old grandmother, Erin Marcove, took her own life Dec. 12, a week after the incident

Child-Resistant Packaging: A Brief History of a Proven Preventive Strategy

In the late 1940s, Jay Arena, MD, a pediatrician at Duke and founder of the second Poison Control Center in the USA, became alarmed at childhood deaths from the new flavored "candy aspirin" – St. Joseph Aspirin for Children.



Dr. Arena persuaded Abe Plough, president of the baby aspirin manufacturer, Plough, Inc., to develop an early version of safety cap, which was introduced on a voluntary basis in the 1950s.

Introduction of the Palm-N-Turn Vial in the 1960s



Under the leadership of Henri Breault, MD of the Windsor Poison Control Center, the Ontario Association for the Control of Accidental Poisoning held a contest in 1964 seeking the best child-resistant closure for medication.



The Palm-N-Turn safety cap was selected as winner among 200 entries

Introduction of the Palm-N-Turn cap was associated with large declines in childhood poisoning from medication in two large population studies:

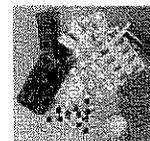
- A decline of 95% at Madigan General Hospital in 1968 – 1970 (Scherz R, NEJM, 285:1361-2; 1971)
- A decline of 91% in Essex County, Ontario in 1967-1972 (Breault, Clin Toxicol 7:91-95; 1974)

The Poison Prevention Packaging Act (15 U.S.C. 1472) was enacted by Congress in 1970

The PPPA, administered by the Consumer Product Safety Commission since 1973, requires child-resistant packaging for household products that present a risk of "serious injury or illness to children under five" who may drink, eat or handle the contents

The PPPA applies to numerous household chemicals, cosmetics, and medications, including most prescription drugs in oral dosage form, and drugs

Poison Prevention Packaging: A Guide For Healthcare Professionals



<http://www.cpsc.gov/cpscpub/pubs/384.pdf>

U.S. CONSUMER PRODUCT SAFETY COMMISSION
Office of Compliance

**Requirements under the Poison Prevention Packaging Act,
16 C.F.R. 1700**

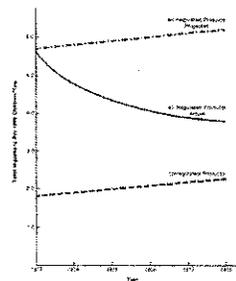
[\[www.cpsc.gov/businfo/regsumpppa.pdf\]](http://www.cpsc.gov/businfo/regsumpppa.pdf)

Under CPSC rules, the efficacy and acceptability of child-resistant packaging is established by structured testing in children age 42 to 51 months, and in senior adults

The package is considered child-resistant if no more than 20 percent of 200 children can open the container within 10 minutes.

The rules also require that 90 percent of 100 adults age 50 to 70 be able to open and properly close the package within 5 minutes

The Poison Prevention Packaging Act has been credited with major reductions in the incidence, and morbidity and mortality, of childhood poisoning



Data from National Electronic Injury Surveillance System: Pediatric ingestion of covered products declined by ≈ 40% from 1973 to 1978

Walton W. An evaluation of the Poison Prevention Packaging Act. Pediatrics 69:363-366; 1982

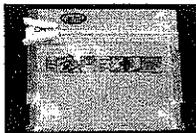
Child-resistant packaging is the standard of care for almost all oral medications and hazardous household products

The PPPA and the CPSC do not specify nor require a specific type of child-resistant packaging design.

It is the responsibility of the manufacturer to devise packaging and to perform tests that demonstrate child-resistance in accordance with CPSC standards. The CPSC assesses compliance on the basis of human performance test results.

CPSC provides a link to externally compiled information on various types of child-resistant packaging that functions in accordance with different ASTM standards [http://www.cpsc.gov/businfo/pppaguid/crpindex.html]

ASTM Type XI includes flexible, reclosable packaging, such as pouches, that could accommodate many THC-infused food products



CRREO Pouch: Child Resistant Reclosable Easy Open 7 x 6 inches [Pactech]

Marijuana "edibles" and THC infused food products:
Are they currently covered by provisions of the Poison Prevention Packaging Act subject to enforcement by state district attorneys or any interested party?

16 C.F.R. § 1700.14 Substances requiring special packaging.

Title 16 - Commercial Practices

§ 1700.14 Substances requiring special packaging...

(4) Controlled drugs. Any preparation for human use that consists in whole or in part of any substance subject to control under the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) and that is in a dosage form intended for oral administration shall be packaged in accordance with the provisions of §1700.15 (a), (b), and (c).

21 USC § 812 {Controlled Substances Act} Schedule I (c) includes marijuana and "tetrahydrocannabinols"

15 USC § 1477 [Enforcement by State Attorneys General] provides specifically for state enforcement of the PPPA; and 15 USC § 2073 allows for any interested person to bring an action seeking enforcement of consumer product safety rules and injunctive relief

Summary

1. Cannabis-containing or THC infused food products sold in Colorado include "candy bars", sweets, and other forms that are highly attractive to young children
2. Some products contain high doses of THC that may result in serious adverse effects, including CNS and respiratory depression, when accidentally consumed by young children,
3. Pediatric ingestion of cannabis or THC infused food products resulting in hospital evaluation and admission have increased significantly since the sale of THC infused "medical marijuana" food products in 2009
4. Child-resistant packaging, required for most oral prescription medications and many hazardous household products under the Poison Prevention Packaging Act since the 1970s, has been proven to be effective in decreasing childhood poisoning
5. CPSC compliant child-resistant packaging that may be suitable for cannabis-containing or THC infused food products is commercially available