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Jim Lindenmayer, PhD, *Ottumwa*

Mark J. Braun, Executive Director

Mr. Charlie Smithson
Secretary of the Senate
State Capitol Building
Des Moines IA 50319

Ms. Meghan Nelson
Chief Clerk of the House
State Capitol Building
Des Moines IA 50319

Gerd W. Clabaugh, Director
Iowa Department of Public Health
Lucas Office Building
Des Moines, IA 50319

Re: 2020 Report on Use of Medical Cannabidiol

Dear Members of the Iowa General Assembly and Director Clabaugh:

Pursuant to the 2014 Iowa Acts Ch 1125, §10h, enclosed is the report on Report on Use of Medical Cannabidiol.

If you have any questions or need more information, please don't hesitate to contact this office.

Sincerely,

Mark J. Braun

\\Box Sync\Board of Regents Shared\BF\Legislative\2020 session\Reports\

Attachments

cc: Robin Madison
Legislative Liaisons
Legislative Log

June 26th, 2020
University of Iowa

Jennifer Harbison
Director Health Policy | Office of the Vice President for Medical Affairs

Re: **2020 Report to the Department of Public Health and the Iowa General Assembly**

Recent Publications and additions since the last review submitted July 2019:

There have only been 4 randomized placebo-controlled trials published since the last review. One focuses on the side effects of medical cannabis, two look at how food and dosage form design can affect the amount of cannabidiol that gets into the body and the last looks at the effectiveness of a use of CBD, although it is not one currently approved in Iowa:

- The first was published by Arkell and coworkers [1] in 2019 in the journal *Psychopharmacology*. In this randomized, double-blind, within-subjects crossover design, healthy volunteers (n = 14) with a history of light cannabis use attended three outpatient experimental test sessions in which simulated driving and cognitive performance were assessed. The main psychoactive component of cannabis, delta-9-tetrahydrocannabinol (THC), can impair driving performance. Cannabidiol (CBD), a non-intoxicating cannabis component, is thought to block or lessen certain adverse effects of THC. It is possible then that cannabis containing equivalent CBD and THC will differentially affect driving and cognition relative to THC-dominant cannabis. The authors concluded cannabis containing equivalent concentrations of CBD and THC appears no less impairing than THC-dominant cannabis, and in some circumstances, CBD may actually make worse the THC-induced impairment.
- The second study by Birnbaum and colleagues [2] in 2019 in the journal *Epilepsia* looked at how the presence in food in the stomach might affect the oral cannabidiol capsules. Eight patients who were receiving purified oral cannabidiol for seizures were given a single 750 mg dose of CBD on two different occasions. One time they fasted overnight and took the dose before breakfast and on the second occasion they did not fast and they had a high fat breakfast (a 800 calorie breakfast burrito). Then the amount of CBD was measured in the blood at different time points for 3 days. The presence of the food increased the maximum concentration of the CBD by almost 14 times and the total amount of exposure to the CBD over the 3 day period was 4 times larger. The authors concluded that taking with food can increase the effectiveness of oral capsules of CBD and that patients should maintain a fairly consistent diet to avoid large fluctuations in CBD concentrations.
- The third study was published by Patrician and colleagues [3] in 2019 in the journal *Advances in Therapy*. In this double-blind, placebo-controlled crossover study in 12 healthy individuals the authors were not evaluating effectiveness of a treatment but testing to see if a new Canadian patented oral capsule that is designed to release CBD quicker and give higher concentrations is better than the currently available capsules. The authors concluded that indeed absorption was enhanced in healthy individuals and they appeared to tolerate the increase blood levels, but they suggested that studies now need to be done in patients needing the medication and to ensure that they can tolerate the higher levels.
- The fourth study by Hurd and coworkers [4] was in the *American Journal of Psychiatry*. It was not

evaluated for one of the approved uses of CBD in Iowa. This study investigated the potential of cannabidiol (CBD), a nonintoxicating phytocannabinoid, to reduce cue-induced craving and anxiety, two critical features of addiction that often contribute to relapse and continued drug use, in drug-abstinent individuals with heroin use disorder. Forty-two adults received either 400 mg or 800 mg of CBD or a placebo (in a randomized, double blind fashion) to see if the CBD could diminish the cravings of withdrawing heroin addicts. Acute CBD administration, in contrast to placebo, significantly reduced both craving and anxiety induced by the presentation of salient drug cues compared with neutral cues. CBD also showed significant protracted effects on these measures 7 days after the final short-term (3-day) CBD exposure. The authors indicate that this initial exploratory investigation suggests CBD's potential to reduce cue-induced craving and anxiety provides a strong basis for further investigation of this phytocannabinoid as a treatment option for opioid use disorder.

The University of Iowa Carver College of Medicine and the University of Iowa College of Pharmacy recommends that based on the approval of oral cannabidiol solution for the treatment of these two epileptic seizure disorders that this new prescription product be used instead of the oral cannabidiol/medical marijuana products produced by the State of Iowa for the treatment of epilepsy. The new prescription product should be covered by Medicare and most private insurance programs; whereas the state products are costly and not covered by Medicare or private insurance.

References

1. Arkell TR, Lintzeris N, Kevin RC, et al. *Cannabidiol (CBD) content in vaporized cannabis does not prevent tetrahydrocannabinol (THC)-induced impairment of driving and cognition.* Psychopharmacology (Berl). 2019;236(9):2713-2724.
2. Birnbaum AK, Karanam A, Marino SE, et al. *Food effect on pharmacokinetics of cannabidiol oral capsules in adult patients with refractory epilepsy* [published correction appears in Epilepsia. 2019 Sep;60(9):2009]. Epilepsia. 2019;60(8):1586-1592.
3. Patrician A, Versic-Bratincevic M, Mijacika T, et al. *Examination of a New Delivery Approach for Oral Cannabidiol in Healthy Subjects: A Randomized, Double-Blinded, Placebo-Controlled Pharmacokinetics Study.* Adv Ther. 2019;36(11):3196-3210.
4. Hurd YL, Spriggs S, Alishayev J, et al. *Cannabidiol for the Reduction of Cue-Induced Craving and Anxiety in Drug-Abstinent Individuals With Heroin Use Disorder: A Double-Blind Randomized Placebo-Controlled Trial.* Am J Psychiatry. 2019;176(11):911-922.

Sincerely,



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Sincerely,



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