Utah Cannabinoid Product Board
Annual Report

November 2021

Prepared by

Cannabinoid Product Board, Utah Department of Health

Current members:
Chair: Perry G. Fine M.D.
Katherine Carlson M.D., M.S.
Edward Redd M.D.
Lauren J. Heath Pharm.D., M.S., B.C.A.C.P.
Brian Keith Zehnder M.D.
Misty Smith Ph.D
Outgoing members:
Michael Crookston M.D., F.A.P.A., F.A.S.A.M.
Karen Wilcox Ph.D

Introduction

The Cannabinoid Product Board (CPB) is the result of the HB 130 - Cannabinoid Research Act (2017). It has been 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 shall consist of seven members "…in consultation with a professional association based in the state that represents physicians." The seven members must consist of:

- Three medical researchers; and
- Four 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.

In June 2020, the CPB selected Perry G. Fine M.D. to be Chair and Michael Crookston M.D., F.A.P.A., F.A.S.A.M. to fill the role of Co-chair.

The CPB meets monthly or on an as-needed basis. Due to COVID-19 the board has held virtual meetings. The agenda of the board meetings consists 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 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.

Current board members include:

Perry G. Fine M.D.	*Professor of Anesthesiology, Dept. of Anesthesiology School of Medicine University of Utah*
Katherine Carlson* M.D., M.S.	*Medical Director, Project Reality Substance Abuse Treatment and Prevention Services*
Lauren J. Heath Pharm.D., M.S., B.C.A.C.P	*Pharmacist, Drug Regimen Center, University of Utah College of Pharmacy. Formerly: Assistant Professor (Clinical), Department of Pharmacotherapy, University of Utah College of Pharmacy*
Edward Redd M.D.	*Internal Medicine/Public Health – Bear River Mental Health Department, and mental health prescriber for Bear River Mental Health and the Cache County Jail*
Brian Keith Zehnder M.D.	*Medical Director, Exodus Healthcare Network, PLLC*

Misty D. Smith Ph.D	*Research Assistant Professor - University of Utah, Research Associate Professor for the School of Dentistry – University of Utah*

*CSAC Member

Outgoing board members include:

Karen Wilcox Ph.D.	*Professor and Chair, Dept. of Pharmacology and Toxicology, College of Pharmacy, University of Utah*
Michael Crookston M.D., F.A.P.A., F.A.S.A.M	*Medical Director, Adult Dayspring*

Staff with the Center for Medical Cannabis continue 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.	*Director, Center for Medical Cannabis, Utah Department of Health*
Marc Babitz M.D.	*Outgoing Division Director, Family Health and Preparedness, Center for Medical Cannabis, Utah Department of Health*
Sarah Woolsey M.D., M.P.H., F.A.A.F.P.	*New Division Director, Family Health and Preparedness, Center for Medical Cannabis, Utah Department of Health*

Process for Reviewing and Classifying Research

The CPB is 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.

The CPB uses 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 at the end of this document. [1] Stating a level of confidence in the available research data does not imply the CPB agrees or disagrees with any conclusion or recommendation.

Updated Guidance on the Suggested Use of Medical Cannabis

From December 2020 through October 2021, 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. Five guidance documents updated and approved include:

- Guidance on the Suggested Use of Medical Cannabis – Dementia
- Guidance on the Suggested Use of Medical Cannabis – Anxiety
- Guidance on the Suggested Use of Medical Cannabis – Autism
- Guidance on the Suggested Use of Medical Cannabis – Epilepsy

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[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.

- Guidance on the Suggested Use of Medical Cannabis – PTSD

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 to these documents is: https://medicalcannabis.utah.gov/resources/cannabinoid-product-board/

Review of Scientific Evidence

The CPB invited eight subject matter experts to present to the CPB between December 2020 and October 2021. Presentation topics are listed along with a conclusion from the presenter and the CPB vote on the conclusion.

December 8, 2020 Presentation: 1) Dr. Katie Carlson, MD *Treating Anxiety with Cannabis* **and 2) Dr. Michael Crookston, MD** *Treating PTSD with Cannabis*

Conclusion: 1) There is insufficient evidence to support the conclusion that medical cannabis or cannabinoids are effective or ineffective treatments for PTSD or symptoms of PTSD. 2) There is insufficient evidence that cannabis is an effective treatment for Anxiety.

CPB Vote: 1) Approve January 12, 2021 – Guidance on the Suggested Use of Medical Cannabis -Anxiety, 2) Not to amend existing guidelines on PTSD

January 12, 2021 Presentation: Adam Gordon, MD *Cannabis and Opioid Use Disorder Treatment*

Conclusion: There is insufficient evidence to recommend cannabis products be used for Opioid Use Disorder (OUD).

CPB Vote: Approval of conclusion January 12, 2021

February 9, 2021 Presentation: Dr. Edward Redd, MD *Medical Cannabis and Autism Spectrum Disorder*

Conclusion: There is currently insufficient evidence to recommend cannabis use in the treatment of core and non-core symptoms of ASD.

CPB Vote: Approve updated Guidance the Suggested Use of Medical Cannabis - Autism document August 10, 2021

March 9, 2021 Presentation: Dr. Deborah Bilder, MD *Cannabinoids and Autism*

Conclusion: There is insufficient evidence to support or refute the conclusion that medical cannabis or cannabinoids are an effective or ineffective treatment for symptoms of Autism or Autism Spectrum Disorder.

CPB Vote: Approve updated Guidance for Use - Autism document August 10, 2021

May 11, 2021 Presentation: Dr. Megan Puckett, MD *Cannabis in the Management of Dementia-Related Neuropsychiatric Symptoms*

Conclusion: The board recommends caution when using medical cannabis or cannabinoids for the treatment of Alzheimer's disease (AD).

CPB Vote: Approve updated Guidance for Use – Alzheimer's Disease document October 12, 2021

June 8, 2021 Presentation: Dr. Karen Wilcox, PhD *Cannabis Suppository Administration*

Conclusion: There is not sufficient evidence to support inclusion of rectal/vaginal delivery for systemic absorption purposes to the current list of approved formulations.

CPB Vote: Document approved on October 12, 2021 with "peak concentration for systemic administration for rectal use" added into document.

August 10, 2021 Presentation: Dr. Misty Smith, PhD *Medical Cannabis for the Treatment of Epilepsy*

Conclusion: Medical cannabis is of "unknown efficacy" to treat epilepsy.

CPB Vote: Approved updated Guidance the Suggested Use of Medical Cannabis – Epilepsy document September 14, 2021 (with abbreviation changes added)

Other Board Activities

- Dr. Perry Fine gave a presentation regarding the use of medical cannabis at the 5th Annual Addictions Update Conference at the University of Utah in June 2021.
- The CPB plans to visit a local medical cannabis processing facility in November 2021 to have further education on the processing of medical cannabis products.

CPB Qualifying Conditions Recommendations

- The CPB has no recommendations to the Utah Legislature regarding the addition of new conditions to add to the list of qualifying conditions. The CPB was informed of the types of medical conditions held by adults approved by the Compassionate Use Board (CUB). With the CUB's approval, these adults received medical cannabis cards despite the fact that their medical conditions were not listed as qualifying medical conditions under 26-61a. While the CPB recognizes the CUB's authority to approve these exceptions, the CPB does not recommend that the list of qualifying conditions appearing in 26-61a be amended to include these or any other additional medical conditions.
- The name of the CPB should be changed from Cannabinoid Product Board to the Cannabis Research Review Board.
- Funding of research in Utah on the health effects of cannabis products.

Next Steps

- The CPB is working on guidance regarding **Delta-8 Tetrahydrocannabinol**. Given recent guidance from the Food and Drug Administration and the Centers for Disease Control and Prevention on safety concerns for this cannabinoid product, the Board will finalize a statement at the December 14th meeting.
- The CPB will continue to meet monthly 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 continue to **update its guidance** documents as new and methodologically sound clinical studies are presented.
- The CPB will invite **additional experts** to assist the board to inform safe and effective use of cannabis and cannabinoid products for the treatment of qualifying medical conditions.
- The CPB will work closely with the UDOH and Center for Medical Cannabis staff to **develop resources and treatment guidelines** to assist qualified medical providers and pharmacists who recommend medical cannabis to patients.
- The CPB anticipates **development of a robust outcomes program** evaluating potential and actual benefits and risks associated with use of cannabis for medical purposes over the next year. The CPB looks forward to collaborative work with others involved in establishing and managing this program.
- Dr. Daniel Odell, pain medicine specialist member of the Supportive Oncology and Survivorship service at the Huntsman Cancer Center, University of Utah, provided an update and evidence-based literature **review on "Cannabinoids and Cancer Pain"** at the October 12, 2021 meeting of the CPB. Recommendations and an updated Guidance Document will be forthcoming.
- The CPB reviewed a recently published peer-reviewed report addressing a **population risk study of acute myocardial infarction** ("heart attack") after short- or long-term cannabis use. The finding of increased risk, especially in younger and middle-aged adults warrants additional concern and added warnings in CPB Guidance Documents.

Research Classifications

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.

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.