STATE OF IOWA DEPARTMENT OF Health and Human services

Medical Cannabidiol Board VAPORIZABLE FLOWER PETITION

Subcommittee Report

February, 2023

Introduction

At its February, 2023 Board meeting, the Board discussed a petition to add "vaporizable flower" as an approved form for Iowa's Medical Cannabidiol Program. This petition, and supplementary materials, were delivered to the Board on December 28, 2022. The Board reviewed these materials, researched their own materials, and reviewed implementation strategies for this form from similar, conservative medical cannabis programs, mainly UT and OH. The Board has expressed support for the current prohibition of a flower (or potentially combustible) form of cannabis, and the intention of IA's medical program to be limited in scope and as medically defensible as possible. However, the Board also understands the ongoing requests and public comments from patients and the industry about the desire for a flower form, and the economic implications of allowing or prohibiting it.

In order to be thoughtful about this decision and do its due diligence, the Board assembled a subcommittee of members to properly articulate their concerns and recommendations to Legislators and interested stakeholders about the significant shift in program mechanics that a raw flower form of cannabis represents. Additionally, at a February 14, 2023 Subcommittee for <u>SSB1113</u> in which the bill passed, this subcommittee believes its intentions of this report were miscommunicated and represented inaccurately.

Background

This is the second instance of a "vaporizable flower" petition that Board has seen. The Board unanimously denied a similar petition at their November, 2019 Board meeting. Of the 37 commercial medical cannabis programs, Iowa and Texas are the only two programs that do not allow a flower form or some kind. Many states started their medical programs without a flower form, but have since added it to their program via <u>legislative action</u> or <u>advisory board approval</u>. Whether driven by science or passion, medical cannabis programs have an empirical tendency to evolve.

It is important to understand the distinction between the terms "vaporizable" or "combustible." "Vaporization" refers to the heating of the flower to a specific temperature using a device, whereby patients receive a similar effect to combustion, but possibly without as many health consequences of combusting and inhaling the product. "Combustion" refers to the addition of a flame to burn the product for inhalation.

While there are obvious health and public health concerns with vaporizing or combusting cannabis, it is unknown if the safety profile of currently available vaporized concentrates is better. If used as intended, it is like that vaporized flower presents the greatest harm reduction profile of all "inhalable" forms; this is an aside from other consequences with a flower form.

The Board is well aware that if a flower form is added for vaporization, a portion of patients would certainly combust or smoke the product. The addition of the form would be a substantial shift in how lowa's program operates, and the subcommittee has listed its relevant concerns below.

Subcommittee Concerns, Comments

- 1. "Combustible" or "Smokable" forms are prohibited by Chapter 124E. While the Board has the ability to recommend approval of this form, it would also be required to pass through the Board of Medicine and State Board of Health; an unlikely path. As the legislature specifically prohibited this form, the Board does not believe it is their place to add it themselves. The Subcommittee believes it to be incompatible with the origin and intent of Iowa's program, which is intended to be "limited" and tightly controlled. If that intent has changed, it is best determined by the legislature.
- 2. Flower may be "combusted" just as easily as it is "vaporized." The petitioner's own citations document persistent combustion by cannabis patients, and common "hybrid" use of both combustion and vaporization.
- **3.** The optics of combustion, even inadvertently allowed by a medical board, normalizes such practice. The Board has particular concern with the normalization of a flower form on lowa's youth.
- 4. The Board has raised concern, and it is actively seeking to correct, issues around telehealth certifications and the rise in THC waivers. In the current landscape, the Board does not have confidence in the intended patient-provider relationship, and has particular concern with how unscrupulous certifiers may grant access to this form.
- 5. The Board has raised concern, and is actively looking to correct, issues around licensee marketing and advertising. Indeed, Iowa's manufacturer transitioned their public and online presence in 2022 to that of a lifestyle or wellness brand, as opposed to a manufacturer of medical products. The Subcommittee has serious reservations with allowing this form in light of these marketing concerns, and the intention to normalize cannabis.
- 6. Metering of flower dose requires grinding to a powder then loading a vaporizer. The Subcommittee believes this to be more inaccurate as compared to currently available vaporizable concentrates.
- 7. The fact that lowa is one of the only programs to not allow a flower form is not of particular concern to the Subcommittee. Iowa implemented a medical-based board that consults the evidence-based medical literature.
- 8. The "entourage effect," as described in anecdotes and mentioned in some studies, is a cultural/social phenomenon centered on cannabis and given scant credence in evidence-based medicine. The Subcommittee searched the term within the National Library of Medicine's website yields only observational and anecdotal articles; UpToDate yields nothing at all.
- **9.** The Subcommittee is aware of the high cost of products and the more favorable economics of the flower form. Cost is a factor in all aspects of medicine and life, but for the Subcommittee, the social and public health implications, and lack of medical defensibility outweigh those cost considerations.
- 10. Based upon the review of the literature on cannabis (especially pertaining to mental health), a vaporized flower product may provide more balance of cannabinoid exposures (THC, CBD, etc.), especially compared to the refined and higher-potency products currently available. Vaporization itself, as it uses less heat compared to combustion, may make this balanced delivery more likely, but the studies around this are limited and inconclusive, as most studies tend to lump together various inhalable routes of administration together.

Subcommittee Recommendations

In light of the limited intent and scope of the program, the construct and duties of this Board, and the series of concerns listed above, this Subcommittee cannot recommend the addition of flower for vaporization, or otherwise. Should the legislature ever consider unilaterally adding a flower form the Board requests that the legislature give thoughtful consideration to the public health and social impacts, the necessity of law enforcement and substance abuse collaboration, and grant the regulatory agency authority to implement robust mechanisms around access and the types of flower available, product testing and safety, prohibitions on social consumption, and advertising and marketing.

The Vaporizable Flower Subcommittee provides the following recommendation to the full Board:

- Dr. Robert Shreck (Oncology) Deny
- Dr. Stephen Richards (Pharmacy) Deny
- Dr. Jacqueline Stoken (Pain Management) Deny

Full Board Vote – February 27, 2023 Meeting

On February 27, 2023, the Medical Cannabidiol Board held a meeting to review the Subcommittee's recommendations and make a full vote.

There was Board consensus on the public health and optics concerns of a medical board allowing this form. The Board firmly believes that if the original intent of the program has changed, or there is broad support for the addition of a flower form, that the legislature makes that determination on its own.

A motion was made by Dr. Stoken, with a second from Dr. Shreck, to deny the petition for the addition of vaporized flower to Iowa's medical cannabidiol program. A roll call vote was taken:

- Cpt. Mike McKelvey (Chair, Law Enforcement) **Deny**
- Dr. Robert Shreck (Oncology) **Deny**
- Dr. Jacqueline Stoken (Pain Management) Deny
- Dr. Stephen Richards (Pharmacy) Deny
- Dr. Andrea Weber (Psychiatry) Deny
- Dr. Mohamad Mokadem (Gastroenterology) Deny
- Dr. Michael Colburn (Pediatrics) Absent

The motion carried unanimously, and the petition is denied.

Subcommittee Responses to Petition Citations

I. Abrams, et al Clin Pharmacol Ther 2007

- Type of study: Pilot, randomized: raw cannabis, smoked v vaporized
- Participants: 18 experienced cannabis users
- Conclusion: THC availability is bioequivalent independent of mode, smoked versus vaporized; carbon monoxide levels high with smoked.
- Subcommittee Comment: Does not address the "flower" issue. No argument here—we know vaporized is preferable to smoked on a number of measures.

2. Aston, et al

- Exp Clin Psychopharmacol 2019
- Type of study: Observational; in-person interview
- Participants: 25 medical cannabis card holders
- Conclusion: Identified multiple merits and demerits of mode of administration, vaporizing versus combusting versus edibles, etc.
- Subcommittee Comment: Observational study via interview. Relative incidence of each choice of delivery system quantified but no conclusions relative to "flower" issue.

3. Bud & Mary

- Unpublished
- Type of study: online survey via email
- Participants: 643
- Conclusions:
 - I. equal numbers obtained card in-person versus online
 - 2. 90% want flower-based product
 - 3. 90% want more dispensaries
 - 4. 4) 80% think telehealth is important
 - 5. 92% want medical cannabis to be cheaper
 - 6. 76% want medical cannabis card to be cheaper
- Subcommittee Comment: Responders are self-selected and incidence of response to the thousands who got the email not noted. This is a market-survey, targeted and self-selected, not medical research.

- 4. Cranford, et al
 - Drug Alcohol Depend 2016
 - Type of study: observational, by email survey
 - Participants: 1,485 Michigan residents applying for or renewing medical cannabis cards
 - Conclusions: 40% vaped, but 87% of vapers also smoked.
 - Subcommittee Comment: This undermines the petitioner's own contention that patients will not smoke the "vaporizable flower" product.

5. Ferber, et al

- Current Neuropharmacology 2020
- Type of study: Meta-analysis of terpenes coupled with cannabinoids in treatment of depression, anxiety and bi-polar disorders.
- Conclusions: ". . .further research is warranted." ". . . such innovative combinations between terpenes and cannabinoids have not been considered earlier in existing scientific research."
- Subcommittee Comment: Depression, anxiety and bi-polar disorders are not specified adverse medical conditions in Iowa. References multiple animal studies; admits there is no "existing scientific research" in humans but calls for some to be done. No support here for human treatment.

6. Hazekamp, et al

- Journal of Pharmaceutical Sciences 2006
- Type of study: Evaluates a "new" (2006) table-top device (The Volcano Medic) for vaporization of cannabis.
- Conclusion: reports 54% average delivery of vaporized THC to the patient.
- Subcommittee Comment: Does not address the "flower" or "entourage" issue, only technical aspects of vaporizing.

7. Iowa IDPH Medical Cannabidiol Program Update

- IDPH website, 2022
- Type of study: market report
- Conclusions: none—a market report
- Subcommittee Comment: reports majority (65%) of product type sold is vaporizable concentrate and majority of formulation (77%) is high THC. Chronic pain accounts for 69% of certifications and PTSD for 19%.

- 8. Lanz, et al
 - Open Access article under Creative Commons Attribution License 2016
 - Type of study: in vitro study of five vaporizing devices
 - Conclusions: Identified four proprietary devices that vaporized cannabis without combustion and one that failed because of combustion.
 - Subcommittee Comment: addresses merits and demerits of several vaporizing devices; does not address the "vaporizable flower" issue.

9. Li, et al

- Complementary Therapies in Medicine 2019
- Type of Study: observational; self-reported via smart-phone app
- Participants: 2,987 current medical cannabis patients self-reported effects of 20,000+ treatments
- Conclusions: higher THC potency and whole flower were reported more effective in transiently relieving pain than lower THC potency and other forms; CBD demonstrated no benefit with or without THC. Vaping (flower versus concentrate is unspecified) was comparable in effectiveness with combusting using a pipe. Admits to self-selection as a bias.
- Subcommittee Comment: observational; self-selecting form and dose.

10. National Academy of Sciences 2017 Health effects of cannabis; the current state of evidence and recommendations for further research.

- Type of publication: 400+ page, one-time tome
- Conclusions: Researchers have also explored vaporization as a method for administering cannabis (Abrams et al, 2007). Cannabinoids vaporize at lower temperatures than the temperature at which pyrolytic toxic compounds are created through combustion; as a result, levels of some carcinogenic compounds are lower in cannabis vapor than in cannabis smoke (Eisenberg et al., 2014). However, there is a paucity of research on the effectiveness of these devices as a mode of drug administration. For example, data on the plasma concentrations of cannabinoids achieved through use of vaporizers exists, but is limited (Abrams et al, 2007; Zuurman et al., 2008). In addition, even less is known about the long-term pulmonary effects of inhaling a vaporized liquid than about the effect of inhaling plant material. As vaporizing devices proliferate and evolve, researchers may benefit from advances in their portability and usability but will also have to account for clinically relevant differences in the functioning and effectiveness of an increasingly wide range of models.
- To circumvent the practical and methodological challenges involved in administration of cannabis through smoking or vaporization, investigators may choose to study the health effects of orally administered dronabinol or nabilone, which offer a more controlled method of drug delivery. However, the effects generated by these isolated cannabinoids might be at least in part different from those produced by the use of the whole cannabis plant, which

also contains cannabidiol (CBD) and other cannabinoids, as well as terpenoids and flavonoids.

- Recent reviews of the by the World Health Organization (World Health Organization, 2016) and the National Academy of Sciences, Engineering, and Medicine (National Academies of Sciences Engineering and Medicine, 2017) suggest that, although cannabis has potential benefit to treat certain types of chronic pain, to be used as an anti-emetic, and to improve patient-reported symptoms of multiple sclerosis, it is linked a number of potential health risks, including chronic bronchitis and increased respiratory symptoms; short- term impairment in learning, memory, and attention; impaired driving and risk for motor vehicle crashes; lower birth weight among babies born to mothers who used cannabis; and increased risk for the development of schizophrenia and other psychoses, cannabis use disorder, and other substance use disorders
- Subcommittee Comment: Few conclusions, largely calls for further study of various issues relating to effectiveness and safety.

II. Polosa, Rocardo

- BioMed Central Medicine, 2015, an Open Access article per Creative Commons Attribution License
- Conclusion: vaporization of tobacco is safer than combustion and less hazardous to the respiratory system.
- Subcommittee Comment: No argument here

12. Russo, Ethan B

- British Journal of Pharmacology 2011.
- Conclusions: Wide-ranging exploration of the "entourage" effect, heavy on speculation and reliant on in-vitro and animal studies. "Phyto-cannabinoid-terpenoid synergy, if proven, increases the likelihood that an extensive pipeline of new therapeutic products is possible from this venerable plant."
- Subcommittee Comment: Dr. Russo at the time of publication, twelve years ago, was an employee of GW Pharmaceuticals the producer of nabiximols. Key word in title of the article is "potential".

13. Russo, Ethan B

- Frontiers in Plant Science 2018
- Conclusions: lengthy exploration of the cannabis plant with emphasis on the putative "entourage" effect.
- Subcommittee Comment: searching "entourage effect" in UptoDate yields no results. It can be found in PubMed, yielding a list of chemistry articles, animal studies, and anecdotal human studies but no randomized controlled trials. All citations reviewed refer to the cannabis plant; none found regarding other medications. See Article 19 for alternative view of "entourage" effect.

14. Schauer, et al

- Drug and Alcohol Dependence 2019
- Type of article: observational, based upon CDC's Behavioral Risk Factor Surveillance System (BRFSS), a telephonic survey.
- Participants: 6174 Americans age 18 or older spontaneously responded to the 2016 Survey's marijuana module. It asked about cannabis use and mode in prior 30 days. 9.1% of responders used cannabis, 58% by smoking, 19% by vaping and multi-modal use by 34%.
- Subcommittee Comment: Further documents that smoking and multi-modal use of flower is common.

15. Shiplo, et al

- Harm Reduction Journal, an Open Access journal under Creative Commons Attribution, 2015
- Type of article: observational; online survey
- Participants: 364 Canadian adult medical cannabis users were recruited by cannabis producers to participate in a survey of cannabis use and mode in last 30 days.
- Conclusions: Vaping was most common (53%), smoking a joint less so (47%). Multi-modal use was common. There is a trend toward vaping for respiratory health and social reasons.
- Subcommittee Comment: observational; self-elected; paid \$10 (Canadian) for participation. This further documents frequent smoking and multi-modal use.

16. Tashkin, Donald

- Publication: Addiction, 2015
- Type of article: letter to editor in response to an article in prior edition.
- Conclusion: health benefit of vaping cannabis versus smoking cannabis, while desirable, are not as great as that seen in tobacco abuse.
- Subcommittee Comment: no argument there

17. Tetrault, et al

- Archives of Internal Medicine, 2007
- Type of publication: meta-analysis of 34 screened articles from 1966 to 2005, each addressing the effects of smoking cannabis.
- Conclusions: Short-term exposure to smoked cannabis is associated with bronchodilation. Long term is associated with increased respiratory symptoms suggestive of obstructive lung disease.
- Subcommittee Comment: You should not smoke anything, including cannabis.

18. Van dam, et al

- International Journal of Drug Policy, 2010
- Type of study: observational
- Number of participants: 20 frequent cannabis smokers switched to vaping for 30 days; pulmonary function assessed before and after vaping trial
- Conclusions: A subset of 12 who did not have an acute respiratory illness during the 30 days significantly improved their pulmonary function studies.
- Subcommittee Comment: You should not smoke anything, including cannabis.

19. Cogan, Peter S.

- Expert Review of Clinical Pharmacology, 2020
- Conclusion: A detailed take-down of the "entourage effect" canard.
- Comment: This is an article attached in rebuttal to the petitioner's promotion of the "entourage effect."