Gerd W. Clabaugh, MPA Director

Kim Reynolds Governor Adam Gregg Lt. Governor

#### **DRAFT Notes**

Iowa Medical Cannabidiol Advisory Board January 19, 2018 9:00 a.m. – 2:00 p.m.

Iowa Laboratory Facility – DMACC Campus 2240 DMACC Blvd. Ankeny, IA

### 1. Call to Order

Mike McKelvey, Chair

Chairman Mike McKelvey officially called to order the January 19, 2018, Iowa Medical Cannabidiol (CBD) Advisory Board Meeting at 9:02 a.m.

2. Roll Call Mike McKelvey, Chair

Present	Absent
Dr. Ken Cheyne	Dr. Archanda Verma
Dr. Jill Liesveld	
Capt. Mike McKelvey	
Dr. Lonny Miller	
Dr. Stephen Richards	
Dr. Bob Shreck	
Dr. Jacqueline Stoken	
Dr. Wendy Zadeh	
Staff	
Heather Adams – Assistant Attorney General	
Sarah Reisetter – Deputy Director	
Randy Mayer – Program Director (via conference call)	
Jennifer Caskey – Executive Officer	

#### 3. Approval of Minutes

Mike McKelvey, Chair

a. December 1, 2017, Medical CBD Advisory Board Mtg.

A motion was made by Dr. Richards, seconded by Dr. Cheyne, to approve the minutes of the December 1, 2017, Medical Cannabidiol Advisory Board meeting.

A verbal vote was taken. Motion Carried.

#### 4. Medical Use of CBD Report – Follow-Up

Dr. Bob Wallace

Dr. Bob Wallace from the University of Iowa, College of Public Health, participated via conference call to discuss the materials he provided regarding the adverse effects of cannabidiol as a requested follow-up to his presentation in October 2017. In addition, a copy of

a research letter regarding the labeling of cannabidiol, as well as information on Marinol was included in the board's materials. Discussion with Dr. Wallace and members of the board included experiences some board member's patients have experienced with the use of Marinol, questions about the THC levels in the dosages used in the shared studies, as well as discussions about to why physicians have not attempted to use Marinol off label.

## 5. Pharmacology Overview

#### Dr. Ron Herman

Dr. Ron Herman from the University of Iowa, Dept. of Pharmaceutical Care, shared a pharmacology presentation on medical cannabidiol and dosing considerations. Dr. Herman's presentation included information and discussions related to patient safety of CBD and THC, dosing, cannabis chemistry and how it works in the human body, general risks and effects of use, as well as other CBD related information.

## 6. Cannabis Scheduling Overview

#### **Andrew Funk**

Andrew Funk, Executive Director of the Board of Pharmacy spoke to the board regarding cannabis scheduling. Andrew provided cannabis scheduling history, the scheduling process, and the recommendations from the Iowa Board of Pharmacy given to the Iowa Legislature in 2014. In addition, Andrew reported that in 2017 an amendment was made to Iowa Code Chapter 124 that requires the board to act if a cannabidiol investigational drug was approved by the FDA and subsequently rescheduled by the federal DEA.

## 7. Department Update

#### Sarah Reisetter

Sarah Reisetter, Deputy Director of the Iowa Department of Public Health (IDPH) provided an update to the board regarding departmental activities and information related to the medical cannabidiol program. Information shared included:

- Cole Memo Rescission by Attorney General Jeff Sessions. The
  Department is moving forward with business as usual. Enforcement will
  be up to individual US Attorneys, in Iowa this means both the Northern
  and Southern districts.
- **2. CBD Position Statement**. IDPH issued a position statement in December 2017, after consultation with the Board of Pharmacy, the Attorney General's Office and the Department of Public Safety in response to a number of inquiries from local law enforcement.
- 3. **Technology Proposals.** The department is still in the process of reviewing the three technology proposals that were received in response to the RFP. BioTrack decided not to apply due to its perception of a limited market and limited investment in Iowa.
- 4. **Dispensary RFP.** IDPH intends to release the dispensary licensing RFP on January 25, 2018, with letter of intent to apply due February 8, 2018, applications due March 8, 2018, and posting of intent(s) to award scheduled for March 30, 2018.
- 5. **Dispensary Locations.** One of the items the board is tasked with is advising IDPH about the location of dispensaries. Iowa maps based on residence and conditions were distributed with the board's materials to aid with this discussion.

6. Tour of MedPharm facilities. MedPharm Iowa has extended an invitation for board members to tour their manufacturing facility in Des Moines. IDPH staff will work with board members to gauge interest and facilitate scheduling.

### 8. Public Comment Period

### Mike McKelvey, Chair

A number of attendees registered to address the board. A wide variety of subjects were covered during the public comment period. Those addressing the board included:

- Mr. Tom Duncan, a 12 year kidney cancer patient expressed his gratitude to the department and board in moving the work forward. Mr. Duncan shared that he felt thousands of patients would be thankful and would benefit from the use of medical CBD.
- Mr. Carl Olsen shared his perspective regarding rescheduling cannabis to a Schedule 2
  narcotic. Mr. Olsen also shared that it was understanding that the THC limits included in
  HF 524 were included in an attempt to limit abuse.
- Mrs. Sally Gaer explained her understanding on how cannabis works together with other
  medications to produce what is known as the entourage effect. Mrs. Gaer also shared
  her personal experience of the benefits of medical CBD by sharing her daughter's usage
  and the benefits gained. Mrs. Gaer urged the board look at helping citizens that need
  the assistance of medical CBD by expanding the conditions allowed by the program, and
  not focus on concerns of abuse which prevent patients from accessing medical CBD.
- Mr. Lucas Nelson, General Manager of Kemin Industries and consultant for MedPharm lowa spoke to the board, providing his perspective on the limits included in HF524 adopted by the 2017 Legislature. Mr. Nelson shared that MedPharm lowa would like to see higher allowances of THC so patients can get what they need in terms of therapeutic effects. Mr. Nelson also noted the need for education regarding the use of medical CBD and THC, recommending IDPH provide continuing education for physicians. Additional remarks touched on MedPharm lowa's proposed product list, their work on formulations, concerns with both quantity and THC limits making available products cost prohibitive for patients in need of higher quantities and the potential of those patients turning to the black market. Quantity limits could also be effected due to location of dispensary, making trips to the dispensary prohibitive to patients, especially if they have to go back frequently.
- Mr. Tom Swegle, consultant for MedPharm Iowa thanked the board for their dedication to the program. In addition, Mr. Swegle also spoke about word cannabidiol and some disagreements on the language of cannabidiol and its definition.
- Mr. Jason Karimi, Iowa Patients for Medical Marijuana spoke to board sharing
  information on effects of medical marijuana for patients, the offer to provide
  recommendations on classes for law enforcement individuals, and his viewpoint of the
  controlled substances acts, and his desire for the Iowa Attorney General's Office to give
  a public opinion on the subject.

#### 9. Form & Quantity Rule Recommendation

#### Sarah Reisetter

A draft administrative rule related to medical CBD form and quantity was drafted per the board's request. This draft rule has been reworked and presented again for review and approval. Per the board's prior request, updates include listing all approved forms, and the quantity limits for possession are limited to a 90 day supply of each product dispensed. Discussion included other possible delivery methods of medical CBD, questions regarding definitions, commonly used terms, possible future forms and debate regarding quantity limits.

A motion was made by Dr. Cheyne to approve the draft rules as presented, seconded by Dr. Richards.

A verbal vote was taken. All members present voted in favor, except Dr. Zadeh who voted in opposition. Motion carried.

## 10. Dispensary Location Discussion

#### Sarah Reisetter

Sarah reminded the board that current law requires consultation from the board regarding location of dispensaries. Due to the fact that there are currently a limited number of card holders to inform the discussion, IDPH used in-patient and out-patient data from hospitals, as well as death data to create maps of patients with the debilitating medical conditions authorized in chapter 124E by county of patient residence. These maps were provided in the board materials to aid in discussion of this topic. Discussion on how other states determined dispensary locations was shared. Board members stated that they like the idea of geographic diversity, agreeing that the department use their best judgment when considering geographic location and awarding dispensary licensing. This may mean as applications are scored, a lower scoring application may get extra consideration due to its geographic location.

#### 11. Laboratory Rules Recommendation

#### **Sarah Reisetter & Don Simmons**

Sarah Reisetter, with assistance from Don Simmons and Pam Mollenhauer from the State Hygienic Laboratory, led the board through the proposed amendments to the administrative rules to add procedures for laboratory testing of medical CBD products.

A motion was made by Dr. Zadeh, with a second by Dr. Miller to approve the draft laboratory rules.

A verbal vote was taken. Motion Carried.

#### 12. Future Meetings Discussion

- a. Friday March 9, 2018
- b. Friday May 4, 2018
- c. Friday Aug. 3, 2018
- d. Friday Nov. 2, 2018

For purposes of scheduling, IDPH proposed meetings in March and May, with quarterly meetings thereafter.

# 13. Adjourn

# Mike McKelvey, Chair

A motion has been made by Dr. Cheyne, seconded by Dr. Stoken to adjourn the January 19, 2018 meeting.

A verbal vote was taken. Motion carried. The meeting officially adjourned at 1: 15 p.m.