Cannabinoid Product Board

Annual Report

November 2017

Prepared by

Cannabinoid Product Board

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Cannabinoid Product Board Annual Report

Executive Summary

November 2017

As medical and recreational marijuana becomes legalized across the United States, the Utah Legislature has taken a proactive approach and in 2017 passed The Cannabinoid Research Act, numbered as HB130. This act established the Cannabinoid Product Board and allowed for the use of Cannabinoid products for research. The purpose of the Cannabinoid Product Board (CPB) is to review available research and provide recommendations to prescribing physicians related to the use of cannabinoid products for treating medical conditions, dosage amounts, and identifying interactions with other treatments. The Board is composed of seven members. Medical researchers, physicians, and three of the Board members are also members of the Controlled Substances Advisory Committee (CSAC).

The Board first met in June 2017 and began holding monthly meetings to review cannabinoid research. Annually, the Board provides recommendations to the legislature regarding their findings. This report contains the finding and recommendations of the Board from June to November 2017. Below, the reader will find the criteria matrix used for analyzing research as well as the studies that have been reviewed at this point. Other activities of the board are explained and limitations, which were identified through discussion and research review, are outlined. The Board has made recommendations as well as identified next steps in this report.

Key Points:

- The Board has limited access to information, which proves difficult to make recommendations based on published research alone. The Board would defer to recommendations from the FDA.
- The Board recommends expanding the 10:1 ratio of cannabidiol to THC in statute so that more studies can be considered for review.
- The Board is unable to recommend appropriate dosages or treatments with cannabinoid products without assurance of quality and consistency throughout the research.
- The Board recommends that cannabinoid product manufacturers adopt guidelines similar to those from the American Herbal Products Association for quality control.
- The Board acknowledges that there is currently not enough literature to make conclusions about cannabidiol effectiveness for specific disease states.
- The Board recommends reviewing research regarding the harms associated with cannabinoid products in addition to the benefits of such products.

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Introduction

The Cannabinoid Product Board is the result of the Cannabinoid Research Act, sponsored by Rep. Brad Daw and Sen. Evan Vickers during the 2017 General Legislative Session. The Cannabinoid Research Act, numbered as HB130, made several changes to the state code:

1. Allow the processing and use of cannabinoid products in academic research;
2. Allow the possession of cannabinoid product by someone participating in approved research; and
3. The creation of the Cannabinoid Product Board and outlines its duties.

The Cannabinoid Research Act received wide support in the legislature. The bill received unanimous support from the House Health and Human Services Committee and received only two nay votes when on the House floor. In the Senate, where HB0130 was introduced by Sen. Evan Vickers, the Senate Health and Human Services committee approved the bill 7-1, and passed the Senate as a whole 27-1-1. The legislation, with its amendments, passed the concurrence calendar unanimously. Gov. Herbert signed the Cannabinoid Research Act into law on March 25th.

The Cannabinoid Research Act directs the Utah Department of Health (UDOH) to form and facilitate the Cannabinoid Product Board. As stated in the legislation, the purpose of the board is to review available research related to the human use of cannabinoid products. Specifically the board is asked to evaluate the safety and efficacy of cannabinoid products in terms of: 1) medical conditions that respond to cannabinoid products; 2) dosage amounts and their medical forms; and 3) interactions between cannabinoid products and other treatments. The board may only review research that has been approved by an Institutional Review Board, or approved/conducted by the federal government.

From this research, the board has been asked to develop prescribing guidelines that may potentially be used by physicians recommending cannabinoid products to their patients. The board is directed to report the findings of their evaluation in writing to the Health and Human Services Interim Committee before November 1st of each year.

The legislation outlines that the Cannabinoid Product Board be made of the seven members "…in consultation with a professional association based in the state that represents physicians." Three of the board members must be medical researchers and four must be physicians. Three of the board members must also be members of the Controlled Substances Advisory Committee (CSAC). The terms of board members, leadership, and voting on recommendations are also discussed.

The Executive Directors Office (EDO) of UDOH began the process of identifying potential board members and issuing appointments in April, 2017.

Those appointed include:

Erik Christensen M.D.*	*Utah Department of Health Office of Medical Examiner*
Michael Crookston M.D., F.A.P.A., F.A.S.A.M.	*Intermountain Medical Group*
Glen Hanson DDS, Ph.D.*	*University of Utah, Health Sciences Center*
Mark Munger Pharm.D.*, F.C.C.P., F.A.C.C., F.H.F.S.A.	*University of Utah, Health Sciences Center*
Ed Redd M.D.	*Utah Legislator*
Perry Renshaw M.D., Ph.D., M.B.A	*University of Utah , Health Sciences Center*
Karen Wilcox Ph.D.	*University of Utah, Health Sciences Center*

* CSAC Members

Facilitation of the Cannabinoid Product Board was delegated to the Tobacco Prevention and Control Program within the Bureau of Health Promotion.

Bylaws

The Cannabinoid Product Board adopted bylaws to define the structure of the Board and to help guide the Boards decisions and operations. The bylaws were adapted from the Colorado Medical Marijuana Scientific Advisory Council bylaws with inclusion of requirements in H.B. 130. The bylaws contain the duties of the board, which are defined as:

ARTICLE IV: Duties of the Board

Section 1. The Board shall:

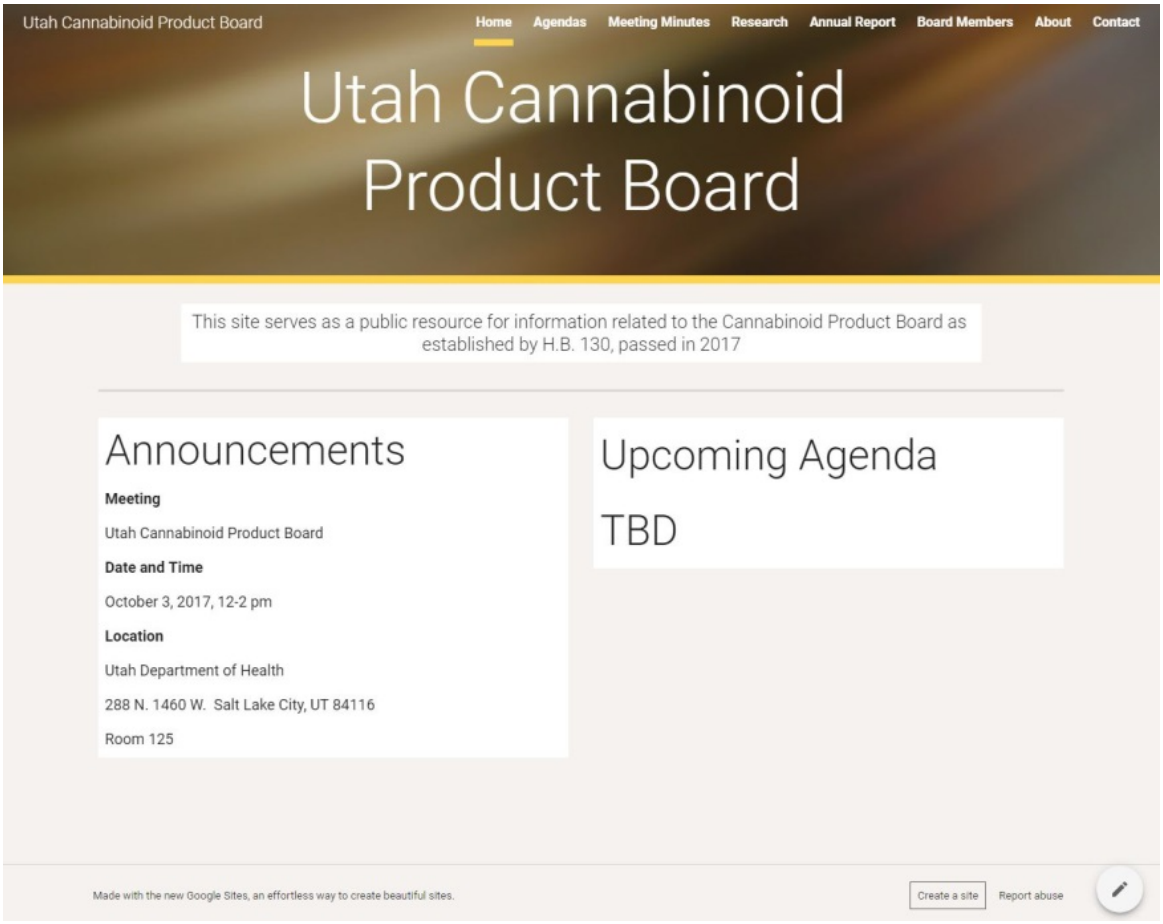
1) Review any available research related to the human use of a cannabinoid product that:
   a) was conducted under a study approved by an IRB, or
   b) was conducted or approved by the federal government
2) Based on the research, the Board shall evaluate the safety and efficacy of cannabinoid products, including:
   a) medical conditions that respond to cannabinoid products
   b) cannabinoid dosage amounts and medical dosage forms; and
   c) interaction of cannabinoid products with other treatments
3) Based on the Board's evaluation, the Board shall develop guidelines for a physician recommending treatment with a cannabinoid product that includes a list of medical conditions, if any, that the Board determines are appropriate for treatment with a cannabinoid product.
4) The Board shall submit the guidelines to:
   a) the director of the Division of Occupational and Professional Licensing
   b) the Health and Human services Interim Committee
5) The Board shall report the Board's findings before November 1 of each year to the Health and Human Services Interim Committee.

The bylaws contain information regarding the responsibilities of the Department of Health and how meetings should be conducted using Robert's Rules of Order, as well as how to deal with conflicts of interest.

Website

The Cannabinoids Product Board developed a free public website for the purpose of organizing research, providing a place for public comment and adding an extra layer of transparency to the proceedings of the board. The website can be found at: https://sites.google.com/utah.gov/cpboard/. The website contains information of when and where the Board meetings will be held, upcoming and past agendas, and meeting minutes for all CPB meetings. The website also contains a section for research, which has copies of all the literature that is being reviewed by the board. This website is also a place for the public to interact with the Board. The public can submit comments or questions to the Board, which the Board will have the opportunity to respond to.

**Below are screenshots of the Utah Cannabinoid Product Board Website*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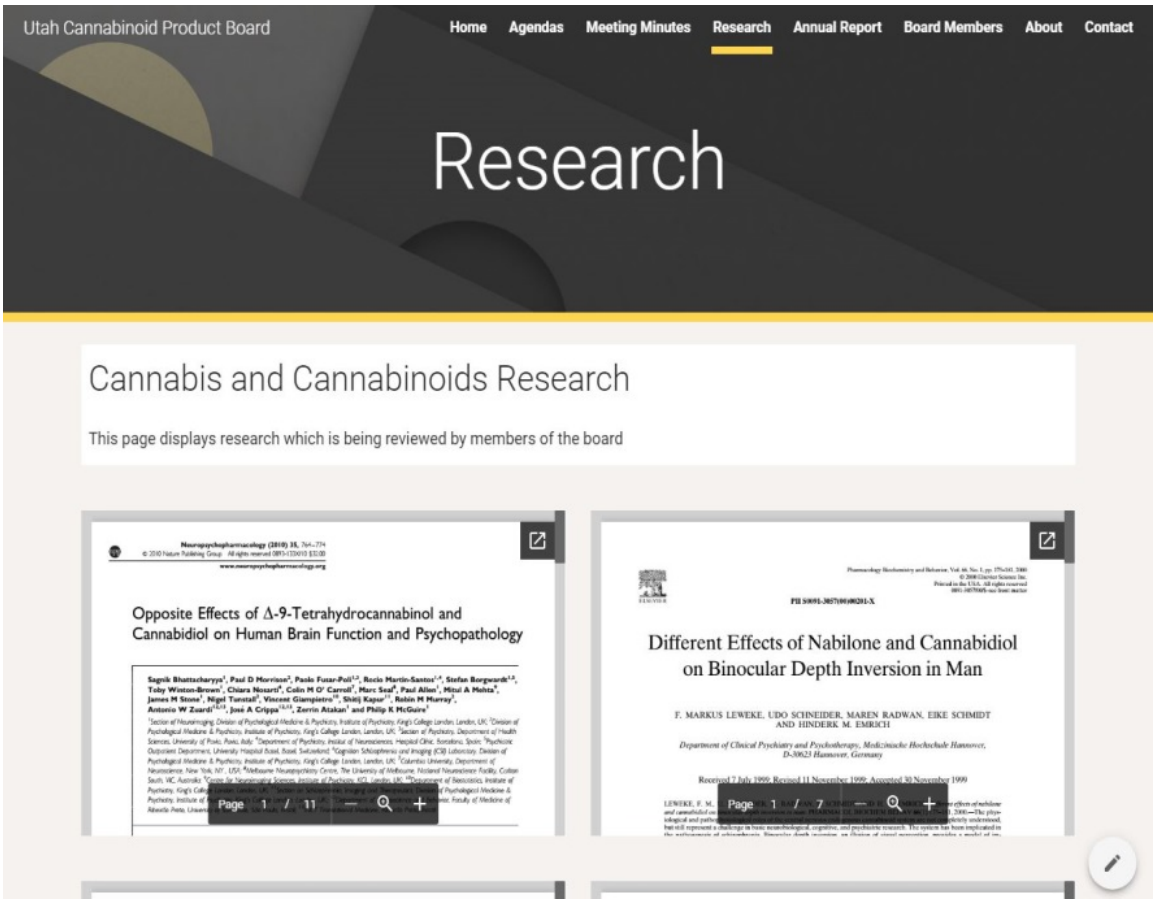
This site serves as a public resource for information related to the Cannabinoid Product Board as established by H.B. 130, passed in 2017
Announcements
Meeting
Utah Cannabinoid Product Board
Date and Time
October 3, 2017, 12-2 pm
Location
Utah Department of Health
288 N. 1460 W. Salt Lake City, UT 84116
Room 125
Upcoming Agenda
TBD
Made with the new Google Sites, an effortless way to create beautiful sites.
Create a site
Report abuse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Cannabis and Cannabinoids Research
This page displays research which is being reviewed by members of the board
Opposite Effects of Δ-9-Tetrahydrocannabinol and Cannabidiol on Human Brain Function and Psychopathology
Different Effects of Nabilone and Cannabidiol on Binocular Depth Inversion in Man
F. MARKUS LEWEKE, UDO SCHNEIDER, MAREN RADWAN, EIKE SCHMIDT AND HINDERK M. EMRICH

Organization

In the initial meeting of the Cannabinoid Product Board, the Board voted on selecting a chairperson. Karen Wilcox, Ph.D. who is a professor and chair of the Department of Pharmacology & Toxicology at the University of Utah was selected to be the chair. The Board does not have a co-chair, though the bylaws allow for one if needed in the future. The Board has decided to meet monthly and will continue to do so as needed. Thus far four board meetings have been held. The agenda of a typical board meeting consists of administrative items such as approving the previous meeting minutes, and review of published research. The research articles are assigned to members of the board to read and then they report on the research at the meeting. After presenting the research, each article is discussed by the Board, and placed into the established matrix for scoring. The research that is reviewed is identified primarily by the Board intern based on the criteria for studies outlined in HB130. Members of the Board also bring relevant research forward for discussion. The Board is interested in having subject matter experts such as researchers and pharmacological organizations present to the Board and provide further information above and beyond what research can provide.

Process for Reviewing and Classifying Research

The Cannabinoid Product Board has been asked to evaluate the safety and efficacy of cannabinoid products in terms of: 1) medical conditions that respond to cannabinoid products; 2) dosage amounts and their medical forms; and 3) interactions between cannabinoid products and other treatments. As such the Board needed to create processes by which they could systematically review the evidence which met the criteria outlined in the statue. The Board agreed upon using the categories used by the Institutes of Medicine to categorize evidence it their book "The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research", to classify study recommendations as well as to determine the level of evidence for each study reviewed. It was decided that all research reviewed would be put into a matrix that identifies the specific disease state or topic the study looked at, study methods (type of study, sample size, location), key findings, key limitations, a determination of the level of evidence as well as a grading or classification of the recommendations. Please see example below. Using this matrix as a guide the Board would systematically work through grading each piece of evidence. The Board also invited representatives from various suppliers of high quality, pharmacy grade, cannabidial products to present to the Board to gain a better understanding of the research being conducted and the products currently on the market. The Board adopted standard language developed by the Institutes of Medicine to categorize the weight of evidence regarding whether cannabinoid use is an effective or ineffective treatment for the specified condition. The Categories and the general parameters for the types of evidence supporting each category are listed below. [1] The evidence categories suggest that the study design was appropriate for the limited conclusions reachable based on the limitations in the data. It does not indicate that the Board agrees or disagrees with any conclusion or recommendation.

Conclusive Evidence:

For therapeutic effects: There is strong evidence from randomized controlled trials to support the conclusion that cannabinoids are an effective or ineffective treatment for the health endpoint of interest.
For other health effects: There is strong evidence from randomized controlled trials to support or refute a statistical association between cannabinoid use and the health endpoint of interest.
For this level of evidence, there are many supportive findings from good-quality studies with no credible opposing findings. A firm conclusion can be made, and the limitations to the evidence, including chance, bias, and confounding factors, can be ruled out with reasonable confidence.

[1] National Academies of Sciences, Engineering, and Medicine. 2017. *The health effects of cannabis and cannabinoids: The current state of evidence and recommendations for research.* Washington, DC: The National Academies Press. doi: 10.17226/24625.

Substantial Evidence:

For therapeutic effects: There is strong evidence to support the conclusion that cannabinoids are an effective or ineffective treatment for the health endpoint of interest
For other health effects: There is strong evidence to support or refute a statistical association between cannabinoid use and the health endpoint of interest.
For this level of evidence, there are several supportive findings from good-quality studies with very few or no credible opposing findings. A firm conclusion can be made, but minor limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.

Moderate Evidence:

For therapeutic effects: There is some evidence to support the conclusion that cannabinoids are an effective or ineffective treatment for the health endpoint of interest.
For other health effects: There is some evidence to support or refute a statistical association between cannabinoid use and the health endpoint of interest.
For this level of evidence, there are several supportive findings from good- to fair-quality studies with very few or no credible opposing findings. A general conclusion can be made, but limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.

Limited Evidence:

For therapeutic effects: There is weak evidence to support the conclusion that cannabinoids are an effective or ineffective treatment for the health endpoint of interest.
For other health effects: There is weak evidence to support or refute a statistical association between cannabinoid use and the health endpoint of interest.
For this level of evidence, there are supportive findings from fair-quality studies or mixed findings with most favoring one conclusion. A conclusion can be made, but there is significant uncertainty due to chance, bias, and confounding factors.

No or Insufficient Evidence to Support the Association:

For therapeutic effects: There is no or insufficient evidence to support the conclusion that cannabinoids are an effective or ineffective treatment for the health endpoint of interest.

For other health effects: There is no or insufficient evidence to support or refute a statistical association between cannabinoid use and the health endpoint of interest.
For this level of evidence, there are mixed findings, a single poor study, or health endpoint has not been studied at all. No conclusion can be made because of substantial uncertainty due to chance, bias, and confounding factors.

Research Review:

The research listed in the matrix below was compiled by the CPB intern and reviewed by the Board. The research presented was identified by having a 10:1 ratio of cannabidiol to THC. This ratio limits the number of studies that can be reviewed, but the review process is ongoing as studies that meet this criterion are identified.

Title and Authors	Journal, Year (reference)	Methods (Type of study, sample size, study, location, etc.)	Weight of Evidence Category	Key Findings	Key Limitations	Comments (Industry ties, etc.)
"Trial of Cannabidiol for Drug-Resistant Seizure in the Dravet Syndrome", Devinsky, et al	N Engl J Med 2017;376:2011-20. DOI: 10.1056/NEJMoa1611618	Randomized Controlled Trial; Double-blind, placebo controlled N= 120 14-week treatment period Dosages of 20 mg per kg of body weight per day of **cannabidiol** oral solution or placebo in addition to standard antiepileptic treatment. Multinational: 23 centers in the U.S. and Europe Sample: Children/young adults (2-18 years old) with the Dravet syndrome (Epilepsy disorder associated with drug-resistant seizures and high mortality rate) Mean age: 9.8 years old 52% male 90% completed the treatment period	Conclusive evidence	Cannabidiol resulted in a greater reduction in convulsive-seizure frequency than placebo among children w/ drug-resistance Dravet syndrome. **Cannabidiol group**: - Decrease in median frequency in convulsive seizures per month from **12.4 to 5.9.** - Percentage of patients w/at least a 50% reduction in convulsive-seizure frequency: **43%**. - 5% became seizure free - No significant reduction in nonconvulsive seizures. - Adverse events: diarrhea, vomiting, fatigue, pyrexia, somnolence, abnormal liver-function test results. -Overall condition improved by at least one category on the 7-category Caregiver Global Impression of Change Scale: **62%** **Control group:**	Data on convulsive seizures (number and type) was recorded each day by patients or their caregivers. Results of Caregiver Global Impression of Change are self-reported on a 7-point Likert-like scale.	Funded, designed, managed, monitored, and analyzed by GW Pharmaceuticals

				- Decrease in median frequency of seizures per month from **14.9 to 14.1**. - Percentage of patients w/at least a 50% reduction in convulsive-seizure frequency: **27%**. - Less adverse events occurred - 0% became seizure free - Overall condition improved by at least one category on the 7-category Caregiver Global Impression of Change Scale: **34%** Median difference between cannabidiol group and placebo group in seizure frequency: -22.8 percentage points; 95% CI, -41.1 to -5.4; P=0.01		
"Cannabidiol enhances anandamide signaling and alleviates psychotic symptoms of schizophrenia", Leweke, et al	Transl Psychiatry (2012) 2, e94, doi:10.1038/tp.2012.15 & 2012 Macmillan Publishers Limited All rights reserved 2158-3188/12	Randomized Clinical Trial; therapeutic-exploratory (phase II); Double-blind: **cannabidiol** vs amisulpride (a potent antipsychotic). N=42 Sample: Age 18-50 years old; male and female; all diagnosed with paranoid schizophrenia	Conclusive evidence	**Both** the cannabidiol treatment and amisulpride were **safe** and equally effective at improving psychotic symptoms. **Cannabidiol treatment**: - Superior side-effect profile: less weight gain and lower prolactin increase- a predictor of galactorrhea and sexual	The primary pharmacological mechanism through which cannabidiol exerts anipsychotic effects in not yet clear. The study could not exclude that cannabidiol may reduce psychotic symptoms through complementary or	The study was supported by grants from the Stanley Medical Research Institute (FML) and the National Institute on Drug Abuse (DP).

		Location: Department of Psychiatry and Psychotherapy of the University of Cologne All patients were hospitalized at baseline and through day 28 after random assignment to treatment. After a screening period of up to 7 days and a minimum period of 3 antipsychotic-free days, patients were randomized (1:1) to receive either cannabidiol or amisulpride starting with 200mg per day each and increased stepwise by 200mg per day to a daily dose of 200mg four times daily (total 800mg per day) each within the first week. Treatments were maintained for another 3 weeks.		dysfunction. Well-tolerated - Significant increase in serum anandamide levels, which was significantly associated with clinical improvement.	even alternative mechanisms to FAAH inhibition, including interactions with serotonin 5-HT1A receptors, GPR55 receptors and transient receptor potential vanilloid-1 receptors. The results provide a rationale for additional clinical testing of selective FAAH inhibitors in schizophrenia.	
"Safety and pharmacokinetics of oral cannabidiol when administered concomitantly with intravenous fentanyl in humans", Manini et al	J Addict Med. 2015 May-Jun; 9(3): 204–210. doi: 10.1097/ADM.0000000000000118	Double-blind, placebo-controlled cross-over study N=34 (each subject had two sessions; n=17) Sample: 21-65 years old; healthy volunteers with prior opioid exposure, regardless of route. Location: Clinical Research Center in Mount Sinai Hospital	Moderate evidence	Cannabidiol does not exacerbate adverse effects associated with intravenous fentanyl administration. Co-administration of CBD and opioids was safe and well tolerated. Importantly,	Subject to potential selection bias due to not including participants across all ages, gender, and ethnic backgrounds. Self-reporting could have led to bias, but	The study was funded by a research grant from the National Institutes of Health.

		in New York City Cannabidiol (CBD) was orally co-administered with intravenous fentanyl. Participants administered either placebo, 400mg oral CBD, or 800mg oral CBD. 2 sessions: Session 1: .5mcg/Kg; Session 2: 1.0mcg/Kg of IV fentanyl. Blood samples were obtained before and after 400 or 800 mg CBD pretreatment, followed by a single 0.5 (Session 1) or 1.0mcg/Kg (Session 2) intravenous fentanyl dose. Primary outcome: Systematic Assessment for Treatment Emergent Events (SAFTEE) to assess safety and adverse effects. Also measured: CBD peak plasma concentrations, time to reach peak plasma concentrations and area under the curve.		fentanyl co-administration did not produce respiratory depression or cardiovascular complications.	the study did utilize a combination of self-reporting and objective measures (vital signs, urine testing, blood sampling). Participants were excluded if they had a current diagnosis of drug dependence (except nicotine) or a positive drug screen. The study noted that it's predicted that CBD would have a significant effect on inhibiting heroin-seeking behavior, but that there are still large gaps of knowledge about CBD actions in the brain.	
"Low-Dose Cannabidiol Is Safe but Not Effective in the Treatment for Crohn's	Dig Dis Sci (2017) 62:1615–1620 DOI 10.1007/s10620-017-4540-z	Randomized Controlled Trial; placebo-controlled N= 19 Sample: 18-75 years old with a Crohn's disease activity index	Insufficient Evidence to Support the Association (small	CBD was found to be safe to administer to Crohn's patients, but displayed no beneficial effects. The average CDAI before cannabidiol consumption was 337 ± 108 and 308 ±	Small dose of CBD was used. Small number of patients in the study. Dosage was given orally, which may be	

Disease, a Randomized Controlled Trial", Naftali et al.,		>200. 11 were males. Patients were randomized to receive 10mg of cannabidiol (CBD) orally or placebo twice daily.	sample size and small dosages)	96 (p = NS) in the CBD and placebo groups, respectively. After 8 weeks of treatment, the index was 220 ± 122 and 216 ± 121 in the CBD and placebo groups, respectively (p = NS). Hemoglobin, albumin, and kidney and liver function tests remained unchanged. No side effects were observed.	less effective than smoking. 6 patients in the study group were current smokers, but none in the placebo group were. Smoking is known to be harmful in Crohn's disease.	

Limitations

Scope of the board

Utah Code §26-61-202 states that the purpose of the Cannabinoid Product Board (the Board) is to review available research to "…evaluate the safety and efficacy of cannabinoid products…" In the Cannabinoid Research Act the term "cannabinoid product" is defined as:

"…a product intended for human ingestion that:

> *(i) contains an extract or concentrate that is obtained from cannabis;*
>
> *(iii) is prepared in medicinal dosage form; and*
>
> *(iii) contains at least 10 units of cannabidiol for every one unit of tetrahydrocannabinol."* (UC § 58-37-3.6(1)(a))

The Board, upon beginning to identify research to review, discovered that there are few publically available research articles wherein the administered product met the definition of "cannabinoid product" as defined in state code.

The lack of available research prevents the board from confidently fulfilling its purpose of evaluating safety and efficacy of these products.

Consistency of products

The purpose of the Cannabinoid Product Board in evaluating the safety and efficacy of cannabinoid products is similar to the mission of the United States Food and Drug Administration (FDA) insomuch that the FDA seeks to ensure the safety, efficacy, and security of drugs, biological products, and medical devices to protect the public. To achieve its purpose, the FDA has put into place regulations for products defined as pharmaceuticals, botanical drugs, or dietary supplements. Such regulations are known broadly as Chemistry, Manufacturing, & Controls (CMC) and Current Good Manufacturing Practices (cGMP).

During the research and development stage of a new pharmaceutical the FDA requires companies to comply with CMC guidance to be granted approval. CMCs involve documentation of:

- Drug composition;
- Manufacture;
- Stability of the active substance;
- Formulation of final product;
- Appropriate variation limits;
- Release criteria (quality standards for when the drug can be made available); and
- The results of analytical testing.

When the pharmaceutical being assessed is botanical in nature and thus has multiple components in the same product, the requirements of CMCs change and also include:

- Authentication of plant source
- Record of plant specimens
- History of the land used to grow the plant source
- A written and approved process of the growing process including the use chemicals on the plant source.
- Packaging
- And specifications of the allowable limits of potentially harmful contaminants.

With this information the FDA can assess and decide whether the producing company can adequately and consistently produce a well-defined product at a high standard.

The need of CMCs is different based on the intent of the product. CMCs are needed for products that are intended for human use to treat disease (pharmaceuticals). Physicians are involved with the use

of pharmaceuticals and wherein the physician prescribes their use and dose. CMCs are not needed for products that are instead intended to supplement diet to support health (dietary supplements). Dietary supplements do not require a physician's prescription. As dietary supplements are not intended to be used to treat a specific disease the standard for their development is less regulated by the FDA and is comparable to the requirements of food products.

Current Good Manufacturing Practices are those regulations enforced by the FDA once a pharmaceutical is on the market to ensure that companies produce safe, consistent, and effective products. Many of these regulations are focused on facilities where manufacturing and processing of pharmaceuticals occur to ensure that they are properly designed, monitored, and controlled. Specifically, cGMPs require:

- Quality management system;
- Use of high-quality raw materials;
- Operating procedures;
- Quality monitoring and investigation;
- Laboratory testing; and
- FDA inspections

cGMPs are required for both pharmaceuticals and dietary supplements. However, in the case of dietary supplements, manufacturers are allowed to set their own cGMP specifications without FDA approval or auditing. Also, unlike in the production of pharmaceuticals the facilities where dietary supplements are produced need not be licensed by the FDA.

As cannabinoid products are neither pharmaceuticals nor dietary supplements there are no CMCs or cGMPs for their development or production from the FDA. For those states that have instituted a system of medical cannabis there are some varying requirements to try and promote quality however such regulations do not meet the standards of CMCs or cGMPs.

The lack of regulatory standards for cannabinoid products is important for several reasons. First, there are no adequate controls to prevent the presence of harmful product constituents that may have been introduced to the product either through the growing, processing, or manufacturing stages. As such it is difficult to evaluate a product for side-effects and interactions with other treatments. This raises ethical issues if these products are recommended to treat vulnerable individuals.

Second, without CMCs or cGMPs it is difficult to ensure the consistency of the end-product. Inconsistent product makes it difficult to evaluate the efficacy of a treatment. Variation in the potency of active ingredients and other product components mean trying to link the use of the product to health benefits is near impossible. Likewise, when physicians recommend such products to patients, physicians would be unable to recommend dosage as each batch of that product may differ from the last.

It is the opinion of the Board that the lack of regulation on cannabinoid products raises serious questions regarding their quality and reproducibility in the academic literature available. Without the assurance of quality and consistency, the board is unable to recommend disease states wherein cannabinoid products could be used to treat, or recommend appropriate dosing.

Recommendations

- The Board has have very limited access to the information necessary to make recommendations regarding conditions that respond to cannabinoid products, prescribing guidelines, and drug interactions. An example is that some research studies do not specify how the cannabinoid product was prepared, or the reasoning behind why certain dosages were used. Alternatively, the FDA has access to a much larger body of information and an established process, which would make their recommendations more accurate and appropriate. Due to this fact, the Board would defer to recommendations from the FDA.

- The scope of what the Board can review as outlined in the statute is very narrow and establishes limits to the cannabinoid products that can be taken into consideration. Currently, a 10:1 ratio of cannabidiol to THC is what is allowed in statute. While conducting literature reviews, it is clear that there are not many studies that meet these criteria. This severely limits the number of studies the Board can review and take into consideration. The Board recommends expanding the ratio beyond the current limitation of a 10:1 ratio of cannabidiol to THC.

- While the Board has been mainly focusing on the potential benefits of cannabidiol, the Board recommends also looking into the harms associated with cannabinoid products as those findings will also be important for physicians prescribing these products.

- As the Board focusses on specific diseases for literature review, it becomes apparent that in most cases there is not literature or not enough literature to make conclusions about cannabidiol effectiveness. The Board highly recommends not making conclusions based on a single or very few studies.

- It is the opinion of the Board that the lack of regulation or Chemistry, Manufacturing, & Controls (CMC) and Current Good Manufacturing Practices (cGMP) on cannabinoid products raises serious questions regarding their quality and reproducibility in the academic literature available. Without the assurance of quality and consistency, the board is unable to recommend disease states wherein cannabinoid products could be used to treat, or recommend appropriate dosing.

- The Board recommends that cannabinoid product manufacturers adopt guidelines similar to those from the American Herbal Products Association for cultivation and processing, manufacturing and related operations, laboratory practice, and dispensing so that research and disease interactions are consistent.

Next Steps

- The Board will continue to meet monthly or as necessary to review research articles and utilize the research matrix to classify cannabinoid studies that show promise or harm for prescribing purposes.

- In addition to research, the Board will bring in experts from a variety of backgrounds to further advance the Board's knowledge of cannabinoid products and research.

- The Board has hired an intern, Ms. Krisana Finlay, who is a student at the University of Utah, studying public policy and public health. Ms. Finlay will assist the board in finding and compiling research, drafting reports, and assisting the Board with various duties as assigned.