



FINAL REPORT

Cannabidiol Implementation Study Committee

January 2015

MEMBERS:

Senator Joe Bolkcom, Co-chairperson
Senator Michael Breitbach
Senator William A. Dotzler Jr.
Senator Charles Schneider
Senator Steven J. Sodders

Representative Walt Rogers,
Co-chairperson
Representative Clel Baudler
Representative John Forbes
Representative Bob M. Kressig
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AUTHORIZATION AND APPOINTMENT

Monitor the implementation of the limited legalization of use in this state of cannabidiol, consider whether the new law is helping the people it is supposed to help, and review the University of Iowa Carver College of Medicine research study called for by the legislation.



Cannabidiol Implementation Study Committee

I. Committee Proceedings

The committee was authorized to conduct one meeting during the 2014 Legislative Interim. The meeting was held on September 11, 2014, in Room 116 of the State Capitol.

II. Background

The Cannabidiol Implementation Study Committee was created by the Legislative Council for the 2014 Interim and was authorized to hold one meeting. The charge of the committee is to monitor the implementation of the limited legalization of use in this state of cannabidiol, to consider whether the new law is helping the people it is supposed to help, and to review the University of Iowa Carver College of Medicine research study called for by the legislation.

III. September 11, 2014, Meeting

Medical Cannabidiol Act Overview. Ms. Rachele Hjelmaas, Senior Legal Counsel, LSA Legal Services, provided a summary overview of 2014 Iowa Acts, SF 2360, the Medical Cannabidiol Act.

The Act includes the following:

- Allows for the medical use of cannabidiol, as defined in the Act, for alleviating symptoms caused by intractable epilepsy under certain narrowly defined conditions. An Iowa neurologist who has examined and treated a patient suffering from intractable epilepsy may provide but has no duty to provide a written recommendation for the patient's medical use of cannabidiol to treat or alleviate symptoms of intractable epilepsy, if certain criteria are met.
- A recommendation for the possession or use of cannabidiol shall be provided exclusively by a patient's in-state neurologist, shall be obtained from an out-of-state source, and shall only be recommended for oral or transdermal administration.
- The Iowa Department of Public Health (DPH) may approve the issuance of annual and renewal cannabidiol registration cards by the Iowa Department of Transportation (DOT) to a patient and to a primary caretaker of the patient who is at least 18 if certain criteria are met, and the patient or primary caretaker submits an application to DPH with certain information.
- A patient must be a permanent resident of Iowa.
- DPH is required to maintain a confidential file of the names of each patient and primary caregiver issued a cannabidiol registration card. However, certain information may be released to authorized persons under certain circumstances.
- The Act provides affirmative and complete defense provisions from criminal prosecution in this state for qualifying neurologists, patients, and primary caregivers who comply with the provisions of the Act for activities arising directly out of or directly related to the recommendation or use of cannabidiol in the treatment of a patient diagnosed with intractable epilepsy, and these defenses apply only if the quantity of cannabidiol oil does



not exceed 32 ounces per patient.

- A person who knowingly or intentionally possesses or uses cannabidiol in violation of the Act is subject to the penalties of Iowa Code chapters 124 (Controlled Substances Act) and 453B (Excise Tax on Unlawful Dealing in Certain Substances).
- The Act is repealed July 1, 2017.
- The University of Iowa Carver College of Medicine and College of Pharmacy are required to submit an annual report detailing the scientific literature, studies, and clinical trials regarding the use of cannabidiol on patients diagnosed with intractable epilepsy to the DPH and the General Assembly on or before July 1 of each year beginning July 1, 2015.

Rulemaking Process and Implementation – Update. Ms. Deborah Thompson, Policy Advisor and Healthiest State Initiative Coordinator, DPH, and Ms. Kim Snook, Director of Driver Services, and Mr. Mark Lowe, Motor Vehicle Division Director, DOT. Ms. Thompson presented an overview of the DPH administrative rulemaking process intended to implement the registration card program, including the application process, and Ms. Snook and Mr. Lowe answered specific committee member questions about the DOT issuance of the registration cards, including expected costs to DOT associated with the issuance.

Ms. Thompson stated that the administrative rules were written in collaboration to reflect the language in SF 2360 with DOT and key stakeholders. Notice of Intended Action was published in the August 6, 2014, Iowa Administrative Bulletin. The majority of public comments to the noticed rules recommended changes to the legislation and therefore fell outside of the scope of the administrative rules. The State Board of Health adopted some changes to the noticed rules on September 10, 2014, including a revised definition of “permanent resident,” an additional option for valid photo identification in the application process, and revisions to the renewal process. The department also removed the requirement for the recommending neurologist to physically examine a patient before issuing a written recommendation to better align with SF 2360 and added language to clarify that aggregate and statistical information that does not provide any patient identifiers can be made available to the public upon request. The rules become effective January 30, 2015.

Ms. Thompson also provided a flowchart on the basic card application process. Ms. Snook and Mr. Lowe answered questions about DOT’s role in issuing the cannabidiol registration cards, as well as funding concerns.

Committee members expressed concern about getting people the help they so desperately need under the law and raised concerns about the January 30, 2015, implementation date. Some members suggested that other administrative processes might have sped up the implementation of the law. Ms. Thompson responded that both the DPH and DOT have made every effort to work as quickly as possible to implement the law, and that there are many moving parts to work through and that additional details are still being worked out. She also noted that DPH may be able to allow people to apply earlier and have the registration cards ready prior to the January 30 date.

Cannabidiol Research Studies. Dr. Charuta Joshi, Clinical Associate Professor of Pediatrics with specialties in Neurology and Epilepsy, University of Iowa Carver College of Medicine, provided information on scientific research evaluating the role of cannabidiol in the control of refractory



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seizures. She explained that two strains of cannabis exist: Sativa, which contains more tetrahydrocannabinol (THC) and indica which contains more cannabidiol (CBD). THC is the psychoactive component of cannabis that produces a high, and CBD is a nonpsychoactive component. Depending upon variables involved in the process of production and processing of cannabis, such as temperature, fertilizer, etc., the concentration of THC and CBD can vary greatly and cannabis on the street may be pure THC. Dr. Joshi stated that intractable epilepsy is based on a person not responding to two or more effective medications, not on the number of seizures a person experiences. She further explained that in a number of research studies, CBD has been shown to be effective as an anticonvulsant in some patients, although what dosage is effective is not known, and that in such research, the use of CBD had no life-threatening side effects. In contrast, the 15-20 medications currently used as anticonvulsants for persons with epilepsy and other psychiatric illnesses have resulted in negative side effects including liver and kidney toxicity. CBD also has been found to not have addictive potential as some other medications do.

Dr. Joshi also noted that when plant extracts are used, there is no way to ensure the ratio of CBD to THC without standardization; however GW Pharmaceuticals is developing a standardized pure strain of CBD. The University of Iowa will be taking part in double-blind studies sponsored by GW Pharmaceuticals to learn more about cannabidiol in ways doctors have not been able to do so far. Participating patients may or may not be from Iowa. The product that will be used at the University of Iowa Children's Hospital test site in the double-blind studies is from a cloned plant that produces pure CBD and is a consistent product. GW Pharmaceuticals will provide all of the CBD used in the study. GW Pharmaceuticals has provided CBD to hundreds of children in the United States with no resultant, life-threatening side effects. The results of the study will be in the public domain.

Committee members posed questions to Dr. Joshi about the research studies including questions relating to the purity of the cannabidiol that patients might obtain now from other states. Dr. Joshi stated that the concern is not with CBD per se but for standardization of the product and the effective concentration amount. She noted that the Iowa Board of Pharmacy had also requested a literature review regarding medical cannabis.

Personal and Professional Perspectives – Impact Panel. Ms. Sally Gaer, Ms. Maria LaFrance, and Ms. April Stumpf, medical cannabidiol consumer advocates; Ms. Roxanne Cogil, Iowa Epilepsy Foundation; and Dr. David Moore, a neurologist specializing in epilepsy and a member of the Iowa Neurological Association, offered personal and professional perspectives on the impact of SF 2360. Ms. Gaer, Ms. LaFrance, and Ms. Stumpf are all parents of children with intractable epilepsy and were very involved in the efforts supporting SF 2360 during the 2014 Legislative Session. They thanked legislators for their work and support in passing the legislation, but expressed concerns with the restrictions in the law that prevent families from getting in-state access to the medical cannabidiol they are in desperate need of to treat their children.

- Ms. Gaer, the parent of an adult daughter with Dravet Syndrome, a chronic illness characterized by persistent seizures, provided comments advocating for in-state access for medical cannabidiol in Iowa and the need for in-state medical dispensaries and greenhouse growing regulations. She also proposed Iowa legislators take a field trip to other states with medical cannabis dispensaries to research well-run cannabis dispensary programs.



- Ms. LaFrance spoke about her six-year-old son, who also suffers from Dravet Syndrome, and the dangerous side effects of his prescription medication. She also spoke about access concerns as well as the excessive costs families face and suggested Iowa should look to states like Oregon, New Mexico, and Colorado for examples of a well-run cannabis program.
- Ms. Stumpf, a parent of a two-year-old daughter who has 50-70 seizures per day, commented that prescription medication has not been effective in managing her daughter's illness. She urged committee members to remove the legal and financial barriers from the current legislation and to allow the Iowa Department of Agriculture or other entity to supervise and control the production of in-state greenhouse dispensaries.
- Ms. Cogil, also a parent of a child with intractable epilepsy, echoed the parents' concerns that the law does not provide meaningful access to cannabidiol because the law does not allow for the in-state production, processing, and dispensing of cannabidiol, which means that persons in Iowa in need of cannabidiol have to travel out of state to obtain the cannabidiol, risking violations of other state and federal laws.
- Dr. Moore, who treats patients with epilepsy and who himself suffers from epilepsy, expressed concern about the fact that although approximately 3 percent of Iowa's population have epilepsy (more than 90,000), only about 12,000 patients are potential candidates for medical cannabidiol under the restrictions in the law. He also expressed concern about the financial burden on families in accessing and using the cannabidiol oil, and that few neurologists practicing in Iowa even treat patients with epilepsy.

Public Comment. Individual commenters included comments from parents of children with intractable epilepsy and persons suffering from other chronic illnesses including chronic pain syndrome, cancer, Ehlers–Danlos Syndrome (EDS) (an inherited connective tissue disorder), and other debilitating illnesses, who spoke about the medical benefits of cannabidiol oil and other forms of medical cannabis as well as financial and legal obstacles to out-of-state access.

IV. Recommendations

Each member of the committee was invited to make recommendations and committee members discussed and voted on each recommendation. The recommendations approved by the committee for further consideration by the General Assembly are summarized as follows:

- Develop a regulated program to produce, process, and dispense medical cannabis and further recommend that medical cannabis not be taxed by the state at any stage of producing, processing, or dispensing the medical cannabis.
- Reschedule marijuana from a schedule I controlled substance to a schedule II controlled substance.
- Further investigate access, standardization, and legalization of cannabidiol.



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V. Materials Filed With the Legislative Services Agency

The materials listed were distributed at or in connection with the meeting and are filed with the Legislative Services Agency. The materials may be accessed from the “Committee Documents” link on the committee Internet website at:

<https://www.legis.iowa.gov/committees/meetings/documents?committee=21380&ga=ALL>.

1. Cannabidiol Implementation Study Committee Meeting Notice
2. Cannabidiol Implementation Study Committee Tentative Agenda Revised
3. Cannabidiol Implementation Study Committee Meeting Briefing
4. Hawaii Legislative Report on State Medical Marijuana Laws
5. Cannabidiol Implementation Study Committee – Public Comment – Brooke Rice
6. DSM Register – Heroin Overdoses
7. AMA - Legalization of Medical Marijuana and Opioid Mortality
8. JAMA International Opioid & Cannabis Commentary August 2014
9. JAMA International Opioid & Cannabis August 2014
10. The Impact of State Medical Marijuana Legislation on Adolescent Marijuana Use February 2014
11. Public Comment From Rose Walker – Additional
12. Public Comment From Rose and Russ Walker
13. Medical Cannabidiol Implementation Act (SF 2360)
14. Adopted - Filed September 9, 2014, Administrative Rules – Department of Public Health (SF 2360)
15. Notice of Administrative Rules – Department of Public Health for SF 2360, ARC 1571C (pp 165-171)
16. Cannabidiol in the Control of Refractory Seizures – Research Studies
17. Epilepsy Foundation Fact Sheet
18. Epilepsy Foundation of North/Central Illinois, Iowa & Nebraska – Committee Letter
19. Medical Cannabidiol Act Registration Card Program – Deborah Thompson (DPH), Kim Snook & Mark Lowe (DOT)