

то:	Paul Hyland, Director, Office of Medical Marijuana (OMM)	
FROM:	Michael Owens, Task Lead, Delta Development Group, Inc.	
SUBJECT:	Medical Marijuana Stakeholder Group Public Meeting	
REFERENCE :	R.22096.00	
DATE:	September 21, 2022	

The Medical Marijuana Stakeholder Group public meeting was held Wednesday, September 21, 2022, at 5:00 p.m., and was conducted using Zoom Webinar virtual meeting platform. The following were in attendance:

NAME/TITLE	ORGANIZATION
Paul Hyland Director	Division of Public Health (DPH)/OMM
Joanna Suder Deputy Attorney General	Department of Justice, Office of the Attorney General
Brett Applebaum	DPH/Office of Public Health Nursing
Clayton Hewes	First State Compassion
Dr. Andrew Willet	Science/Health Professional
Emily Wilkins	Patient
Hannah Iglesias	CannTech Research
Aaron Epstein	CannTech Research
Holly Megan Smith	Patient
Dr. Jason Silversteen	Science/Health Professional
Dr. John Demarion	Science/Health Professional
Jessica Heesh Mensack	Caregiver
Kevin Kriss	American Fiber
Pamela Stampul	Patient
Volley Hayhurst	Columbia Care
Ngiste Abebe	Columbia Care
Jennifer Stark	The Farm
Justin Weisser	Fresh

NAME/TITLE	ORGANIZATION
Michael Owens Associate/Task Lead	Delta Development Group, Inc. (Delta)
Robert Ross	Delta
Vice President	
Diane Lizambri	Delta
Associate	

I. Welcome and Introductions

- A. Michael (Mike) Owens welcomed everyone to the initial public meeting for the Medical Marijuana Stakeholder Group. Mike discussed housekeeping announcements for the proceedings of the webinar and explained that during the public comment period those attending the meeting as audience members would be provided the opportunity to speak and share any comments or feedback with the panelists, which incorporated the members of the stakeholder group.
- B. Mike provided a brief review on the background of the Medical Marijuana Stakeholder Group. The stakeholder group was established as part of a legislature ruling to provide a platform for communication and feedback to occur between the state entities, the organizations that work in the industry, and the patient and advocate groups associated with the state of Delaware's Medical Marijuana Program (MMP) following the sunset of the Medical Marijuana Act Oversite Committee. The stakeholder group includes representatives from each of these groups as well as science and health professionals that have expressed interest in the program who will provide additional viewpoints and perspective in terms of information regarding medical marijuana.

II. Medical Marijuana Program Discussion

- A. Mike shared that OMM recently completed a survey where patients provided feedback regarding various MMP components, and Paul Hyland noted that the survey results along with current events were used to develop the meeting agenda topics. One of the questions within the survey asked about concerns patients have about the MMP and it was noted that participants were concerned about product variety and availability. The results from another question included in the survey revealed that most patients had only visited one or two of the dispensaries located throughout the state, and patients were typically traveling either less than 10 miles or between 10 20 miles to get the product they desired. Paul stated that the program is determined to make sure that there are adequate options available to patients when choosing a dispensary and purchasing products.
 - 1. Paul stated that currently the MMP has about 15,500 patients, which are distributed throughout the state with 51% in New Castle County, 18% in Kent County, and 31% in Sussex County. To account for the population size and to ensure product is available, there have been three recent new retail facilities opened with an additional two coming. Aaron Epstein with CannTech Research and doing business with Best Buds commented that in September, their organization opened a new location in Dover and are expecting to open a Georgetown location in October. Jennifer Stark with The Farm mentioned that their retail location in New Castle had just opened the week previously. Paul mentioned that Fresh Delaware and Valor both have facilities that are beginning the process of developing retail locations, but opening dates are not established currently.

- a. Aaron and Jennifer both commented that a noticeable struggle is getting the word out to the patient population that these newer retail locations are open. Paul responded that he has been working to find a balance where he is not overstepping his boundaries in terms of advertising compassion centers but noted that when the patient blast was sent out, as well as when new cards are sent to patients, there is an updated list of retail locations included.
- B. Paul stated to the group that the MMP still views CBD as an important topic and would like to see additional one-to-one product availability particularly for the 104 patients with the CBD-rich cards and for the pediatric patients. Paul explained to the group that one-to-one refers to a product that is equal or near equal part CBD and THC.
 - Jennifer with The Farm provided a review of the one-to-one product availability that they offer which includes: half gram and gram cartridges, tinctures, salve, gummies, and pediatric formulas. Clayton Hewes with First State Compassion stated that their available products include: tinctures, waxes and salves, half gram and gram cartridges, and they will be coming out with a new line of edibles and gummies. Ngiste Abebe with Columbia Care noted that their products include tinctures, and they are releasing a press 2.0 tablet.
- C. Paul stated to the group that he would like to hear feedback from the group about their thoughts on having a three-year program card; currently, by law, a patient must see a medical provider every year to be recertified for the program.
 - Dr. Jason Silversteen noted that there is a similar process with handicap placards in the state of Delaware. The decision is on the provider to make the determination on whether the placard is good for one year or three years, and this process could be used for making the determination when filling out the MMP application where the provider determines the appropriate duration of time or usage of product for each patient. It is the onus of the physician to keep track of and follow the patients if the provider signs for a three-year time frame.
 - a. Members representing the scientific and health professionals stated their support for the idea that Dr. Silversteen provided, as it gives the provider the ability to choose between the length of the program card. Brett Applebaum, Dr Andrew Willet, and Dr. John Demario all noted favoring the capability for a physician or provider to have the option to initially approve someone for a one-year period, but with time spent successfully in the program, it would be suitable to extend to three years. The group stated that the purpose of having the ability to still select a one-year card rather than going right into a three-year card is so that as someone enters the program, the provider to be able to monitor the patient to see how they respond to the treatment and react to any side effects that may occur.
 - b. Clayton Hewes inquired if there were considerations for this type of card for the patients, would there be a similar process made available for employees in the program? Paul responded that they had not previously thought about the three-year care for employees when they originally began thinking about the idea but noted the value and will review what that would require.
- D. Mike asked if any members of the stakeholder group had any questions or discussion topics to bring up to the group that were not included on the agenda before moving on to the medical subject matter discussion.

- 1. Emily Wilkins asked if patients would be able to get higher dose THC products (20 mg) such as edibles because currently the product available is in pill form and people can have difficulty when swallowing larger pills. Paul responded that it is unlikely that those type of products, particularly edibles, would be made available at a higher dose than the 10mg it comes in currently. Paul explained that the reservation comes from a survey of product overconsumption and emergency room visit that have resulted from that, and for products like the edibles with higher potency, it is easy for the effects to overwhelm someone who is new user or overconsumes the product. For those patients, they could possibly investigate alternative options and formulas for tinctures or chewable tablets.
- 2. Brett inquired about the requirements for a provider to be able to write recommendations for medical marijuana patients. Paul commented that as long as the provider has prescriptive authority such as a Physician, Advance Practice Nurse, or Physician Assistant, the program will accept the recommendation. Dr. Silversteen commented that Delaware is one of the most streamlined states for endorsing a patient for medical use, and does not require certain certifications, training, or classes. Dr. Willet noted that as a physician they are not really prescribing marijuana, but rather certifying that the patient has a condition that might benefit from marijuana use.

III. Scientific/Medical, Marijuana Subject Matter Discussion

- A. Delta 8 THC Surge
 - 1. Dr. Silversteen stated that this topic of Delta 8 THC was briefly brought up in their last Medical Marijuana Act Oversight Committee meeting before it was cut short and was something that he was unaware of at the time. There have been Delta 8 THC products found in stores in Middletown and the surrounding areas. From his understanding, as a result of the Farm Bill, there is an abundance of hemp which contains CBD, and through an unregulated process and use of basic chemistry and chemicals, the structure of CBD is being altered into the Delta 8 THC, a "cousin" of the classic Delta 9 THC, which is a general form of THC that is present in marijuana products. Dr. Silversteen noted that it is illegal in Delaware, but it appears to be rampantly sold.
 - a. Ngiste commented to the group that Delta 8 is being seen more commonly throughout the country and is glad that the group is having this conversation to bring awareness to the topic. Ngiste stated that the FDA had noted an uptick in the amount of poison control calls in response to Delta, with 40% of those affecting children. It is important that awareness is spread to business owners about the product being illegal to sell in the state, but it is also important that there is more effort to focus on educating consumers, so they have an understanding about cannabis products that are flooding the market such as these Delta 8 THC products.
- B. Drug Interactions with Cannabis

Attachment 1

1. Dr. Jason Silversteen provided a presentation on cannabis drug interactions. The presentation reviewed how CBD and THC are broken down and metabolized, what prescription drugs may result in an inducing or inhibiting influence on the effect of the cannabis products, and shared information that has been found through published drug interaction studies.

IV. Public Comment Period

A. No public comments or feedback were provided by those attendees in the audience.

V. Wrap-up and Next Steps

- A. Paul Hyland wrapped up the meeting thanking everyone for attending the event.
- B. Delta will create a new Doodle poll to be sent to members of the stakeholder group for feedback on the best date for the next public meeting.
- C. Delta will develop the meeting minutes for the stakeholder group and will provide the approved minutes to be placed onto the DPH public meeting calendar.

VI. Adjournment

A. With there being no further business, the meeting adjourned at 6:15 p.m.

Attachment 1 – Cannabis Drug Interactions Presentation Slides



"The State of Cannabis"

- ♦ Growing acceptance of cannabis for medical use
- ♦ 39 states approved for medical use; 19 have legalization for recreational use
- ♦ At least 2/3rds of Americans support legalization
- ♦ Opiate epidemic continues and dissuades providers from utilizing opiates
- Growing utilization and endorsement of cannabis by medical providers
- ♦ Limited knowledge of and "not top of mind" for drug-cannabis interactions

Drug Interactions Cytochrome P450 Enzymes

- ♦ THC and CBD are metabolized by CYP3A4 and CYP2C9 (Yamaori et al 2012, Watanabe et al 2007).
 - ♦ CYP3A4 inhibitors may increase THC and CBD levels.
 - ♦ CYP3A4 inducers may decrease THC and CBD levels
- * CBD, but not THC, is metabolized by CYP2C19 (Stout and Cimino 2014)
- ♦ CBD also inhibits CYP2C19 and CYP3A4

Inhibiting Effects

♦ CYP3A4 inhibitors

- ♦ Ketoconozole
- ♦ Erythromycin
- ♦ Carbamazepine
- ♦ Verapamil/Diltiazem
- ♦ Amiodarone

- ♦ CYP2C9 inhibitors
 - ♦ Omeprazole
 - ♦ Clopidogrel
 - \Leftrightarrow Fluoxetine
 - ♦ Leflunomide
 - ♦ Dilantin

Inhibiting effects augment psychoactive effects of THC and dose related effects of CBD(somnolence, transaminase elevation)



- ♦ CYP3A4 inducers
 - ♦ Cyclosporin
 - ♦ Carbamazepine
 - ♦ Barbiturates
 - ♦ St Johns Wort

- ♦ CYP2C9 inducers
 - ♦ Rifampicin
 - ♦ Phenobarbital(weak)
 - ♦ St Johns Wort(weak)

Inducing effects lead to a greater metabolism of the substrate and could result in higher doses of cannabis required

Drug Interactions Cytochrome P450 Enzymes

♦ THC is a CYP1A2 inducer.

- ♦ Theoretically, THC can decrease serum concentrations of clozapine, duloxetine, naproxen, cyclobenzaprine, olanzapine, haloperidol, and chlorpromazine (Flockhart 2007, Watanabe et al 2007).
- ♦ CBD is a potent inhibitor of CYP3A4 and CYP2D6.
 - ♦ As CYP3A4 metabolizes about a quarter of all drugs, CBD may increase serum concentrations of macrolides, calcium channel blockers, benzodiazepines, cyclosporine, sildenafil (and other PDE5 inhibitors), antihistamines, haloperidol, antiretrovirals, and some statins (atorvastatin and simvastatin, but not pravastatin or rosuvastatin).
 - CYP2D6 metabolizes many antidepressants, so CBD may increase serum concentrations of SSRIs, tricyclic antidepressants, antipsychotics, beta blockers and opioids (including codeine and oxycodone).



♦ Warfarin

- ♦ THC and CBD increase warfarin levels(inhibits CYP3A4 and CYP2C19) (Yamaori et al 2012).
- ♦ Frequent cannabis use has been associated with increased INR.
- ♦ Alcohol
 - ♦ Alcohol may increase THC levels (Hartman 2015).
- ♦ Theophylline
 - ♦ Smoked cannabis can decrease theophylline levels (Stout and Cimino 2014)
- Sclobazam
 - ♦ In children and adults treated with CBD for epilepsy, CBD increased clobazam levels(CBD inhibits CYP2C19) (Geffrey et al 2015).

Take Home Message

- Cannabis, both CBD and THC, have proven and theoretically impact on drug-drug interactions(potentiate effect or inhibit effect of other prescription drugs)
 - ♦ May lead to reduce effect of a prescription drug
 - ♦ May also lead to reduced effect of cannabis or increase psychoactive effects of cannabis
- ♦ Unknown what dose or frequency of THC/CBD use leads to drug-drug interactions
- Must maintain vigilance prior to and subsequent to endorsing Medical cannabis to assure no signs of drug-drug interactions