

Is PPPA DOA For CBD?

JAMES O'REILLY*

ABSTRACT

Wide access to and extensive marketing of flavored forms of cannabidiol (CBD) is likely to lead to many child ingestion incidents, exceeding the current dozens of published medical reports about harms to children. Refusal by the federal agency responsible for child protective packaging use with drug products, the Consumer Product Safety Commission (CPSC), to impose package safety control measures, because of CBD's status as a federally controlled substance, is a missed opportunity to protect against accidental injuries.

IS PPA DOA FOR CBD?

We face an emerging child safety problem in the United States. The remarkable growth of sales for edible cannabinoid (CBD) products in this decade has outpaced the coverage of prior law. The legal system for requiring protection for children from harm seems to be beyond the ability of federal regulators. So the decades-old condemnation of *cannabis sativa* as a dangerous Schedule I drug under the 1970 Controlled Substances Act¹ is claimed to foreclose the use of the safety measures provided under the Poison Prevention Packaging Act (PPPA).² This Article critiques the 2019 federal decision of the Consumer Product Safety Commission (CPSC) to avoid mandating child protection rules for the safety packaging of cannabis-derived CBD edibles.

As of 2021, cannabis is still federally illegal for sale. Many states have changed their regulatory regimes to allow for consumer sales to replace their prior bans against both marijuana and the related "CBD edibles" as derivatives of the *cannabis sativa* plant. Cannabidiol is derived by heat or other means from the cannabis plant. The majority of states are instead now developing a stream of lucrative tax income from legalized commercial sales of these cannabis-derived edible substances. But the federal dysfunction of drug policy making in a harshly divided Congress has inhibited any changes that could enhance child safety from cannabis-related product ingestion.

Some of us are aging veterans of drug labeling and packaging conflicts of the past. We recall the years before the 1970 adoption of the Poison Prevention Packaging Act (PPPA),³ when different states addressed ingestion risks of products differently. Back in those days, the tort law of various states was invoked to sue the marketers of chemical or drug products, after a fatal or harmful child exposure, and the risks would be widely publicized after the child ingestion occurred. That statute gave FDA the power to regulate drug packaging, and FDA implementing rules became the basis on

* University of Cincinnati College of Medicine

¹ Controlled Substances Act, 21 U.S.C. § 801 et seq., Pub. L. 91-513, 84 Stat. 1236 (1970).

² 15 U.S.C. § 1471.

³ *Id.*

which private sector consensus standards for package security were expanded into mandates.⁴ These safety standards and their governmental equivalents⁵ were intended to shield the dangerous products, such as pesticides or prescription drugs, from easy access by curious children.

A child can act like a food explorer, attracted to small colorful items with pleasant smells that might taste better than the child's usual breakfast or lunch snacks. A handful of cannabis-derived gummy bears made with CBD may seem very tasty to the inquisitive three-year-old toddler. "What's this yellow pill in the dish next to mom's bedside? How does it taste?" But the products might be potent enough in their brain effects to raise medical concerns about possible consequences for the safety of the child.

The 1970 PPPA was intended to be the shield that assured parents that dangerous drugs would be out of reach of children, and FDA was the original user of its package limitation powers.⁶ So when CPSC was established in the 1972 Consumer Product Safety Act, this transferred statute was hailed as a great legal resource for keeping risky substances away from toddlers, whose attraction to pills and tablets could lead to serious adverse effects.⁷ Subsequent amendments allowed CPSC to "prohibit the packaging of such substance in packages which it determines are unnecessarily attractive to children."⁸

Fast forward a half century: CBD edibles are a remarkably fast-selling group of products. They draw their potency for adult consumers from the chemical and heat extraction of liquid cannabidiols, derived from the active cannabis material within cannabis flower and stems.⁹ These become edible through inclusion into tasty and well-fragranced candy-like vehicles into which the CBD is suspended.¹⁰

Is there a risk? How severely these cannabis-derived drug effects will impact the child's brain is a function of the child's age, the evolution of the child's digestive system, and the number of candies ingested. Because I lack the credentials to pack that medical assessment into a law journal article, I leave specific epidemiological evaluation of the risks of adverse effects to the growing amount of discussion in the pediatric medicine journals.¹¹ The sophisticated reader, like the manufacturers of these attractive cannabis-derived candies, could spend hours absorbing the many pediatric journal findings about child ingestion risks.¹² These risks from child ingestion are undeniable.

⁴ See INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, ISO 8317 (2015); INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, ISO 13127 (2012); ASTM INTERNATIONAL, ASTM D3475 (2020).

⁵ 16 C.F.R. § 1700-1-20.

⁶ These rules were transferred from the now-deleted FDA rule 21 C.F.R. Part 295 and transferred to the Consumer Product Safety Commission at 16 C.F.R. § 1700-1-20 in 38 Fed. Reg. 21,247 (Aug. 7, 1973).

⁷ MICHAEL R. LEMOV, CONSUMER PRODUCT SAFETY COMMISSION §15.21 (1981).

⁸ 15 U.S.C. § 1472(d).

⁹ LEMOV, *supra* note 7, §15.21; JAMES T. O'REILLY & EDGAR J. ASEBEY, LEGAL GUIDE TO THE BUSINESS OF MARIJUANA: CANNABIS, HEMP & CBD REGULATION (2020).

¹⁰ LEMOV, *supra* note 7, §15.21; O'REILLY & ASEBEY, *supra* note 9, at 15-21.

¹¹ John R. Richards, Nichelle E. Smith & Aimee J. Moulin, *Unintentional Cannabis Ingestion in Children: A Systematic Review*, 190 J. PEDIATRICS 142-52 (2017).

¹² Alice E. White, Christine Van Tubbergen, Brianna Raymes, Alexandra Elyse Contreras & Elaine J. Scallan Walter, *Cannabis-Infused Edible Products in Colorado: Food Safety and Public Health*

But we can pose the systemic question: is there a proper federal role for protection of young children from inadvertent ingestion of CBD, in the dosage forms that tend to be attractive? The PPPA undoubtedly applies to prescription drugs such as Epidiolex, a prescription drug that is derived from cannabis and from conventional cancer medications.¹³ Why shouldn't makers of candies such as gummy bears with CBD contents be required to place their cannabinoid products in similar safeguard packaging? Why would career safety regulators choose to remain mute?

The criticism is well asserted: CPSC abdicated its primary role in poison prevention when it ruled in December 2019 that it cannot apply the federal PPPA to products that contain CBD, because these cannabis-infused products are deemed unlawful in interstate commerce under the 1970 Controlled Substances Act.¹⁴

Should the federal statutory prohibition on sales of cannabis excuse CPSC from making any effort to apply poison prevention techniques to CBD gummy bears and other cannabis-derived candies? If not CPSC, then who at the federal level should be expected to intervene to help children?

A state safety regulator could do so, yet cross-border shipments of CBD are so frequent that they defy any willing state's ability to regulate packaging. Can the child ingestion impacts of CBD products be considered important enough for a new federal rule? Please read the medical literature and examine the existing subcategories of rules before responding. CPSC special packaging rules have regulated prescription drugs, acetaminophen, aspirin, ibuprofen, naproxen, and many drugs that have been moved to over-the-counter (non-prescription) sales.¹⁵ Why not also regulate CBD? Will a patchwork of multiple states with varying requirements be an adequate response to the tearful parent whose child lies on the gurney in the emergency room? Yes, caregivers, parents, and grandparents could have prevented the child from experiencing these harmful consequences.

We acknowledge that CBD regulatory efforts have varied widely among the states. Observers have seen that in a few states, there are active cannabis regulatory supervision roles with staffs of administrators who are tasked to oversee the sites of cannabis and CBD marketing.¹⁶ We can speculate that some states might have a field auditing unit reporting to their cannabis regulatory agency, and we could suppose that the state field unit might have the capacity and time with which to investigate and respond against CBD ingestion reports . . . or not. We can speculate that state poison control centers may be gathering CBD ingestion reports from emergency room statistics . . . or not.

Implications, 110 AM. J. PUB. HEALTH 790–95; Jennifer M. Whitehill, Julia A. Dilley, Ashley Brooks-Russell, Lucia Terpak & Janessa M. Graves, *Edible Cannabis Exposures Among Children: 2017–2019*, 147 PEDIATRICS 147 (2021).

¹³ Press Release, U.S. Food & Drug Admin., FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy (June 25, 2018), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms> [<https://perma.cc/HB7G-JGH2>]; 16 C.F.R. § 1700.14(a)(4).

¹⁴ OFF. OF THE SEC'Y, CONSUMER PROD. SAFETY COMM'N, letter to J. O'Reilly denying petition to regulate (Jan. 2019) (on file with the author).

¹⁵ 16 C.F.R. § 1700.14.

¹⁶ State regulatory coverages vary. See O'REILLY & ASEBEY, *supra* note 9, §16:7.

Are those putative state requirements for CBD-derived products sufficient to deal with risks from nationwide distribution of these products? Are deaths or more likely neurological harms going to be enough of a track record to induce state regulators to sound the alarm? The lobbying power of the CBD industry seems to be growing in recent years at the state level.

Why would I care? After decades of teaching tort classes and updating my texts on product safety, marijuana, hemp, and administrative rulemaking, I worry that a wide variety of lax state regulations are inadequately formulated and sparsely enforced, where they even exist. A state-by-state evaluation of regulations on CBD safeguards has not yet been accomplished. I expect that numerous fragmented state-level rules will allow many cannabis-derived product manufacturers to package their CBD gummy bears in one state and sell these packages in many other states without inhibition by varying or absent state rules. Simply put, state variations do not uniformly protect America's children, and uniform federal packaging rules may save children from harm.

Could CPSC have chosen to act? The federal budget¹⁷ for CPSC is \$140,000,000 in fiscal 2022, and a total of 516 employees are budgeted for its safety activities nationwide.¹⁸ By contrast, the several state resources for policing CBD sales vary. To my knowledge, no one source has compiled the data points showing how much each state's budget will expend in 2022 for state regulation of CBD products packaging. So, the debate over operational responsibility for CBD childproofing goes muted and virtually unnoticed, below the radar of other safety measures.

I concede to the reader that any proposal for new regulatory oversight roles is likely to be confronted by the industry's avid (and very well-funded) defenders, as immediate resistance can be expected: "What's that professor smoking? He is making this up! Just trust the parents to prevent child ingestion problems! Who needs to interfere with the cute bowl of yellow gummy bears?"

Some will aver that products liability exposure might stimulate insurance companies to become the surrogate safety police. "Jane's CBD Gummies, Inc." might seek to purchase liability insurance. The loss control manager of the insurer might send its underwriter to examine the clinical experiences of the CBD product line, for which liability insurance coverage policies are going to be written and renewed. Readers of *Business Insurance* magazine are conscious of the conflicts that frequently arise when an insurance carrier rejects a marketer's request for prospective coverage of its product liability risks.

If the insurance underwriter is even aware of the ingestion risk medical issues, the marketing company might tell the underwriter that the liability risks are miniscule, because the child's caregiver would certainly safeguard the child from ingesting gummies. But pause and reflect on the scenario: assuming that the CBD parent is "getting a buzz on," will that mellow-mood cannabis consumer be cognizant of the risks that toddler "consumers" are confronting in their home?

Look beyond insurance underwriting to the specific steps of a product liability case: the tort is claimed to be a CBD company's negligent failure to package its CBD candy-flavored edibles in child-resistant packaging (there are no absolutely "child proof"

¹⁷ OFF. OF MGMT. & BUDGET, EXEC. OFF. OF THE PRESIDENT, THE BUDGET FOR FISCAL YEAR 2022, OTHER INDEPENDENT AGENCIES FY22 1255 (2021), https://www.whitehouse.gov/wp-content/uploads/2021/05/oia_fy22.pdf [<https://perma.cc/8V7Z-7VZ6>].

¹⁸ *Id.*

packages, only child-resistant ones). Is the tort of parental negligence foreseeable? The parent's opening of their purchased bottle of fifty CBD edibles is step one. The parent's careless placement of perhaps twenty candies in a bowl next to their living room couch is step two. Step three, the child's eating those gummies, might lead to the parent's call for the ambulance. A potential products liability claim against the CBD edibles maker may be asserted at step four, after the medical recovery or a sad ending for that child.

The neglect of any physical security for access to the edible candies, such as a shrink-wrapped card inside that package, was the cost-saving decision the CBD marketing company made as it designed its packaging. The consequence of that casual corporate package-design decision is that the company manager opted to save costs and to forego the benefit of securing these CBD edibles against the risk of the child's foreseeable access.

As the longtime editor of the American Bar Association's *Products Liability Newsletter*, I can attest that insurers rarely study product packaging failure events. The West Publishing monthly *Verdicts Settlements & Tactics* has chronicled accidental injury data for many years, yet I have not found reports of jury awards or settlements for CBD edible products. So we may ask, are the medical literature reports of child ingestion harm all wrong? Just how remote is the risk of adverse effects from CBD child ingestion? Would a defense-funded clinical study among parents of toddlers who would ingest CBD be ethically feasible to conduct? How much would a local civil jury award for long-term brain-impairment claims by an aggrieved parent on behalf of their toddler or young child?

Assume the plaintiff's expert testimony in an edible-CBD tort case will track with the medical literature, such as articles that can be readily located.¹⁹ The insurer of the CBD marketer knows of this historical pattern of risk or should have competent technical advisors who will easily find it in minutes within a pediatric literature data base. Parental fault is likely to be the defendant's mantra: "The mother was a cannabis user, the child was her victim, don't blame my company!" Would the average juror so disdain that parent for her use of cannabis that the juror would hold the plaintiff-parent solely accountable for harm in this CBD ingestion scenario?

And, is strict liability in tort still available? Those plaintiff attorneys, once forced to memorize Restatement of Torts clauses on foreseeability and remember avoidable and preventable injuries as part of their bar exam preparation, may vaguely recall that the marketer of the dangerous product can be held strictly liable in some instances for foreseeable injuries. Where will CBD edible risks be considered by the typical juror? Sympathies for the toddler who eats a dozen sweet CBD candies, and who then manifests abnormal brain effects, is likely to be the focus of the plaintiff's counsel.

Most tort claims will settle before verdicts, of course. But by the time the appellate court receives the disputed tort claim on appeal, the losing party's counsel will be assessing the likelihood that the three judges on that panel would be sympathetic toward the parent who left their gummy bears within the reach of the child. Judges who had reached their appellate bench after years of hearing criminal defendants

¹⁹ See, e.g., Eric E. Kaczor, Bonnie Mathews, Kara LaBarge, Brittany P. Chapman & Stephanie Carreiro, *Cannabis Product Ingestions in Pediatric Patients: Ranges of Exposure, Effects, and Outcomes*, 17 J. MED. TOXICOLOGY 386–96 (2021); April J. Kam, *Grandma's Brownies Are Not What They Used to Be: Acute Intoxication From Cannabis Ingestion*, 25 (Supplement 1) PAEDIATRICS & CHILD HEALTH S3–S4 (2020).

ascribe their criminal conduct to “bad weed made me do it!” may be less empathetic toward the parent’s pattern of conduct in having left the CBD within the child’s reach. Did the parent read the CBD candy’s label, and what warnings was she or he given about risks of child access?

Settlement factors include the defendant CBD company’s ability to pay. Financial aspects of edible CBD sales are reported frequently and enthusiastically by the specialized cannabis news media, whose coverage lauds the business development efforts of the entrepreneurs.²⁰ Assume that the rapidly growing defendant CBD marketer had saved manufacturing overhead cost by not placing its CBD gummy bears into sealed “blister pack” pouches, because no federal rule had required protective packaging. Assume that the marketer who wants that retail advantage was blithely ignorant of its tort liability exposure from child ingestions. How much is at risk?

The demands for compensation might be larger than the CBD seller had expected. Should the parent of the CBD-ingesting toddler be held liable to pay all the costs of their child’s subsequent treatment? Could the errant parent rely on the good will of the distant manufacturer to rapidly reimburse the parent for ambulance and hospital charges, as well as the expenses of pediatric follow-up evaluation and therapy?

Finally, what should be done next? CPSC should accept the need to cover edible CBD, in the recognition that its PPPA rules apply to other drug products.²¹ CPSC’s statutory mission is to save children from avoidable harm, so defining CBD edibles under the PPPA umbrella would make sense. The CBD edibles industry should anticipate regulation and should pursue an expanded ASTM or ISO voluntary safety standard. Insurers should make the insured company’s use of child resistant packaging a checklist item during their underwriting of CBD clients’ liability exposures.

Will patterns of fatal child ingestions draw news media attention? Yes. Will Congress consider the safety aspects of CBD in future cannabis legislation? Perhaps. Will juries in future tort cases award large damages against the CBD companies? Probably. Will the CPSC act to protect children from CBD ingestion risks? Time will tell!

²⁰ See, e.g., MJBIZDAILY, <https://mjbizdaily.com/>.