MINUTES

Cannabidiol Implementation Study Committee

September 11, 2014

MEMBERS PRESENT:

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
Representative Linda J. Miller

MEETING IN BRIEF

Organizational staffing provided by: Rachele Hjelmaas, Senior Legal Counsel, (515) 281-8127

Minutes prepared by: Patty Funaro, Senior Legal Counsel, (515) 281-3040, and Joe McEniry, Senior Legal Counsel, (515) 281-3189

I. Procedural Business

Call to Order and Adjournment. The meeting of the Cannabidiol Implementation Study Committee was called to order by temporary Co-chairperson Bolkcom at 10:02 a.m., Thursday, September 11, 2014, in Room 116 of the State Capitol, Des Moines. The meeting was adjourned at 4:00 p.m.

Election of Permanent Co-chairpersons. Members of the committee unanimously elected temporary co-chairpersons Senator Bolkcom and Representative Rogers as permanent co-chairpersons.

Adoption of Rules. Members of the committee adopted procedural rules which are available from the Legislative Services Agency (LSA).

Review of Committee Charge. Co-chairperson Bolkcom reviewed the charge of the committee.

Opening Comments and Introductions. Co-chairperson Bolkcom noted that when lawmakers and the Governor learned about the plight of children and families suffering from the effects of uncontrolled seizures, the majority acted in a bipartisan fashion to support a measure to provide legal, affordable access to medicine that would help. The charge of the committee is to consider whether the new law is helping the people it is supposed to help. While the Department of Public Health (DPH) and others have worked to implement the legislation and provide a registration card program that will allow possession of a limited amount of cannabidiol, it is increasingly clear that having the card may not translate into actual access to the medicine due to severe legal risks and severe financial barriers. There are problems with the legislation that the committee can address through the interim meeting.

Co-chairperson Rogers said he looked forward to listening and learning and that the committee was organized to consider if the legislation is helping those it was meant to help. He had met with several families who are affected and he looked forward to the committee process to ensure that these families are being helped.

The remaining members of the committee introduced themselves.

II. Overview of SF 2360, Medical Cannabidiol Act

Ms. Rachele Hjelmaas, Senior Legal Counsel, LSA, Legal Services Division, provided an overview of the Medical Cannabidiol Act (SF 2360). The Medical Cannabidiol Act will be codified at chapter 124D of the Iowa Code.

Ms. Hjelmaas reviewed the definitions provided in the Act including “cannabidiol” and “intractable epilepsy.”

Under the bill, a neurologist who is licensed under Iowa Code chapter 148, is in good standing, and 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 no other satisfactory alternative treatment options exist for the patient and the patient meets certain conditions. The conditions the patient must meet are: the patient is a permanent resident of Iowa; a neurologist, including an out-of-state licensed

neurologist in good standing, has treated the patient for intractable epilepsy for at least six months; the neurologist has tried alternative treatment options that have not alleviated the patient's symptoms; the neurologist determines the risks of recommending the medical use of cannabidiol are reasonable in light of the potential benefit for the patient; and the neurologist maintains a patient treatment plan.

In order for a patient to obtain the recommended cannabidiol, the patient or a patient's primary caregiver must first obtain a cannabidiol registration card issued by the Department of Transportation (DOT). A patient who is at least 18 years of age and is a permanent resident of Iowa may request the patient's neurologist to submit a written recommendation to the DOT signed by the neurologist that the patient may benefit from the medical use of the cannabidiol, and submit an application to the DOT with information specified in the Act and by administrative rule, and may then obtain a cannabidiol registration card. If a patient is in a primary caregiver's care, a cannabidiol registration card may be issued by the DOT to the primary caregiver if the primary caregiver is at least 18 years of age, requests a patient's neurologist to submit a written recommendation to the DOT signed by the neurologist indicating that the patient may benefit from the medical use of the cannabidiol, and submits an application to the DOT with information specified in the Act and by administrative rule. The Act specifies the content of both a patient's card and a primary caregiver's card.

Under the Act, a cannabidiol registration card issued by the DOT expires one year from the date of issuance and may be renewed.

The Act directs the DPH, in consultation with the DOT, to adopt rules to implement the Act and provides for confidentiality of patient and primary caregiver information as well as limited release of such information.

The Act specifies that a recommendation for the possession or use of cannabidiol authorized under the Act is to be provided exclusively by a neurologist for a patient who has been diagnosed with intractable epilepsy and that the cannabidiol must be obtained from an out-of-state source and only recommended for oral or transdermal administration. The Act requires that a neurologist shall be the sole recommender as part of a treatment plan by the neurologist of a patient diagnosed with intractable epilepsy and the neurologist has the sole authority to recommend the use or amount of cannabidiol. The Act specifies the circumstances under which a neurologist, a patient, and a primary caregiver have immunity from prosecution or an affirmative and complete defense to prosecution. The Act is repealed July 1, 2017.

The Act also directs the University of Iowa Carver College of Medicine and College Of Pharmacy, on or before July 1 of each year beginning July 1, 2015, to submit a 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.

III. Rulemaking Process and Implementation—Update

Ms. Deborah Thompson, Policy Advisor and Healthiest State Initiative Coordinator, DPH, Ms. Kim Snook, Director of Driver Services, DOT, and Mr. Mark Lowe, Motor Vehicle Division Director, DOT (by phone), reviewed the rulemaking and implementation processes related to the Act.

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 the DOT associated with the issuance.

Ms. Thompson stated that the administrative rules were written narrowly to reflect the language in SF 2360 and to limit interference with the doctor/patient relationship. DPH collaborated with the DOT, other key agencies including the Governor's Office of Drug Control Policy, the Department of Public Safety (DPS), the Board of Pharmacy, and DPH's Assistant Attorney General, the Board of Medicine, providers, consumer families, the Iowa Epilepsy Foundation and staff from their national organization, and other key stakeholders in crafting the rules. Notice of Intended Action was published in the August 6, 2014, Iowa Administrative Bulletin. The majority of the public comments received regarding the noticed rules recommended changes to the legislation and therefore fell outside 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 for those unable to provide a driver's license or nonoperator's ID due to ineligibility, and revisions to the renewal process. The DPH 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 additional 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.

In response to a question regarding who would be ineligible for a driver's license or nonoperator's ID, Ms. Snook and Mr. Lowe responded that circumstances might include situations where a person's license is under suspension, there is no birth record because a person is elderly and does not have a birth record on file, a person has had a name change, a person was adopted, or a person is only temporarily in the country or is a foreign national. If only temporarily in the country or a foreign national, the person must have verifiable proper documentation before a license or ID will be issued for the time the person is in the country, but no longer than two years. In response to a question about why the cannabidiol registration card was not just incorporated into a person's regular driver's license, Mr. Lowe and Ms. Thompson noted that the legislation was specific regarding utilizing a separate card.

Ms. Thompson reviewed a flow chart on the basic card application process. Once the application form becomes available, it will be available on the DPH website. A patient, parent, or legal guardian initiates the process for themselves and for primary caregivers. The patient, parent, or legal guardian provides the application to the treating neurologist, who provides the written recommendation on the standard form included in the application. The neurologist then sends the completed application to DPH. If DPH verifies that the application is complete, including that the patient, primary caregiver and neurologist meet all the specified criteria, DPH then notifies the DOT that the applicant may be issued a cannabidiol registration card. The applicant, primary caregiver, and neurologist also receive notification of the approval. The patient, if over 18 years of age, and the primary caregiver must then go to their local DOT location to obtain the card. If a patient is unable to go to a physical DOT location, they may contact DOT's driver services central administration for assistance. If an application is denied, the applicant is asked to provide all of the

required information. The application may be denied by DPH for any reason, but the rules provide a procedure for the applicant to appeal the denial. The card expires one year from the date of its issuance. The renewal process may begin at least 60 days prior to the expiration date. Ms. Snook and Mr. Lowe answered questions about DOT's role in issuing the cannabidiol registration cards, as well as funding concerns.

With regard to the renewal process, Ms. Thompson stated that specific details have not been finalized yet, but the intent is to be flexible, not require an applicant to start the entire process over from the beginning, and to allow applicants to start the renewal process as early as possible.

Committee members expressed concern about expediting the process to allow patients to get the help they need and also raised concerns about the January 30, 2015, implementation date. Mr. Lowe explained that the DOT wanted to wait for the rules to be adopted before their card vendor began the implementation process. There were also some issues with funding, since the DOT could not use Road Use Tax Fund moneys for the purpose of the Act. There were also concerns with maintaining the integrity of the process. Senator Sodders suggested that there might be funds available through funds that have been confiscated by law enforcement. Mr. Lowe noted that the development of the cards is estimated to cost about $115,000 and the cost going forward will be the same as any other card at a total of $10.00/card with $3.29/card for administrative costs and a county treasurer fee of $7.00/card. Senator Dotzler queried why the DOT could not just keep a list of those who apply and meet the requirements, until such time as a card can be issued. He noted that law enforcement can access a person's license information and this information could just be added. Mr. Lowe agreed that the information could be linked to the DPS database, but that the legislation requires a separate card.

Other states that have enacted similar legislation are also still working through the implementation phase and many have contacted Iowa agencies to inquire how it's being implemented here. There is currently not a system in place in another state that could be replicated in Iowa. Co-chairperson Bolkcom stated that in the process of writing the legislation, the Governor's Office suggested the DOT as the issuer of the cards. No one likes delay and the process seems to focus on treating everyone as a potential criminal. The focus should really be on the patients and health care. The departments are all doing the best they can, but maybe the system does not have to be as secure as that used for driver's licenses. Mr. Lowe stated that the rules are effective January 30, 2015, because the DOT wanted to ensure that their vendor would have enough time to make the system workable. The departments were open to taking applications prior to January 30, 2015, to have the registration cards ready prior to the January 30 implementation date. Mr. Lowe also noted that the DOT was offered as a potential issuer of the cards since they have locations in every county and they could leverage their existing system.

Ms. Thompson added that both the DPH and DOT have made every effort to work as quickly as possible to implement the law, that there are many moving parts to work through, and that additional details are still being worked out. Ms. Snook added that the intent is to make the renewal process as easy as possible even to the point of making it automatic. Ms. Thompson also noted three issues that the General Assembly might want to review going forward. They include the possibility of complicating the process if a new card must be issued each time there is primary caregiver turnover and the privacy issues created when a primary caregiver has to put the patient's

name on the card; the potential duplication of treatment efforts by Iowa and out-of-state neurologists based on whether the language in the law is interpreted to mean that both neurologists have had to have tried different treatment options; and the authorization of a fee structure to cover associated costs.

IV. Cannabidiol Research Study

Dr. Charuta Joshi, Director of Pediatric Epilepsy in the Division of Pediatric Neurology, University of Iowa Carver College of Medicine, University of Iowa, provided information regarding scientific research related to medical cannabidiol.

Dr. Joshi spoke about her background including her medical education at Grant Medical College, Bombay University, India; residency in pediatrics at The Brooklyn Hospital Center, Brooklyn, New York; residency in pediatric neurology at The New York Presbyterian Hospital, Weill Medical College of Cornell University, New York, New York; and a fellowship in clinical neurophysiology, at the Children's Hospital of Michigan, Detroit Medical Center, Detroit, Michigan. Since 2008, she has been treating children with intractable epilepsy. Dr. Joshi noted that adults may also have intractable epilepsy.

Dr. Joshi explained that there are two strains of cannabis: Sativa, which contains more THC (tetrahydrocannabinol) and Indica which contains more CBD (cannabidiol). THC is the psychoactive component of cannabis that produces a "high," and CBD is the 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.

With regard to defining "intractable epilepsy," Dr. Joshi stated that this condition is based on a person not responding to two or more potentially effective medications, not on the number of seizures a person experiences.

Dr. Joshi referred to a handout "Cannabidiol in the Control of Refractory Seizures" and explained that in a number of double-blind randomized studies, CBD has been shown to be effective as an anticonvulsant. Dr. Joshi stated that what can be said to date is that CBD is effective, although what dose is effective is not known, and that such use of CBD had no life-threatening side effects. In contrast, the 15-20 medications currently used as anticonvulsants have negative side effects including liver and kidney toxicity. Additionally, studies have shown that CBD has been effective as a treatment for psychosis and may help delusions in schizophrenia. CBD also has been found not to have addictive potential unlike some other medications.

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.

Dr. Joshi indicated that the University of Iowa is going to participate in a double-blind study sponsored by GW Pharmaceuticals. It is difficult to find patients to participate in a double-blind study because some will receive a placebo, but anyone participating must not change any other medications. Since only the patients will potentially be receiving the CBD, Dr. Joshi did not

foresee that the new law in Iowa would interfere with the study. The patients may or may not be from Iowa. She currently has six or seven potential patients, but not all will be part of the study.

Dr. Joshi has had inquiries from parents about the product they might get from out of state and how much should be given to a patient. What she tells parents is that 200-300 milligrams a day is effective. Dr. Joshi noted that no studies have determined the ratio of CBD to THC that is effective. The product that will be used at the University of Iowa Children's Hospital test site in the double-blind study 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.

Concerns were expressed about the product that patients might obtain from other states. Dr. Joshi stated that the concern is not with CBD per se but about standardization of the product. The concentration of CBD may vary even within the same dosage amount. As far as the dosage amount, Dr. Joshi suggested that no more than 300 milligrams per dose be administered. In summary, Dr. Joshi noted that CBD is a good anticonvulsant, is effective, is not addictive and does not, like all the existing available pharmaceuticals, have life-threatening side effects. There are still concerns and questions about the standardization of the product and the effective concentration amount. Dr. Joshi noted that the Iowa Board of Pharmacy had also requested a literature review regarding medical cannabis.

V. Public Comment

Mr. Matt Bear told the story of Braedy Grittman and his family. Braedy was diagnosed with intractable epilepsy. Today, he is not a typical three year old — he has low body weight and rarely shows emotion. Modern medicine has not worked for him. The family decided to move to Colorado in April 2014 to establish residency and have legal access to medical cannabis. The family has recounted the stress of moving from their home state, away from all family. However, Braedy has gone three months without seizures, has gained weight, reaches out for his mother, and smiles. Mr. Bayer stated that the legislation enacted in 2014 is just a start, but there are still issues with availability. The Grittman family would like to come home to Iowa.

Ms. Kim Novy spoke of her two 12-year-old identical twin girls who suffer from Dravet Syndrome, a rare form of intractable epilepsy. The girls can never be left alone and the family is always on edge waiting for the next seizure. The girls have life-threatening seizures 2-3 times per week, often resulting in injuries. The family is out of pharmaceutical choices. The family has reached out to their neurologist and will apply for a card, but it will sit in their wallet, because they will not be able to use it. They would have to travel out of state to obtain CBD and break federal and state laws, putting them in an unfair position. They would have to travel with the girls or have someone stay with the girls, but they should not be forced to leave them. They should not have to risk the girls' lives to get CBD. If they did go to another state, they would then have to find CBD in oil form, which is hard to find and very expensive. They will incur expenses for travel, lodging, food, and the medicine. Ms. Novy said the Legislature could do better and urged the committee to work together to produce and distribute medical cannabis in Iowa.

Mr. Craig Miller spoke about his wife Debbie. Debbie has Ehlers-Danlos Syndrome (EDS). The disease affects collagen structure and function in the body. This means that her ligaments and soft tissues cannot hold her joints together like they are supposed to. Debbie dislocates and subluxes many areas of her body easily and often, and her tissue bruises and can tear easily, even on the inside. She is in constant pain. Debbie has been on opiates for years and they have not helped the pain very much. The side effects of many of the medications are worse than the disease, one of the side effects being "possibility of death." If Debbie accidentally took the wrong dosage of these medications, she could die. There are no reports of death from using cannabis. Debbie has no quality of life now, and her doctors do not know what to do. Debbie has tried numerous treatments, but nothing has worked. A number of doctors have told them to fight to make medical cannabis available to Debbie. Mr. Miller said that in the past year he has become involved in the fight to have a medical cannabis program in Iowa. He said that as the caregiver of a loved one with a disease such as Debbie's, everything seems like a fight. He fights the urge to confront people who stare at his wife in her scooter because she does not look sick to them. He fights the urge to confront friends who do not come around anymore because Debbie is sick, or doctors who do not know what to do. But he is no longer fighting the urge to confront lawmakers about making medical cannabis available. There is too much evidence that cannabis is helpful in the EDS community. From EDS conferences they have learned that medical cannabis is a viable treatment for EDS to help with pain control, appetite, sleeping, and ease joint pain and provide more energy. He keeps hearing that legislators need more time. What they do not understand is that patients are dying while they wait for the government. Iowa needs to stand up with other states and implement a full medical cannabis program run by doctors. He asked the committee to consider a full medical cannabis law in the state to provide the medication to those who desperately need it.

Ms. Kathy Krug, a life-long Iowan and 32-year-old mother of two, has had ulcerative colitis for eight years. She lives with severe pain, multiple trips to the bathroom, arthritis, fever, depression, fatigue, adrenal insufficiency and a host of other symptoms. Her daughters are used to her being sick. She has tried all the medications and her last resort is to have her colon removed, which subjects her to huge risks. She cited an American Medical Association study that found that after an 8-week course of cannabidiol, 91 percent of the patients showed improvement. She suggested that given the chance to use a plant made by God, she could remain a productive citizen and a normal 32-year-old mom.

Ms. Lori Tassin was diagnosed with stage IV lung cancer. Thirteen months later, her husband was diagnosed with a malignant brain tumor, but is now two years cancer-free. She has gone through seven types of chemotherapy, but the cancer has spread and they found five metastases in her brain**.** She has tried many alternatives to make her body stronger, much of which has to do with diet. With the changes in her diet, there are only four brain metastases remaining. She has been told, though, that the cancer will come back. She reported that cannabis has been found to be highly effective with cancer patients. Cannabis is currently a schedule I drug, meaning that it is classified as having no acceptable medical use. However, studies have shown that medical cannabis is highly effective. There are reports that cannabis targets brain cancer and eliminates it. There are only so many types of chemotherapy available and she has been on seven. All the steroids, chemotherapy, and other drugs she has been on have had side effects and are mind-

altering, but they continue to be used. She is an educated advocate for her own health and wants to be able to choose. Legalizing and approving cannabis for medical use could help those with cancer and others.

Mr. Jay Pedelty, an addictions counselor with Prairie Ridge Addiction Treatment Services, noted that during his career he has helped over 30,000 people with addictions. He hears the hope in the voices of those who speak about medical cannabis and its efficacy. He asked the committee to consider certain basics in making a determination about medical cannabis including that people are involved because they perceive benefits and potential use and problematic use is proportional to availability — even if the availability is only for medical use, the availability, along with problematic use, is increased. He does hope that the cannabidiol oil is effective for those who can use it.

VI. Consumer Advocates

Ms. Sally Gaer recounted the story of her daughter who has intractable epilepsy. She asked the committee to consider making a full medical cannabis program, from growing to dispensing, available in Iowa. She suggested that the God-made medicine could improve the health and happiness of her child and family. She and other advocates were told that a medical cannabis law would not pass in an election year, but they did not give up. The state cannot rely on the federal government which is currently providing medical cannabis to two Iowans. Iowa can be a leader. She noted that initially advocates were told that cards would be fast-tracked and be available in October, but now they will not be available until the end of January 2015. She suggested that a legislative delegation travel to another state that has a successful full medical cannabis program for replication in Iowa.

Ms. Marie LaFrance thanked the committee for passing the legislation. She shared that she and her husband, a coach at Drake University, have a son, Quincy, who has Dravet Syndrome and has had seizures and other medical issues since he was five months old. They have tried nearly every FDA-approved drug for his seizures, but nothing has helped, many are harmful, and none of them were ever tested on children. They contacted Dr. Joshi about the upcoming clinical trial, but are not going to be able to be part of the clinical trial. They determined that it would be a good idea to be knowledgeable about the topic of medical cannabis, so their family, including Quincy, visited Colorado where they also have relatives. During their stay, Quincy had to be hospitalized. They went to a dispensary, but the staff would not sell them cannabis because they did not have a valid card. The dispensaries sold creams, patches, and other items that provided cannabis in the form of CBD, THC, or cannabinol (CBN). They also sold different tinctures. Each form of cannabis addressed different things. Each product was labeled with the exact milligram content of significant cannabinoid. They also noted that the costs are severe including those for transportation, food, lodging, and the hospital stay which may not be covered by insurance. She noted that it felt like the movie Thelma and Louise without the joyride. She also was concerned about the legality of transporting cannabidiol. If she were in prison, who would take care of Quincy? All of the issues would be resolved if Iowa would produce and dispense medical cannabidiol. The Governor goes to Arizona every year where medical cannabis is legal and may be used for a variety of conditions. The cost of the product itself is great with one ounce costing about $150. Ms. LaFrance shared a document summarizing information about the 23 states where

medical cannabis is legal, which included the amount that is legal to possess and the fees charged. Ms. LaFrance urged the committee to adopt a full CBD program that is comprehensive in scope.

Ms. April Stumpf spoke about her two-year-old daughter, Quinn, who has intractable epilepsy and suffers 50-80 seizures daily. The family has three children all under the age of six. Quinn is developmentally at zero to three months of age, she cannot talk, sit up, speak, or hear, and has a feeding tube to bypass her stomach. Seventy-five to 100 times a day she has severe arching spells as a response to severe pain. In the emergency room it is difficult to put in an intravenous tube. She has been to the University of Iowa, Mayo Clinic, and Chicago for care. Quinn takes 10 different medications twice daily, and all of the side effects are severe. There is no good way for her and her husband to travel to get the CBD out of state. If Quinn travels with them, she would have a seizure and arching spells every 15 minutes, so driving is not an option. Commercial flights are not an option since Quinn could not sit in her own seat. Private planes are not affordable. Since the passage of the legislation, people assume that they are able to access CBD. She has been asked how the CBD has worked, because people do not realize they do not have access. There are too many barriers. They are frustrated and just want Quinn to have an option without severe side effects. They want to stay in their home state, keep their three children in Iowa schools, and work in Iowa, especially since her husband's family business is located here. She suggested asking the Iowa Department of Agriculture to take the lead and travel to other states to get the facts about how a full medical cannabis program would work. She worries that Quinn's little body will not be able to take the abuse much more and she just wants a medical approach that will help. Sometimes they get a smile or giggle and this keeps them going.

Ms. Roxanne Cogil, director of Iowa Epilepsy Services, Epilepsy Foundation of North/Central Illinois, Iowa and Nebraska, welcomed the Iowa General Assembly's interest in providing safe, legal access to CBD, but expressed concerns about the lack of meaningful access. The question of where the CBD will come from remains unanswered, because the law does not allow for the growing, processing and dispensing of CBD. Families would have to break the law or take their chances with unregulated products to obtain the CBD. She noted that one in 26 Americans will develop epilepsy at some point in their lifetime, 2.8 million people living with epilepsy experience uncontrolled or intractable seizures despite available treatments, and there is not a one-size-fits-all treatment option. The foundation is committed to supporting physician directed care and to exploring and advocating for potential treatment options for epilepsy, including CBD oil and medical cannabis. If a patient and their health care professional feel that the potential benefits of medical cannabis outweigh the potential risks for treatment of uncontrolled seizures, the families should have that legal option. The current state program does not allow for the growing, processing, and dispensing of cannabis and products derived from the cannabis plant, resulting in the need for patients to travel out of state and break federal laws. Out of the 34 states that have passed some form of medical cannabis law, only Oregon allows out-of-state residents to legally access CBD oil, and even in Oregon a person must obtain a registration card and recommendation from a physician licensed in Oregon. Minnesota and Illinois have passed legislation to allow the cultivation and distribution of medical cannabis by state-approved entities.

Ms. Cogil stated that families seeking CBD may obtain CBD oil that is unsafe and which has little or no medical benefit. Clinical trials have limitations, making it hard or impossible for families to

access medical cannabis through this alternative. The foundation calls on the Legislature to expand the medical cannabis program to include state oversight of legal growth, processing, and dispensing of cannabis and CBD oil. The state can play a critical role in ensuring that access to CBD is safe and reliable.

Dr. David 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 and 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 especially since the costs are not covered by Medicaid or private insurance, legal issues with transporting the product from out of state, issues with the consistency in and concentration of the product itself, and with the fact that there are very few neurologists practicing in Iowa and the fact that an even smaller number of these neurologists who treat patients with epilepsy.

In response to a question from Senator Schneider to Ms. Gaer regarding her experience with trying to access cannabidiol, Ms. Gaer stated that they had talked with their neurologist in Illinois and they were hopeful that they could get her daughter in a study, but she is too old. She said that Charlotte's Web, a strain of medical cannabis processed into an extract that is high in CBD content, is a good product. The Illinois law has not been implemented yet, and to have access to the product in Colorado, a person has to have a Colorado registration card. The Iowa card will not provide them access there. Senator Schneider emphasized that even if medical cannabis were grown in Iowa, possession and use of it would still violate federal law. The FDA does have a compassionate use program that began in the 1970s which a limited number of people are able to utilize.

Co-chairperson Bolkcom noted that with 34 states moving toward some form of medical cannabis program, the federal government might change its approach. There are states that are far ahead of Iowa in providing for the growing, processing and distribution of medical cannabis. He suggested sending a delegation of legislators and staff to New Mexico or another state with an established program to get the facts and see how the program operates. Co-chairperson Bolkcom noted that during the legislative process, the medical community was consulted and their recommendations were incorporated, and that he was appreciative of Dr. Moore's expertise in pointing out facts regarding the numbers of neurologists and other implementation issues.

Senator Dotzler stated that he had been involved in similar meetings on the implementation of the Act in the Waterloo/Cedar Falls area and very similar issues were raised. The cost is a big factor in having access.

Representative Forbes suggested that children many times do not die from their disease, but from complications of the drugs they are given. Not all children would see improvement with CBD, but CBD has the potential to enhance their quality of life. He suggested that medical cannabis should be reclassified as a Class II medication like morphine, oxycontin, and hydrocodone, instead of as its current designation as a Class I medication which is characterized as having no medical value. If it were rescheduled, it would be subject to quality control measures that would provide for consistency in the product. This change would also allow the product to be covered by insurance. He suggested the state work with the FDA and Drug Enforcement Administration (DEA) to have

medical cannabis rescheduled. He reported that he had recently been on a conference call with Senator Grassley's office and they seemed open to the subject and said they would look into it.

In response to a question from Representative Baudler regarding what causes intractable epilepsy and whether there has been an increase in the number of diagnoses, Dr. Moore stated that there are many causes and that the more they study epilepsy the more they know what they do not know. He said that over the last 30-40 years, the percentage of those diagnosed with epilepsy has not changed.

VII. Public Comment

Ms. Kathy Schnell said that her sister is a hospice nurse and that the end of life is one of the times when access to medical cannabis is most needed. Her niece's stepsister, Zoe, was born in Iowa but lives in Israel. Three years ago, when she was 16 years old, Zoe was diagnosed with Osteogenic Sarcoma, a cancer that starts in the bones. She underwent 23 chemotherapy treatments and her parents also approved the use of liquid cannabis. At 19 she was diagnosed with a different type of cancer and at first did not want to use the liquid cannabis. She underwent chemotherapy again but lost weight and was not able to function on her own. She then decided to use the liquid cannabis and credits it with saving her life and providing her with quality of life again. If she had lived in Iowa, she might not have been saved.

Mr. Boris Shcharansky, chief executive officer of iCann, an Urbandale-based cannabis products company, shared that he suffers from both psoriasis and psoriatic arthritis, and could benefit from an expanded medical cannabis program because CBD is a very effective treatment for inflammation, with none of the long-term side effects associated with traditional treatments. However, he stated that even if the program were expanded to other conditions, the underlying problem with the new law is accessing the CBD. He had previously submitted a detailed description of the current process for accessing CBD and encouraged the members to review these comments. The current system forces people to overburden themselves financially and physically, and to break the law. He advocated for an effective distribution and eventually a production system in Iowa. Currently, CBD is only available from medicinal cannabis and hemp. Oil derived from medicinal cannabis is illegal to ship out of recreational and medical marijuana states. The other option is online distributors of hemp oils with high-CBD content that is of questionable quality. The high-quality and tested CBD oils are very expensive at 25 cents per milligram or about $650/month. If just distribution were legal in Iowa, the cost could be reduced by over 40 percent. States such as New Mexico, Oregon, Washington, and Colorado have effectively implemented distribution and production systems under strict state regulations, and their residents benefit from lower prices, guaranteed access, and quality-tested, locally produced products. He queried whether the committee and the Legislature are content with making criminals out of the patients that are supposed to be helped because, without accessibility, that is all that has been accomplished.

Ms. Crissie Brunt, Iowa NORML Women's Alliance, is a 34-year-old mother of four and a recovering addict, who spoke on behalf of a number of individuals who suffer from chronic pain, Multiple Sclerosis, Post-Traumatic Stress Disorder (PTSD), and other conditions who would like

the choice of access to medical cannabis. She stated that people should not be asked to break the law to get the help they need and that it is a quality of life issue.

Ms. Shelly Van Winkle, a registered nurse, came to Iowa from California to raise her children as a single parent. She met an Iowan and married, and became pregnant five years ago. During the pregnancy, she developed HELLP Syndrome, a life-threatening pregnancy complication, and had her baby at 33 weeks. She has never fully recovered, but still suffers with fibromyalgia, arthritis, nausea, migraines, and other problems. She tries to stay busy consulting, but is not able to go back to being an ER nurse as she was before. She is also a veteran. She believes people like her should have options, especially when research demonstrates that medical cannabis can be used to treat pain. She currently is limited to the use of opiates, which limit her ability to work on the floor as a nurse. She asked the committee to consider expanding the law to address other conditions.

Ms. Shannon Peterson has Crohn's disease, an inflammatory bowel disease, and described her daily struggle with its symptoms including abdominal pain, diarrhea, fever, extreme weight loss, and a pain in her rib cage which she described as having an alien baby inside.

Mr. Bill Malanoski, whose son is in a vegetative state, described his son's struggles with seizures. He emphasized that cannabidiol is the only drug that stops the seizures. He stated that cannabidiol does not make a person high. He further stated he would like cannabidiol manufactured in Iowa.

Ms. Connie Norgart, who has post-polio syndrome, described her difficulty with walking and with chronic, severe pain because she contracted polio when she was a child. She stated overdose deaths from pain pills would go down if medical cannabis is legalized because more people would use medical cannabis and medical cannabis does not kill.

Dr. Ed Hertko is a board-certified internist who has had an interest in medical uses for marijuana for a long period of time. He provided the committee with background information about the debate to legalize medical marijuana within the Iowa Medical Society and in Iowa. He emphasized that physicians should be allowed to prescribe medical marijuana.

Ms. Corey Maylone, the spokesperson for the National Multiple Sclerosis Society, stated that the National Multiple Sclerosis Society supports access to medical marijuana for treatment. However, he acknowledged the need to further study the issue.

Ms. Kathy Goulden stated that her son developed epilepsy at 18 years of age. She further stated her son is a student at the University of Northern Iowa but he is unable to drive because of the number of seizures he experiences. She noted that cannabidiol would be a great option for her son because cannabidiol would reduce the number of his seizures so he would be able to drive again.

Mr. Wayne Cohn said his wife suffers from severe arthritis. He stated that many prescription pain pills have unnecessary side effects while cannabidiol would help her deal with the pain without these adverse side effects. He emphasized that the dangers of cannabidiol have been exaggerated.

Mr. Ray Lakers, representative of the Iowa Clemency Project, stated that many Iowans who suffer from chronic illnesses have fled the state in order to treat their illnesses with medical marijuana in other states. He expressed frustration with legislators about the legalization of medical marijuana in this state. He thanked the doctors who support legalizing medical marijuana and stated it is the right path to practicing safe medicine.

Ms. Chrystal McClain, who suffers from a connective tissue disorder and chronic fatigue syndrome, stated that prescription narcotics and sleeping medications have too many side effects. She said medical marijuana takes her pain away without all of the side effects.

VIII. Committee Discussion

Co-chairperson Bolkom thanked Representative Baudler for his efforts on Senate File 2360 during the 2014 Legislative Session. Senator Dotzler commented that the Medical Cannabidiol Act was a giant step forward. He further recommended that the legislature fix the law so that parents of children with intractable epilepsy have access to the cannabidiol through dispensaries in this state and that marijuana be reclassified from a schedule I controlled substance to a schedule II controlled substance. Representative Kressig commented that patients should have access to cannabidiol in Iowa through a university in the state. He also commented that under current law a person who uses cannabidiol is not able to know their correct dosage with an acceptable degree of certainty. Representative Forbes stated that access to cannabidiol should be addressed by the legislature next session and reiterated that marijuana should be reclassified from a schedule I controlled substance to a schedule II controlled substance. Senator Schneider emphasized that cannabidiol should be standardized and safe. He also stated that he would like to review the process used by other states to solve the standardization and access issues related to the dispensing of cannabidiol. Senator Sodders agreed that the current law was too narrow and stated accessibility issues should be addressed. Co-chairperson Bolkcom urged people to speak to their senator and representative about the current law.

IX. Recommendations

The members of the committee voted on and approved the following three recommendations:

1. Co-chairperson Bolkom moved that the General Assembly develop a regulated program to produce, process, and dispense medical cannabis. Senator Dotzler seconded the motion. Representative Baudler asked to amend Senator Bolkom's recommendation to include that medical cannabis not be taxed by the state at any stage of producing, processing, or dispensing the medical cannabis. Senator Bolkom agreed with Representative Baudler's amendment to the recommendation. Senator Breitbach cautioned that if the recommendation passes, much of the production, processing, and dispensing should be performed at a university because it would not be very profitable. The committee adopted the following recommendation by a short form voice vote:

> 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.

Co-chairperson Rogers, Senator Breitbach, Senator Schneider, and Representative Miller were recorded as "no" votes.

2. Co-chairperson Bolkom moved that marijuana be rescheduled from a schedule I controlled substance to a schedule II controlled substance. Representative Miller seconded the motion. The committee adopted the following recommendation by a short form voice vote:

> Marijuana be rescheduled from a schedule I controlled substance to a schedule II controlled substance.

3. Co-chairperson Rogers moved that the General Assembly further investigate access, standardization, and legalization of cannabidiol. Senator Sodders seconded the motion. Committee discussion ensued about distributing the cannabidiol oil from a producing state to a university in this state in order to improve access. Representative Forbes stated distributing cannabidiol oils produced in another state for dispensing by a university in this state for would be a bureaucratic nightmare for the university. Senator Schneider commented he would like to focus on improving standardization and access. Representative Kressig stated people need access to cannabidiol so they do not break the law when they bring it back though other states to Iowa. The committee adopted the following recommendation by a short form voice vote:

> The General Assembly further investigate access, standardization, and legalization of cannabidiol.

The members of the committee also considered a motion by co-chairperson Bolkom that the General Assembly add other chronic conditions to the Medical Cannabidiol Act. Senator Dotzler seconded the motion. Representative Miller stated she is not comfortable with the motion. The motion failed on a record roll call vote. Co-chairperson Bolkom, Senator Breitbach, Senator Dotzler, Senator Schneider, Senator Sodders, Representative Forbes, and Representative Kressig were recorded as "yes" votes, and Co-chairperson Rogers, Representative Baudler, and Representative Miller were recorded as "no" votes.

X. Materials Filed With the Legislative Services Agency

The materials listed were distributed at or in connection with the meeting and are filed with the LSA. 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 (IDPH), Kim Snook & Mark Lowe (IDOT).

3989IC