

Utah Cannabinoid Product Board Annual Report

November 2020

Prepared by

Cannabinoid Product Board

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Cannabinoid Product Board Annual Report

Executive Summary

November 2020

To help guide the treatment aspects of this complex program and improve short and long-term overall outcomes, the Utah State Legislature has taken a proactive approach by establishing the Center for Medical Cannabis (CMC) and the Cannabinoid Product Board (CPB). The purpose of the CPB is to review the available research literature and assist the Utah Department of Health (UDOH) and CMC in their efforts to provide useful treatment recommendations to qualified medical providers regarding the use of cannabis and cannabinoid products for treatment of certain medical conditions identified as “qualifying medical conditions.”

The CPB is composed of seven members who are medical researchers, physicians, and one of the members must also represent the Controlled Substances Advisory Committee (CSAC).

This report contains the findings and recommendations of the CPB from January to November 2020.

Key Points:

- The CPB successfully assisted the CMC in drafting standard guidance language for medical cannabis products to be sold in Utah. The guidance documents were posted online on the CPB and the CMC’s website and consists of one complete full length document plus eleven corresponding guidance documents specific to each qualifying condition. The guidance documents are formatted similarly to package inserts for FDA-approved prescription medications and are based on findings of the CPB research efforts. As such, the guidance documents include:
 - Utah statute-approved indications for use and research data regarding the use of cannabis and cannabinoids for treatment of the approved conditions;
 - strength of evidence guiding treatment recommendations;
 - starting dose and dose titration suggestions;
 - THC:CBD ratio suggestions for specific approved conditions;
 - warnings and contraindications;
 - potential adverse reactions;
 - cannabis and cannabinoid pharmacodynamics and pharmacokinetics; and potential drug-drug interactions.
- The Utah Legislature, under Utah Code, 26-61-202, approved a change allowing the CPB to review and consider studies conducted outside the United States that may not have been approved by the United States federal government or a United States Institutional Review Board (IRB).
- Two experts in their respective fields presented detailed literature reviews and summary conclusions on cannabis use for state-approved qualifying conditions (i.e., Multiple Sclerosis; Pain). The CPB voted unanimously to accept those conclusions as updates to the guidance documents. This process will continue through the upcoming year on a monthly basis at scheduled CPB meetings as a means of continuously updating and informing all participants in the program on the evidence base for qualifying conditions.
- The CPB has been kept abreast of Compassionate Use Board (CUB) proceedings at its monthly meetings and does not have any recommendations to add a new qualifying condition to the list of state-approved qualifying conditions at this time. Communications between the CPB and the CUB along with ongoing literature reviews will inform recommendations going forward.

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Introduction

The Cannabinoid Product Board (CPB) is the result of the Cannabinoid Research Act (H.B. 130) that was passed during the 2017 Utah General Legislative Session and amended during subsequent sessions to include review of research regarding “expanded cannabinoid products” which includes cannabinoid products with significant tetrahydrocannabinol (THC) content.

The Cannabinoid Research Act directs the Utah Department of Health (UDOH) to form and facilitate the activities of the CPB. As stated in Utah statute, the purpose of the CPB is to review available research related to the human use of cannabinoid products. Specifically, the CPB evaluates the safety and efficacy of cannabinoid products and expanded 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, expanded cannabinoid products, and other treatments.

Utah Code 26-61-201 states that the CPB consist of seven members “...in consultation with a professional association based in the state that represents physicians.” Three of the CPB members must be medical researchers and four must be physicians. One of the CPB members must also be a member of the Controlled Substances Advisory Committee (CSAC). The CPB may elect their own leadership and vote on recommendations they will make as a board to the legislature.

The CPB selected Perry G. Fine M.D. to be Chair for the 2020 year (filling outgoing Chair Edward Redd’s position), and Michael Crookston M.D., F.A.P.A., F.A.S.A.M. to fill the role of Co-chair for the 2019-2020 year.

Current board members include:

Michael Crookston M.D., F.A.P.A., F.A.S.A.M.	<i>Medical Director, Adult Dayspring</i>
Katherine Carlson* M.D., M.S.	<i>Medical Director, Project Reality Substance Abuse Treatment and Prevention Services</i>

Perry G. Fine M.D.	<i>Professor of Anesthesiology, Dept. of Anesthesiology School of Medicine University of Utah</i>
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Lauren J. Heath Pharm.D., M.S., B.C.A.C.P.	<i>Assistant Professor (Clinical), Dept. of Pharmacotherapy, College of Pharmacy, University of Utah</i>
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Edward Redd M.D.	<i>Internal medicine/public health – Bear River Health Department, and mental health prescriber for Bear River Mental Health and the Cache County Jail</i>
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Karen Wilcox Ph.D.	<i>Professor and Chair, Dept. of Pharmacology and Toxicology, College of Pharmacy, University of Utah</i>
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Brian Keith Zehnder M.D.	<i>Medical Director, Exodus Healthcare Network, PLLC</i>
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* CSAC Member

Staff with the Center for Medical Cannabis continues to work in conjunction with the CPB to facilitate the function of the CPB.

Key UDOH staff members working with the CPB include:

Richard Oborn M.P.A.	<i>Director, Center for Medical Cannabis, Utah Department of Health</i>
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Marc Babitz M.D.	<i>Division Director, Medical Director, Health Clinics of Utah, Utah Department of Health</i>
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Reshma Arrington M.P.H.	<i>Epidemiologist, Center for Medical Cannabis, Utah Department of Health</i>
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Kayla Strong M.A. *Program Manager,
Center for Medical
Cannabis, Utah
Department of Health*

Katie Barber *Program Specialist,
Center for Medical
Cannabis, Utah
Department of Health*

Sarah Ponce M.S., R.N. *Snr. Registered Nurse,
Center for Medical
Cannabis, Utah
Department of Health*

Bylaws

The CPB operates under bylaws which were established in 2017. These bylaws define the structure of the CPB and help guide decisions and operations. The bylaws were adapted from the Colorado Medical Marijuana Scientific Advisory Council bylaws, with inclusion of requirements in H.B. 130 (2017). The bylaws were updated to reflect the changes which occurred with subsequent changes in the statute. The bylaws contain the duties of the CPB, which are defined as:

ARTICLE IV: Duties of the CPB

Section 1. The CPB shall:

- 1) Review any available research related to the human use of a cannabinoid product or an expanded 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 CPB shall evaluate the safety, risks, and efficacy of cannabinoid products and expanded cannabinoid products, including:
 - a) medical conditions that respond to cannabinoid products and expanded cannabinoid products;
 - b) cannabinoid dosage amounts and medical dosage forms; and
 - c) interaction of cannabinoid products and expanded cannabinoid products with other treatments.
- 3) Based on the CPB's evaluation, the CPB shall develop guidelines for a physician recommending treatment with a cannabinoid product or an expanded cannabinoid product that includes a list of medical

conditions, if any, that the CPB determines are appropriate for treatment with a cannabinoid product or an expanded cannabinoid product.

- 4) The CPB shall submit the guidelines to:
 - a) the director of the Division of Occupational and Professional Licensing; and
 - b) the Health and Human Services Interim Committee.
- 5) The CPB shall report the CPB findings annually to the Health and Human Services Interim Committee.

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

Website

In 2020, the CPB transferred its website (formerly a google site) to a website housed in the Center for Medical Cannabis' website. The CPB page can be found at <https://medicalcannabis.utah.gov/resources/cannabinoid-product-board/>. The website contains information regarding when and where the CPB meetings will be held, upcoming and past agendas, and meeting minutes. The website also contains a section for research, which has copies of all the literature being reviewed by the CPB. All guidance documents can also be found in the publications link on this page. This website is also a place for the public to interact with the CPB. The public can submit comments to the medical cannabis staff (medicalcannabis@utah.gov) or questions to the CPB and board members can respond.

Organization

During the June 2020 CPB meeting, Edward Redd, M.D. stepped down as Chair and members voted in Perry G. Fine, M.D. as 2020 Chair.

The CPB meets monthly or on an as-needed basis. Due to COVID-19 the board converted its meetings to virtual meetings starting in March, to resume in-person meetings when deemed safe to do so. The agenda of the board meetings consist of administrative items, presentations, review and discussion of published research, as well as collaboration with UDOH staff to develop resources and guidelines for qualified medical providers. Research reports and findings are shared via email with members of the CPB followed by discussion during CPB meetings regarding the quality of the data and implications for medical cannabis use in Utah. The CPB uses this research to assist staff with the UDOH and the Center for Medical Cannabis in their efforts to develop resources and treatment guidelines for qualified medical providers. The CPB invites subject matter experts to present at the meetings and provide in-depth analysis of contemporary peer-reviewed literature on cannabis use as medicine for various clinical conditions.

Process for Reviewing and Classifying Research

The CPB was asked to review available peer-reviewed medical literature and evaluate the safety and efficacy of cannabinoid products in terms of:

- 1) medical conditions that respond to cannabinoid products;
- 2) dosage amounts and their medicinal forms; and
- 3) drug interactions between cannabinoid products and other treatments.

As such, the CPB needed to adopt processes by which they could systematically review the strength of evidence supporting therapeutic effects and reporting adverse effects of cannabis and cannabinoids. The CPB agreed to adopt the strength-of-evidence categories used by the National Academies of Science, Engineering, and Medicine (National Academies) in their book, *“The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research.”* The categories and the general parameters for the types of evidence supporting

each category are listed below. ¹ Stating a level of confidence in the available research data does not imply the CPB 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.

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.

cannabinoids: The current state of evidence and recommendations for research. Washington, DC: The National Academies Press. doi: 10.17226/24625.

¹ National Academies of Sciences, Engineering, and Medicine. 2017. *The health effects of cannabis and*

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.

Insufficient or No Evidence

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.

Guidance on the Suggested Use of Medical Cannabis

Throughout much of 2019 and into 2020, CPB board members and Center for Medical Cannabis and DOH

staff researched and drafted standard guidance language for medical cannabis products to be sold in Utah, based on the process described above. The guidance documents provide treatment suggestions and safety precautions. These guidance documents consist of one full length document (*Guidance on the Suggested Use of Medical Cannabis*) plus eleven shorter descriptions based on conditions as listed below

- Guidance on the Suggested Use of Medical Cannabis – Chronic Pain
- Guidance on the Suggested Use of Medical Cannabis – ALS
- Guidance on the Suggested Use of Medical Cannabis – Alzheimer’s
- Guidance on the Suggested Use of Medical Cannabis – HIV/AIDS & Chronic Pain
- Guidance on the Suggested Use of Medical Cannabis – Multiple Sclerosis
- Guidance on the Suggested Use of Medical Cannabis – Autism
- Guidance on the Suggested Use of Medical Cannabis – Cancer
- Guidance on the Suggested Use of Medical Cannabis – Cancer and Chemotherapy-Induced Nausea and Vomiting
- Guidance on the Suggested Use of Medical Cannabis – Crohn’s Disease and Ulcerative Colitis
- Guidance on the Suggested Use of Medical Cannabis – Epilepsy
- Guidance on the Suggested Use of Medical Cannabis – PTSD

The over-arching guidance document is organized around:

- Definitions
- General Instructions and Understanding of this Document
- Medical Cannabis Dose-Response Variables to Consider
- Contraindications
- Warnings, Precautions, and Adverse Reactions
- Cannabis Drug Interactions
- State-Approved Qualifying Medical Conditions
- References

A link to the guidance documents is shared with all qualified medical providers (providers who may legally recommend medical cannabis) and pharmacists involved in recommending medicinal cannabis for patients with qualifying conditions. The web address is: <https://medicalcannabis.utah.gov/resources/cannabinoid-product-board/>

Cannabis Expert Presentations

The CPB invited two subject matter expert presentations to take place in 2020. Below is a description of each presentation including a conclusion from the presenter. Also included is a vote from the CPB on approval of the conclusion.

- June 9, 2020 Presentation: Dr. Joel Erhenkranz
MS and Cannabis

Conclusion: The National Academy of Sciences recognizes medical cannabis delivered orally as effective add-on therapy for the treatment of patient-reported MS-related muscle spasms in 60% of individuals and for the symptomatic relief of central pain. Medical cannabis is not effective for MS bladder symptoms or MS-related tremor nor does it have disease-modifying effects. CBD as a single agent has not been shown to have therapeutic efficacy in MS. Animal models of MS, in which parenteral administration of high doses of cannabinoids alter disease expression, do not reflect MS in humans and animal findings should not be extrapolated to humans. Lastly, a number of anti-inflammatory compounds found in medical cannabis, such as phosphatidylethanolamine (PEA) and beta-caryophyllene, are found in a number of other plant

extracts, such as peanut oil and cinnamon, which are FDA-approved dietary ingredients.

CPB Vote: Approve

- August 11, 2020 Presentation: Dr. Perry G. Fine
Are Cannabinoids Analgesics?

Conclusion: Most systematic reviews of controlled clinical trials using cannabis and cannabis-based medicines support the conclusion that cannabis and cannabis-based medicines demonstrate a modest analgesic effect and may provide a viable option for treatment of certain types of pain in some patients. Risk-benefit should be determined on the basis of each individual's circumstances as ascertained by appropriate clinical assessment.

CPB Vote: Approve

CPB Qualifying Conditions Recommendations

Currently the CPB has no recommendations to the Utah Legislature regarding the addition of new conditions to add to the list of qualifying conditions.

Summary of Key Activities in 2020

- The CPB completed and published on-line guidance documents for medical cannabis products that are sold in Utah.
- The CPB was approved to review studies outside of the United States on the use of medical cannabis.
- The CPB approved the conclusions of two presentations: *MS and Cannabis* and *Are Cannabinoids Analgesics?*

Next Steps

- The CPB will continue to meet regularly or as necessary to review emerging research regarding the potential benefits and risks of medicinal use of cannabis and cannabinoid products for treatment of various medical conditions.
- The CPB will continually review all guidance documents and update them as new and methodologically sound clinical studies are presented.
- The CPB will invite additional experts from a variety of backgrounds to assist the board in their designated duties to inform safe and effective use of cannabis and cannabinoid products for the treatment of qualifying medical conditions.
 - The CPB has scheduled additional presentations to discuss the evidence for medical cannabis to treat anxiety and PTSD (planned for December 2020), and autism (planned for January 2021).
- The CPB will continue to work closely with UDOH and Center for Medical Cannabis staff to develop needed resources and treatment guidelines to assist qualified medical providers and pharmacists who recommend medical cannabis to patients.
- CPB members and DOH staff will pursue grant funding to further clinical outcomes data analysis
 - The CPB has begun preliminary talks with research faculty at the University of Utah regarding the potential for research efforts related to medical cannabis.
- DOH staff will pursue means to link DOPL controlled substances data base and the cannabis program data base both to reduce barriers to program access and improve patient safety.
- The CPB supports efforts to have medical cannabis products be included in the Controlled Substances Database when they are provided to a patient. It was noted that this is already done in 15 other states.