Additional medical cannabis dosage forms

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- Medical cannabis dosage forms allowed in other medical-only states
- 2. Edibles in the Utah medical cannabis market
- 3. Infused chocolate and other fat-containing dosage forms
- 4. Concerns with adding additional dosage forms
- 5. Recommendation options

Presentation outline

Background

Basis for proposal: there are dosage forms that are not allowed in the state medical cannabis statute that could benefit some patients more than existing dosage forms.

- At the last MCPAB meeting, the board voted 5 to 2 for recommending that suppositories be added to the list of medical cannabis legal dosage forms.
- The board also voted to table consideration of recommending new dosage forms.

Dosage forms allowed in other medical-only states

- 9 of 16 medical cannabis-only states have dosage forms that aren't allowed in the Utah medical cannabis program.
- Florida, Oklahoma, and Texas have no limits on dosage forms.
- The remaining 6 states have laws that allow for only specific dosage forms to be manufactured.
- The most common dosage forms allowed in other medical states are:
 - Suppositories (6 states);
 - Smokable flower (5 states); and
 - Various edible products (5 states).

Refer to the appendix in the memorandum for more information.

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." 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."

Infused chocolate







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

What are the arguments for infused chocolate?

Claim:

- Cannabinoids like THC and CBD tend to more easily combine with fats and other lipids.
- 2. Chocolate is high in fat.
- 3. When eaten with cannabinoids, it may increase their absorption and bioavailability, or access, to the human body.

What are the arguments for infused chocolate?

 Chocolate may benefit patients with eating or sensory-related concerns, since it has a better flavor and texture than other dosage forms.

2016 University of **Nottingham study**

- **Experiment:** Researchers administered THC and CBD separately to rats in both a lipid-free and lipid-based formulation.
- **Results:** 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.
- **Conclusion:** "the amount of lipids present in cannabis-containing foods, or following a high-fat meal...lead(s) to increased systemic exposure to cannabinoids."

2019 University of Minnesota study

Experiment: Researchers administered 99% pure CBD capsules to 8 volunteers, once with no breakfast and once with a fatty breakfast. **Results:** When compared to fasting, taking CBD

with the provided food increased its amount in

the body by 4-times on average.

Conclusion: When taken with fatty foods, CBD exposure to the human body dramatically <u>increases</u>.

Concerns with adding additional dosage forms – appealing to children

- Utah Code Section 4-41a-603
 prohibits the production of products that appeal to children.
- Whether infused chocolate would be inherently appealing to children is contested.
- Infused chocolate products may appear to be more recreational than medical.

Edible cannabis product exposure to children

- There has been a substantial rise in accidental consumption of edible cannabis products by children.
- 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.
- These exposures can put a child at risk of acute cannabinoid intoxication.
- The Utah Poison Control Center reports that while there's a small number of exposures to cannabis products in children <6 years old, about half of reported cases involve an edible product.
- **Exposures aren't exclusive to medical cannabis products**. Recreational cannabis products illegally imported from neighboring states and hemp products also play a role.

Medical cannabis pharmacy pharmacist in charge (PIC) thoughts on infused chocolate

9 of 15 PICs joined a virtual meeting to discuss additional dosage forms.

- Support for chocolate as a dosage form.
- Support for individual pieces rather than chocolate bars.
- Lack of support for individually wrapped pieces.
- Support for flavored chocolate.

- 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 to complete a scientific review a specific dosage form or certain forms beyond those already allowed in state statute.

Recommendation options