Executive Summary
November 2018

As medical and recreational marijuana becomes legalized across the United States, the Utah State Legislature has taken a proactive approach by establishing the Cannabinoid Product Board. 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 CPB is composed of seven members who are medical researchers, physicians, and one of the members must also be a member of the Controlled Substances Advisory Committee (CSAC).

The CPB met five times during 2018 and identified areas of current cannabinoid research that the CPB members are now reviewing. Annually, the CPB provides recommendations to the legislature regarding their findings. This report contains the findings and recommendations of the CPB from January to November 2018.

Key Points:

- The CPB is unable to recommend appropriate dosages, drug interactions, or treatments with cannabinoid products without assurance of product quality and consistency throughout published human subject research.

- After reviewing medical literature regarding cannabinoid use during pregnancy, the CPB recommends that the use of cannabis and cannabinoids during pregnancy should be discouraged.

- The CPB recommends that cannabinoid product manufacturers adopt guidelines similar to those from the American Herbal Products Association for quality control.

- The CPB acknowledges that there is currently not enough credible human subject literature to make conclusions about cannabidiol effectiveness for specific diseases, with the exception of FDA-approved Epidiolex for use in treating Dravet Syndrome and Lennox-Gastaut syndrome.
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Introduction

The Cannabinoid Product Board (CPB) is the result of the Cannabinoid Research Act, (H.B. 130) that was passed and was signed into law during the 2017 Utah General Legislative Session. During the 2018 Utah General Legislative Session, amendments (H.B. 25) were made to Cannabinoid Research Act as follows:

1. The composition of the CPB was modified from three board members being members of the Controlled Substance Advisory Committee to one; and
2. The duties of the CPB were broadened 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 CPB. As stated in the legislation, 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. The CPB may only review research that has been approved by an Institutional Review Board, or approved/conducted by the federal government.

From this research, the CPB is directed to develop prescribing guidelines that may potentially be used by physicians recommending cannabinoid products to their patients. The CPB 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 the CPB be made of the 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 terms of board members, leadership, and voting on recommendations are discussed at their meetings.


Current board members 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
  - **Edward Redd M.D.** Utah House of Representatives, District 4
  - **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 CPB was delegated to the UDOH Tobacco Prevention and Control Program.

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 have been updated to reflect the changes that occurred with the passage of H.B. 25 in 2018. 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 before November 1 of each year 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 2017, the CPB 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 CPB. The website can be found at: [https://sites.google.com/utah.gov/cpboard/](https://sites.google.com/utah.gov/cpboard/). The website contains information of 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 that is being reviewed by the CPB. This website is also a place for the public to interact with the CPB. The public can submit comments or questions to the CPB and the CPB can respond.

*Below are screenshots of the Utah Cannabinoid Product Board website*
During the May 2018 CPB meeting, which marked almost one year since the first board meeting, Edward Redd, M.D. was voted into the role of Chair for the 2018-2019 calendar year. Dr. Redd currently serves as a Representative in the Utah State Legislature as well as a practicing physician with the Bear River Health Department in Logan Utah. In the September 2018 board meeting, Dr. Michael Crookston was voted into the role of Co-chair. The CPB continues to meet monthly or on an as-needed basis. Since January 2018, the CPB has met four times. 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 CPB to read and then report on the research at the following meeting. After presenting the research, each article is discussed by the CPB. The research for review is identified primarily by the CPB policy analyst based on the criteria for studies outlined in the Cannabinoid Research Act (H.B. 130). Members of the CPB also bring relevant research forward for discussion. The CPB is interested in having subject matter experts such as researchers and pharmacological organizations present to the CPB and provide further information above and beyond what research can provide.

Process for Reviewing and Classifying Research

The CPB 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 CPB needed to create processes by which they could systematically review the evidence which met the criteria outlined in the statue. The CPB agreed upon the categories used by the National Academies of Science, Engineering, and Medicine (National Academies) to categorize evidence in 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. The CPB adopted standard language developed by the National Academies 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 conclusions based on the limitations in the data. It does not indicate that 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.

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**

As access to legal cannabis has expanded each year in the United States, more research on the effects of human cannabis use has emerged since the publication of the National Academies report in 2017. To ensure the research the CPB reviews is the most current, the CPB voted to review the clinical trials and research articles approved by an Institutional Review Board since the National Academies report was published. Using the scales of evidence set forth by the National Academies, the CPB voted to create a list of the most recent clinical trials or peer-reviewed articles published or currently underway between August 2, 2016 and August 2, 2018. This endeavor resulted in 627 peer-reviewed articles and clinical trials not included in the National Academies report that meet criteria for CPB review.

To systematically review each of the articles and clinical trials, the CPB is categorizing these by disease state and clinical outcomes and effects of cannabis modeled after the format from the National Academies report. As CPB members review articles, they are asked to consider five questions related to their reading.

1. Is the report or article academically credible?
2. What conclusions, if any, can be drawn from the article?
3. Do the results and conclusions add to or alter in a significant way the conclusions of the National Academies report?
4. Are the results of the review or clinical research data in the assigned article robust and of sufficient importance to include them in the report to the legislature?
5. What recommendations, if any, would you make to the legislature as a result of your review?

Below are samples of some of the conclusions reached in the 2017 report from the National Academies.

**CONCLUSIONS FOR: THERAPEUTIC EFFECTS**

There is conclusive or substantial evidence that cannabis or cannabinoids are effective:
- For the treatment for chronic pain in adults
- Antiemetics in the treatment of chemotherapy-induced nausea and vomiting
- For improving patient-reported multiple sclerosis spasticity symptoms

There is moderate evidence that cannabis or cannabinoids are effective for:
- Improving short-term sleep outcomes in individuals with sleep disturbance associated with obstructive sleep apnea syndrome, fibromyalgia, chronic pain, and multiple sclerosis

There is limited evidence that cannabis or cannabinoids are effective for:
- Increasing appetite and decreasing weight loss associated with HIV/AIDS
- Improving clinician-measured multiple sclerosis spasticity symptoms
- Improving symptoms of Tourette syndrome
- Improving anxiety symptoms, as assessed by a public speaking test, in individuals with social anxiety disorders (cannabidiol)
- Improving symptoms of posttraumatic stress disorder (nabilone; one single, small fair-quality trial)
- There is limited evidence of a statistical association between cannabinoids and:
  - Better outcomes (i.e., mortality, disability) after a traumatic brain injury or intracranial hemorrhage
  - There is limited evidence that cannabis or cannabinoids are ineffective for:
  - Improving symptoms associated with dementia
- Improving intraocular pressure associated with glaucoma
- Reducing depressive symptoms in individuals with chronic pain or multiple sclerosis

**CONCLUSIONS FOR: PRENATAL, PERINATAL, AND NEONATAL EXPOSURE**

There is substantial evidence of a statistical association between maternal cannabis smoking and:
- Lower birth weight of the offspring

There is limited evidence of a statistical association between maternal cannabis smoking and:
- Pregnancy complications for the mother
- Admission of the infant to the neonatal intensive care unit (NICU)

There is insufficient evidence to support or refute a statistical association between maternal cannabis smoking and:
- Later outcomes in the offspring (e.g., sudden infant death syndrome, cognition/academic achievement, and later substance use)

**CONCLUSIONS FOR: PSYCHOSOCIAL**

There is moderate evidence of a statistical association between cannabis use and:
- The impairment in the cognitive domains of learning, memory, and attention (acute cannabis use)

There is limited evidence of a statistical association between cannabis use and:
- Impaired academic achievement and education outcomes
- Increased rates of unemployment and/or low income
- Impaired social functioning or engagement in developmentally appropriate social roles

There is limited evidence of a statistical association between sustained abstinence from cannabis use and:
- Impairments in the cognitive domains of learning, memory, and attention
CONCLUSIONS FOR: MENTAL HEALTH

There is substantial evidence of a statistical association between cannabis use and:

• The development of schizophrenia or other psychoses, with the highest risk among the most frequent users

There is moderate evidence of a statistical association between cannabis use and:

• Better cognitive performance among individuals with psychotic disorders and a history of cannabis use
• Increased symptoms of mania and hypomania in individuals diagnosed with bipolar disorders (regular cannabis use)
• A small increased risk for the development of depressive disorders
• Increased incidence of suicidal ideation and suicide attempts with a higher incidence among heavier users
• Increased incidence of suicide death
• Increased incidence of social anxiety disorder (regular cannabis use)

There is moderate evidence of no statistical association between cannabis use and:

• Worsening of negative symptoms of schizophrenia (e.g., blunted affect) among individuals with psychotic disorders

There is limited evidence of a statistical association between cannabis use and:

• An increase in positive symptoms of schizophrenia (e.g., hallucinations) among individuals with psychotic disorders
• The likelihood of developing bipolar disorder, particularly among regular or daily users
• The development of any type of anxiety disorder, except social anxiety disorder
• Increased symptoms of anxiety (near daily cannabis use)
• Increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder

There is no evidence to support or refute a statistical association between cannabis use and:

• Changes in the course or symptoms of depressive disorders
• The development of posttraumatic stress disorder

Dixie State University Student Research Assistance

In spring 2018, UDOH staff were approached by Dr. Erin O’Brien, the Biological Sciences Department Chair at Dixie State University, to see if there were research opportunities for her senior biology students to complete. The Senior Seminar course is an opportunity for students to conduct a literature review on a current issue, write a synthesis paper, and do a presentation on the findings of the research. With the vast numbers of research articles for the CPB to review, it was a good fit to have students assist in reviewing the research. For the fall 2018 semester, students will look at cannabis research which falls into the research criteria as outlined in legislation and by the CPB. The students will submit written synthesis papers outlining the finding of the research as well as be a resource to the CPB to further explain the research and provide context. This collaboration may continue into the future, but currently the plan is to work with students at Dixie State through the fall semester of 2018. Students are expected to present their research summaries to the CPB in December 2018.

FDA Approval of Epidiolex

In June 2018, the United States Food and Drug Administration (FDA) announced that, for the first time, a drug that contains cannabidiol, an active ingredient found in cannabis, was approved for use. Epidiolex contains less than 0.1% of tetrahydrocannabinol (THC) and is specifically used to treat Dravet syndrome and Lennox-Gastaut syndrome (LGS), which are both forms of epilepsy that are difficult to control. GW Pharmaceuticals developed Epidiolex after a series of clinical trials which showed the drug was effective in reducing the frequency of seizures when compared with placebos, and that the side-effects were minor in these trials.
Drug Enforcement Administration Scheduling

In late September 2018, the Drug Enforcement Administration (DEA) decided to give Epidiolex a Schedule V classification, which is the lowest of the drug schedules, indicating it had a low abuse potential. Patients will need a prescription from their medical provider to get the drug. The main benefit of using Epidiolex versus another form of unregulated cannabidiol is that GW Pharmaceuticals employs strong manufacturing practices in the production of the drug. Because of this, patients and parents of young patients will know this drug has been through rigorous testing and is safe for them to use at the recommended doses.

Cost

While the drug appears to be an answer for controlling some seizure-inducing diseases, the price of Epidiolex is approximately $32,500 per year per patient, pre-insurance. The drug may be cost prohibitive to some patients, but is being priced similarly to other branded epilepsy drugs.

Implications

There is the potential for some physicians to prescribe Epidiolex off-label for other diseases where they feel it would have efficacy. GW Pharmaceuticals is looking into using CBD drugs to treat autism. With the issuance of the DEA scheduling order on Epidiolex, other cannabidiol drug products which are developed, are FDA-approved, and contain no more than 0.1% THC, will also be classified as schedule V substances.²

Limitations

Limitations of Cannabis Research

The National Academies report discusses common themes in the type of study limitations found in the evidence base. The most common are limitations in the study design (e.g., a lack of appropriate control groups, a lack of long-term follow-ups), small sample sizes, and research gaps in examining the potential therapeutic benefits of different forms of cannabis (e.g., unprocessed cannabis plant vs. processed cannabinoids in capsules).

These limitations highlight the need for substantial research to provide comprehensive and conclusive evidence on the therapeutic effects of cannabis and cannabinoids.3

Consistency of Products

The purpose of the CPB in evaluating the safety and efficacy of cannabinoid products is similar to the mission of the 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, and Controls (CMC) and Current Good Manufacturing Practices (cGMPs).

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 to 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 determine 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

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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 companies produce safe, consistent, and effective products. Many of these regulations are focused on facilities where manufacturing and processing of pharmaceuticals occur to ensure 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.

Current Good Manufacturing Practices are required for both pharmaceuticals and dietary supplements. However, in the case of dietary supplements, manufacturers are allowed to set their own cGMPs 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 to 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 CPB that the current lack of regulation on the cultivation and processing of cannabis and cannabinoid products raises serious questions regarding their quality and reproducibility in the academic literature available. Without the assurance of product quality and consistency, the CPB is unable to extrapolate results from clinical trials and recommend disease states for which cannabinoid products could be considered, or recommend appropriate dosing.
Summary and Recommendations

• The CPB has very limited access to information necessary to make firm recommendations regarding conditions that respond to cannabinoid products, specific prescribing guidelines, and drug interactions.

• The CPB has reviewed medical literature regarding cannabinoid use in pregnancy. With an absence of studies that demonstrate safety in that setting, and with known studies showing potential for significant adverse effects, the use of cannabis and cannabinoids during pregnancy should be discouraged.

• It is the opinion of the CPB that the current lack of regulation on cannabis production and processing such as Chemistry, Manufacturing, & Controls (CMC) and Current Good Manufacturing Practices (cGMPs) raises serious concerns regarding the inter-study consistency of medical cannabis being used in clinical trials. This leads to significant concerns about reproducibility of results of clinical trials, and the advisability of applying results of such clinical trials to recommendations for general use of cannabis or cannabinoid products in the treatment of serious health conditions. Without the assurance of product quality and consistency, the CPB is unable to recommend disease states for which cannabinoid products could be considered, or recommend appropriate dosing.

• The CPB recommends that cannabis growers and 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 results, disease interactions, and clinical outcomes are as consistent and predictable as possible.

Next Steps

• The CPB will continue to meet monthly or as necessary to review research articles and utilize the National Academies report to classify cannabinoid studies that show promise or harm for prescribing purposes.

• In addition to research, the CPB will bring in experts from a variety of backgrounds to further advance the knowledge of cannabinoid products and research.

• If Proposition 2 the Utah Medical Cannabis Act, passes during the November 2018 election cycle, the CPB will work with appropriate partners to determine the best way to communicate with the Compassionate Use Board regarding medical cannabis recommendations for Utah.