

Drug Enforcement Administration

PETITION FOR EXEMPTION

August 27, 2020

Exhibit #3



Gerd W. Clabaugh, MPA
 Director

Kim Reynolds
 Governor

Adam Gregg
 Lt. Governor

DRAFT Notes
Iowa Medical Cannabidiol Advisory Board
February 1, 2019
10:00 a.m. – 12:30 p.m.
Iowa Laboratory Facility – DMACC Campus
2240 DMACC Blvd.
Ankeny, IA

1. Call to Order

Mike McKelvey, Chair

The February 1, 2019, Iowa Medical Cannabidiol Advisory Board Meeting was officially called to order at 10:05 a.m.

2. Roll Call

Mike McKelvey, Chair

Members	Absent
Dr. Ken Cheyne	Vacant - Gastroenterologist
Dr. Jill Liesveld	
Mr. Mike McKelvey	
Dr. Lonny Miller	
Dr. Stephen Richards	
Dr. Bob Shreck	
Dr. Jacqueline Stoken	
Dr. Wendy Zadeh	
Staff	
Sarah Reisetter	Heather Adams – Asst. Attorney General
Randy Mayer – via conf. call	
Owen Parker	
Jennifer Caskey	

3. Approval of Minutes

Mike McKelvey, Chair

a. November 2, 2018, Medical CBD Advisory Board Mtg.

Dr. Richards motioned to approve the November 2, 2018 meeting minutes, with a second from Dr. Shreck.

A verbal vote was taken. Motion carried unanimously.

4. Presentation – AC4C Dr. Ed Gogek

The Alliance of Coalitions for Change (AC4C) invited Dr. Ed Gogek, licensed psychiatrist from Phoenix, AZ, to speak to the board regarding Iowa’s current 3% THC limit and THC’s effects on the brain. Dr.

Gogek shared his concerns with THC and its side effects, spoke in support of CBD and suggested Iowa should not move to a medical marijuana law that allows more THC for patients. Dr. Gogek shared information from several sources, including abuse rates in medical marijuana states, statistics related to teenage use and school drop-out rates, college attendance rates, and future wage earning by teenage marijuana users. Opinions and observations based on his experience working with substance abusers in the penal system were also shared.

5. Public Comment Period

Mike McKelvey, Chair

- Carl Olsen – private citizen, addressed the board with a single question. “Is everything authorized by 124E a federal crime?” Mr. Olsen indicated that he has also submitted this question in writing to the Iowa Dept. of Public Health for comment.
- Peter Komendowski – AC4C, shared his comments with the board, acknowledging that CBD can be a product that helps patients, but that the currently allowed THC level is too high. Mr. Komendowski shared his opinion that products should be pure CBD only and that amounts of THC should be held at current limits or lowered.
- Kymm Loeffler – Loeffler Group, LLC. spoke to the board stating her opinion that the state needs to keep a list/data bank at dispensaries of doctors who are willing to accept new patients so that patients may get products and try them. Ms. Loeffler explained her understanding of how patient certifications are handled in California, as well as other recreational states. Her opinion of product options and strengths as well as suggesting people educate themselves and do their own research was also shared.
- Merea Bentrrott – Iowa Health Care Association (IHCA), addressed the board, sharing their appreciation of the CBD law. Ms. Bentrrott shared IHCA’s concerns with CBD patients in federally regulated facilities and issues/concerns with access to the products, continuing to seek guidance and clarification on product administration, federal restrictions due to the current Schedule I product status and potential staff licenses being at risk. IHCA would like to see a balance between patient rights to access vs. federally funded facilities and risk to staff licenses.
- Joselyn Shirval – patient advocate, spoke to the board regarding her adult son who suffers from the version of Autism that was passed at the November Board Meeting. Ms. Shirval is seeking assistance with research to create a petition to add an adult form of this Autism petition. IDPH staff offered to speak with her following the meeting to discuss her request.

6. Petitions to Add Qualifying Conditions

Sarah Reisetter, Deputy Director

Sarah Reisetter, Deputy Director for the Iowa Dept. of Public Health led the discussion regarding the two petitions received for the board’s consideration to add as approved conditions for the Iowa Medical Cannabidiol Program.

a. Corticobasal Degeneration

Dr. Zedah shared her opinion that this request is reasonable as compassionate care use, especially due to its relation to Parkinson’s Disease, a previously included condition. Additional discussion included the possibility of expansion of the petition to neurodegenerative disorders,

possible expansion under the Parkinson's disease definition and eligibility under terminal illness.

A motion was made by Dr. Zadeh, with a second from Dr. Shreck to approve the addition of Corticobasal Degeneration as an approved debilitating medical condition. A verbal vote was taken:

Cheyne = aye
Liesveld = aye
McKelvey = aye
Miller = aye
Richards = aye
Shreck = aye
Stoken = aye
Zedah = aye

Motion carried.

b. Pulmonary Hypertension/Right-Heart Failure

Dr. Shreck shared personal experience of knowing someone who is afflicted with this condition, noting that it is a terminal illness. Dr. Shreck noted that he could not find any research related to the use of CBD or cannabis products for therapeutic use, but did see that there are CBD receptors the lungs. Additional discussion included the agreement that this condition already qualifies under the definition of terminal illness, as well as untreatable pain, noting that the only treatment would be a lung transplant.

A motion has been made by Dr. Shreck, with a second from Dr. Richards to approve the addition of Pulmonary Hypertension/Right-Heart Failure as an approved debilitating medical condition. A verbal vote was taken:

Cheyne = no
Liesveld = no
McKelvey =no
Miller = no
Richards = no
Shreck = no
Stoken = no
Zedah = no

Motion Failed.

7. Department Updates

Sarah Reisetter, Deputy Director

Sarah provided an update on work and activities by the department since the November meeting included:

- New Staff
 - Joe Husak – Compliance Officer, started January 16, 2019

- Trevor Peters – Patient Application Clerk, started in November 2018 and has been busy processing applications, and talking with patients and caregivers about the application process.
- Registration Update
 - Due to the swift increase in the number of applications being received, the department is currently in the process of establishing a second clerk to assist in handling the volume of applications and paperwork.
- Legislation & Administrative Rules
 - To date there have already been several medical cannabidiol program related bills introduced. Highlights from those bills include:
 - Language to address the administration of medical cannabidiol products by a registered care giver while the patient is on school property
 - Increasing the THC limits to 13%
 - Allowing doctors to certify any condition they feel would benefit from the use of medical cannabidiol products
 - Changing THC cap from 3% to allowing the purchase of up to 90 grams of THC in a 90 day period.
 - A bill very similar to the bill passed in 2017 – expansion of existing program adding conditions, allowing the licensing of up to 12 dispensaries and four manufacturers, adding edibles, prohibiting smokeable, and adding two patient card holders to the board membership.
 - A member of the board commented, questioning the continued purpose of the Advisory Board, suggesting that perhaps they should make the recommendation to abolish themselves due to lack of ability to effect changes. Several members agreed, feeling that it is important that the legislature know it makes them extremely unhappy that they have no authority, or voice, and that the board is trying to bring science to a non-science industry.
 - Discussion regarding lobbying, working through the various physician societies and groups, and IDPH’s role in working with the legislature was shared.
 - **Vaporized Forms:** The Advisory Board recommended vaping as an allowable form at the November meeting, with this recommendation being further approved by the Board of Medicine in December. The related administrative rules were noticed at the January State Board of Health meeting. If approved, these rules would become effective in May.
 - **Membership Terms:** Drs. Zadeh, Shreck and Miller were reminded that their current membership terms expire in June and if interested in continuing to serve on the board, will need to reapply through the Governor’s Office.
 - A meeting with the Department of Inspections and Appeals (DIA) is scheduled for early February to discuss the issue of use of medical cannabidiol products in Long Term Care facilities.
- **Hemp Legislation/Over The Counter (OTC) CBD Sales**
 - With the presidential approval of the December 2018 Farm Bill comes another wave of advocates saying OTC products are now legal, resulting in multiple calls to various state agencies. Noting in Iowa has changed at this point as all CBD products remain classified as Schedule I substances in Iowa. IDPH has learned there is an anticipated a bill to be introduced during this legislative session to address this issue. It is the department’s

understanding that if this bill is similar to those introduced in the past, it would continue to prohibit CBD product production in Iowa.

- **Iowa Relief Facility Update**

- IDPH has approved a modification to the facility in Cedar Rapids. The first approval was the use of cultivation cubes inside the building. The second request and approval is to move from a physical building structure, but to the use pods as their manufacturing facility. These would be shipping container type structures that are placed on permanent concrete slabs and complete with perimeter security.

8. **Dispensary Sales Update**

Owen Parker, Program Manager

Owen Parker, Program Manager for the Office of Medical Cannabidiol provided an update on the number of applications approved and cards issued. The program has noted a 100% increase in applications reviewed and approved. There has been a 30% increase in physicians approving patents for enrollment into the program. The top two conditions continue to be untreatable pain and cancer. IDPH has been conducting educational presentations to a number of physician's groups. Dispensary sales information since the program launch on December 1 was shared.

9. **Manufacturer & Dispensary Updates**

- a. **Have A Heart Compassion Care** – Joe Staub (via phone call) – provided an update on behalf of Have A Heart's two Iowa locations. Highlights included getting inventory figured out, tracking guests who are simply seeking information only, and noting that patients are sharing that some are already seeing results in the use of the products purchased.
- b. **Iowa Cannabis Company** – Shannon Cretsinger – provided a presentation on behalf of the Iowa Cannabis Company. Ms. Cretsinger shared that they are hearing that some patients are finding relief, with some noting their ability to discontinue use of other medications. Other client feedback indicates they are not finding relief with the current products available, possibly due to the current THC levels. Ms. Cretsinger shared what they are experiencing as best and least selling products, the need for more compassionate doctors and better understating of their role, as many think they are prescribing, with others that are certifying yet unwilling to take on new patients. Additional feedback included the need to expand certifying authorization to nurse practitioners. The Iowa Cannabis Company has not noted profit at the dispensary at this time, stating the need to double patients to reach profits. To date they have spoken with approximately 40-50 patients who are experiencing difficulties with getting enrolled into the program, either due to physician refusal to certify, or being diagnosed with non-qualifying conditions.
- c. **MedPharm Iowa** – Lucas Nelson, General Manager and Kat Anderson, Patient Consultant – provided updates on behalf of MedPharm Iowa. Dispensaries are currently operating with cash only, but are currently working with an electronic payment processor to be able to begin using electronic banking. To date zero security or theft issues have been experienced at any of their facilities. Information shared included product updates, and an overview of what their patient consultants do when meeting clients. It was noted that many of the patients visiting their stores are elderly, with staff giving them information and recommendations on products and use. Feedback received from patients indicates many are finding relief from the comfort

and balance lines. Some do report set-backs or little relief from products available. Some patients are sharing that they are trying medical cannabidiol products with support of their doctors and are able to reduce opioid use. Patient consultants are noticing changes in patients on return visits. Product costs is an issue for many patients, several needing to purchase more products to get ample relief due to low THC levels. Patients are also sharing difficulties with providers willing to certify patients, whether it be unwilling or unable due to the health care agency they work for. MedPharm is discovering that nursing staff are very interested in the products, the process and are the ones who sit with the patients and talk about the products.

Additional comments from the board in relation to the MedPharm Iowa presentation include:

- Encouragement to produce pure CBD tincture and capsule products.
- Show their research
- Suggestion to compete with the OTC market and produce a CBD only product
- Insight that across the state conversations are being held in hospitals noting that seizure patients come in stable with use of CBD products. Their issue is then allowing a patient or care giver to self-administer CBD products while in the hospital, the pharmacy staff have difficulty verify the products. It was suggested that perhaps marketing and information could be shared with pharmacist for product identification purposes.
- Suggestion to reach out to Iowa's federal delegation and lobby at the federal level to effect change. Educate doctors and health care agencies.
- One members of the Advisory Board shared that they carefully screen and work with long time patients on what they have tried, before providing certification for enrollment into the program. Continuity of care taken is into consideration. MedPharm is being asked to be cautious about the recommendations and conversations they have with patients.

10. Future Meetings

- a. Friday May 3, 2019**
- b. Friday Aug. 2, 2019**
- c. Friday Nov. 1, 2019**

11. Adjourn

Mike McKelvey, Chair

A motion to adjourn the meeting was made by Dr. Cheyne, seconded by Dr. Miller.

A verbal vote was taken. Motion carried. The meeting was officially adjourned at 12:07 p.m.