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To: Medical Cannabis Policy Advisory Board

From: Trevor Eckhoff, policy analyst, Utah Department of Health and Human Services (DHHS), Center for Medical Cannabis

Subject: **Additional medical cannabis dosage forms**

Introduction

The board may consider the following options for making a recommendation to amend the statute regarding legal dosage forms that are processed and sold in the state medical cannabis market:

1. Don't allow additional medical cannabis dosage forms beyond those already allowed.
2. Allow additional medical cannabis dosage forms, such as:
 - a. Edible products, like:
 - i. Chocolates;
 - ii. Cookies, brownies, and other infused baked goods;
 - iii. Infused oils and butters;
 - iv. Hard molded confections made primarily from sugar or syrup;
 - v. Honey;
 - vi. Beverages;
 - vii. Powdered beverage mixes or beverage additives; or
 - viii. Syrup beverage mixes or beverage additives;
3. Request the Cannabis Research Review Board review a specific dosage form or forms beyond those already allowed in state statute.

Background

At its last meeting, the board voted for recommending a statute change allowing suppositories to be added to the list of medical cannabis legal dosage forms in [Utah](#)

[Code Section 26B-4-201\(42\)](#). The board also voted to table consideration of recommending new dosage forms. This memorandum will explore additional medical cannabis dosage forms the board may consider recommending be allowed in the state medical cannabis program.

Analysis

Medical cannabis dosage forms allowed in other medical-only states

Among medical cannabis-only states, 9 of 16 programs have dosage forms that aren't allowed in the Utah medical cannabis program. Notably, Florida, Oklahoma, and Texas have no limits on dosage forms.

- The Florida medical cannabis statute has approved routes of administration, such as oral administration, which allows manufacturers to produce a variety of orally administered products.
- Oklahoma allows any route of administration, but does have administrative rules that set manufacturing standards for certain products.
- The Texas low-THC cannabis program allows for any route of administration except for smoking.

The remaining 6 states have laws that allow for only specific dosage forms to be manufactured. Mississippi is an exception, as processors are unrestricted in the creation of edibles but restricted in all other dosage forms. The most common dosage forms allowed in other state medical cannabis programs that are not allowed in Utah include the following:

- Suppositories (6 states);
- Smokable flower (5 states; and
- Various edible products (5 states).

The **Appendix** lists all dosage forms allowed in other medical cannabis-only states.

Edibles

Edibles in the Utah medical cannabis market

[Utah Code Section 26B-4-201\(42\)](#) limits orally administered medical cannabis products to specific “medicinal dosage forms,” which allows the manufacturing of certain products. Orally administered products allowed under the statute are:

- a tablet (i.e. mints);
- a capsule;
- a liquid suspension that does not exceed 30 ml (i.e. tinctures)
- a sublingual preparation (i.e. tinctures, strips, syringes); and
- a gelatinous cube, gelatinous rectangular cuboid, or lozenge in a cube or rectangular cuboid shape (i.e. gummies).

The most commonly sold edible product in the Utah market is gelatinous cubes, or “gummies.”

Edibles in other state medical cannabis markets

The incorporation of cannabinoids into edible products and the sheer variety of edible products in medical cannabis states, not to mention adult use states, begs many questions about the safety and efficacy of various dosage forms. Currently, there is a lack of research on specific edible dosage forms, which adds to the concerns of their safety and efficacy. In addition, there are concerns about certain edible products’ inherent or perceived appeal to children and the potential abuse or accidental consumption of edible cannabis products. The following section will explore infused chocolate in detail and offer consideration for edibles containing fat and/or sugar.

Infused chocolate

Infused chocolate is sold in the Florida, Hawaii, Mississippi, Oklahoma, and Texas medical cannabis markets.



Florida medical cannabis chocolate from MÜV



Texas medical cannabis chocolate from goodblend



Hawaii medical cannabis chocolate from HawaiianEthos

There are a number of claims about infused chocolate and a few studies that give limited insight. The primary claim in favor of infused chocolate and other high fat edible cannabis products is that cannabinoids like THC and CBD have high lipophilicity, meaning they tend to more easily combine with fats and other lipids. Because chocolate has a higher fat content, when it's eaten with cannabinoids, it may increase their absorption and bioavailability, or access, to the human body.

An additional claim about infused chocolate is that it may benefit patients with eating or sensory-related concerns, since it has a better flavor and texture than other dosage forms. Patients with autism who can't chew and swallow gummies due to sensory perception issues could benefit from chocolate. Geriatric patients who reject food and medication may find chocolate easier to eat. This is a common use for the calcium supplement Viactiv®, which is made with chocolate and caramel to make supplements easier to consume. Ex-lax® is another medication brand that offers chocolate pieces as an alternative to caplets.

While there is some academic literature on the topic, the board should consider asking the Cannabis Research Review Board to evaluate existing literature on infused chocolate as a medical cannabis dosage form. A number of studies suggest that ingesting cannabinoids with dietary fats increases their systemic exposure to the human body, effectuating greater bioavailability to systemic circulation.

[One such study](#)¹ was led by researchers at the University of Nottingham School of Pharmacy in 2016. Researchers administered THC and CBD separately to rats in both a lipid-free and lipid-based formulation. The results demonstrated that the co-administration of cannabinoids with lipids enhances the bioavailability of both THC and CBD in rats, with 2.5-fold and nearly 3-fold respective increases when compared to lipid-free administrations. Researchers concluded that “the amount of lipids present in cannabis-containing foods, or following a high-fat meal, is sufficient to activate intestinal lymphatic transport and lead to increased systemic exposure to cannabinoids.” A greater exposure may lead to more pronounced therapeutic effects but can carry a higher risk of acute toxicity.

[Another similar study](#)² was conducted by pharmacological researchers at the University of Minnesota in 2019, but this time with 8 human volunteers with refractory epilepsy. The volunteers were given 99% pure CBD capsules from a state medical cannabis company with 4 different lot numbers. A control group fasted breakfast and the experimental group ate a fatty breakfast burrito. There was no group that ate a low or no fat breakfast. The results indicated that when compared to fasting, taking CBD with the provided food increased its amount in the body by 4-times on average. The highest amount recorded in the blood was 14-times the

¹ Zgair, A., Wong, J. C., Lee, J. B., Mistry, J., Sivak, O., Wasan, K. M., Hennig, I. M., Barrett, D. A., Constantinescu, C. S., Fischer, P. M., & Gershkovich, P. (2016). Dietary fats and pharmaceutical lipid excipients increase systemic exposure to orally administered cannabis and cannabis-based medicines. *American Journal of Translational Research*, 8(8), 3448–3459.

² Birnbaum, A. K., Karanam, A., Marino, S. E., Barkley, C. M., Rummel, R. P., Roslawski, M., Gramling-Aden, M., & Leppik, I. E. (2019). Food effect on pharmacokinetics of cannabidiol oral capsules in adult patients with refractory epilepsy. *Epilepsia*, 60(8), 1586–1592.

<https://doi.org/10.1111/epi.16093>

control group. Researchers concluded that when taken with fatty foods, CBD exposure to the human body dramatically increases.

These studies suggest that cannabis and cannabinoid products containing fat—like chocolate, baked goods, butters, and oils—may increase cannabinoid absorption when compared to other edible products and different routes of administration like inhalation. More research on other dosage forms from both the scientific community and Medical Cannabis Policy Advisory Board staff is needed to determine safety concerns and efficacy. This would require assistance from Lauren Heath, an academic pharmacist employed by the University of Utah, with whom the DHHS Center for Medical Cannabis has contracted to search research databases and review scientific studies.

Concerns with adding additional dosage forms

What is “appealing to children?”

Medical cannabis statute regulates the ability of medical cannabis processors to create and label products that appeal to children. [Utah Code Section 4-41a-603](#) states:

- (1) A cannabis processing facility:
 - (a) may not produce a cannabis product in a physical form that:
 - (i) the facility knows or should know appeals to children;
 - (ii) is designed to mimic or could be mistaken for a candy product; or
 - (iii) for a cannabis product used in vaporization, includes a candy-like flavor or another flavor that the facility knows or should know appeals to children;

Whether infused chocolate would be inherently appealing to Utah children is contested. Advocates for infused chocolate highlight the state legality of gummies, which have various flavorings and can be coated in granulated sugar. As noted above, there are examples of conventional medications and supplements using

chocolate in their formulations. However, this appears to ease administration issues, not increase the absorption or effectiveness of the drug.

Edible cannabis product exposure to children

There has been a substantial rise in accidental consumption of edible cannabis products by children. This is a natural consequence of cannabis products becoming increasingly available across the United States. While cannabis companies and public health officials often urge cannabis users to store their products securely and safely, people don't always heed this advice. The [American Academy of Pediatrics \(AAP\) reported](#) a nationwide 1,375% increase in edible cannabis product exposure among children less than 6 years old, according to data from the National Poison Data System (NPDS) collected between 2017 and 2021. Two-year-olds accounted for 27.7% of cases, the largest number among each age group, followed by 3-year-old patients at 24.6% of cases. 97.1% of cases occurred in a residential setting. These exposures can put a child at risk of acute cannabinoid intoxication. Common symptoms reported by NDPS include dizziness, lack of coordination, rapid heart rate, and vomiting. Fortunately, no deaths were reported in the timeframe of this study.

[The Utah Poison Control Center reports](#) that while there are a small number of exposures to cannabis products in children less than 6 years old, about half of reported cases involve an edible product. It is important to note that exposures aren't exclusive to medical cannabis products. Recreational cannabis products illegally imported from neighboring states and hemp products also play a role.

AAP recommends that public health entities and lawmakers consider implementing policies that include the following prevention strategies:

- Changing product packaging and labeling requirements to reduce curiosity and attraction to children;
- Regulating the maximum allowable dose in a package to prevent accidental overconsumption; and

- Increasing public education to mitigate household risks, such as storing cannabis products in a secure location and keeping cannabis in childproof packaging.

Options

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 - v. Honey;
 - vi. Beverages;
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Appendix: Dosage forms allowed in other medical-only states

State	Medical cannabis dosage forms
Alabama	<ul style="list-style-type: none"> • Suppositories
Florida	<p>No approved dosage forms, but there are approved routes of administration:</p> <ul style="list-style-type: none"> • Edibles without sprinkles or icing; • Inhalation, including smoking; • Oral; • Sublingual; • Suppository; and • Topical
Hawaii	<ul style="list-style-type: none"> • Smoking; • Infused oils and butters; • Hard molded confections made primarily from sugar or syrup; • Chocolates; • Cookies and brownies; • Honey; • Beverages; • Powdered beverage mixes or beverage additives; and • Syrup beverage mixes or beverage additives
Iowa	<ul style="list-style-type: none"> • Suppositories
Louisiana	<ul style="list-style-type: none"> • Smoking; and • Drinks;
Mississippi	<ul style="list-style-type: none"> • Smoking; • Edibles; • Beverages; and • Suppositories
Oklahoma	<ul style="list-style-type: none"> • No approved classes, but the state has rules regarding the manufacturing of smokable, nasal, orally consumed, and rectally/vaginally administered products.
Pennsylvania	<ul style="list-style-type: none"> • Suppositories (considered a topical form, which are legal)
Texas	<ul style="list-style-type: none"> • Low-THC cannabis can be legally consumed for medical use in any way except smoking