

Idaho's Expanded Access Program (EAP) for Epidiolex® (Updated March 16, 2016)

OFFICE OF DRUG POLICY

Epidiolex® is pure CBD extracted using medical equipment. It is rigorously tested to ensure that it is consistent and free from contaminants.

In contrast, **Artisanal CBD oil**, such as Charlotte's Web, does not only contain CBD, but also other plant material. There is no testing requirement to determine the levels of THC or other contaminants, such as mold or fungi.

	Artisanal CBD	Epidiolex®
Plant product	✓	✓
Claims not to cause impairment	✓	✓
Prescribed by a physician		✓
Free from potential contaminants		✓
Regulated and consistent		✓
Legal		✓
Undergoing scientifically sound research to measure effectiveness		✓

"We are however **opposed** to the use of artisanal preparations of **unregulated** compounds of cannabis that contain **unverified** content and are produced by people with **no experience** in pharmaceutical production (7/13/2015)."

Amy Brooks-Kayal, MD
American Epilepsy Society, President
Children's Hospital of Colorado, Chief & Ponzio Family Chair

Science, Fraud & False Hope

- Using artisanal CBD oils can cause risk in patients because the products are unregulated.
- Researchers have found that CBD may interact with other anti-epileptic medications¹, warranting the need for oversight by a neurologist.
- This is the first time in recent history that "medication" has gone through a legislative process instead of the FDA process.
- In 2015, the FDA sent 18 warning letters to "CBD" dispensing companies for health fraud. As of February, the FDA has sent 22 letters in 2016.
- Families that moved to Colorado to use oral cannabis extracts were 3 times as likely to report a reduction in seizures as families already living in Colorado using oral cannabis extracts.²

"... We must let the **science**, and not anecdotal success stories and high media interest, lead this national discussion. Taking CBD in a controlled medical setting is vastly different from going to a state where **medical marijuana** is legal and **experimenting** with dosing and CBD strains (12/23/2015)."

Orrin Devinsky, MD
NYU Comprehensive Epilepsy Center, Director

"... **Not a single pediatric neurologist** in Colorado recommends the use of artisanal cannabis preparations (7/13/2015)."

Amy Brooks-Kayal, MD
American Epilepsy Society, President
Children's Hospital of Colorado, Chief & Ponzio Family Chair

Idaho's EAP

- **No placebo.** This is an EAP, not a clinical trial; therefore, all participants enrolled receive Epidiolex®, not a placebo.
- **Legal Access.** Because the EAP is FDA approved, Epidiolex® is legally available to all participants. There is no need to travel great distances and break federal law.
- **Quality.** Epidiolex® is a pure, plant-derived medication that is consistent and contaminant free.

Participant Update

- **20** patients are receiving Epidiolex®.
- **1** person did not pass the screening process.
- The remaining slots will be filled by the end of March 2016.

¹ Friedman, D., Cilio, M.R., Tilton, N. Sullivan, J., Hedlund, J., Rosenberg, E., Bluvstein, J., & Devinsky, O. (2014). The effect of epidiolex (cannabidiol) on serum levels of concomitant anti-epileptic drugs in children and young adults with treatment-resistant epilepsy in an expanded access program. Abstract presented at the annual meeting of the American Epilepsy Society, Seattle, WA.

² Press, C., Knupp, K., & Chapman, K. (2014). Parental reporting of response to oral cannabis extract as adjunctive treatment for medically refractory epilepsy. American Epilepsy Society. (Abstract #1.326).