CANNABIDIOL IN IDAHO

EPIDIOLEX® VERSUS ARTISANAL CANNABIDIOL (CBD)

EPIDIOLEX® is **pure**, **plant-based**, **pharmaceutical grade** cannabidiol (CBD) extract. It is **consistent**, free from contaminants, and proven **effective** in treating seizures among individuals with Dravet and Lennox-Gastaut Syndrome. It is FDA-approved and is **now legally available by physician prescription**. It is the only legal form of CBD for sale in the state of Idaho.

VS

In contrast, the content of **ARTISANAL CBD OIL** is **not verified** and it may not contain CBD or may contain other components of marijuana. There is **no testing requirement** to determine the levels of THC or other **contaminants**, such as mold or fungi. There is also no regulation on the extraction process, which may incorporate **toxins** such as butane.

> "So, right now, if you buy a Hershey bar, you know it has been checked over; you know how many calories are in it, you know it has chocolate as an ingredient, you know how much chocolate is in there. Selling these oils without oversight, there is no way to know what is actually in the bottle. It's crazy to have **less oversight** and information about a product being **widely used for medicinal purposes**, especially in very **ill children**, than a **Hershey bar**."

Dr. Marcel Bonn-Miller
University of Pennsylvania, Department of Psychiatry
(11/7/2017)

THE COST

EPIDIOLEX®

Epidiolex is priced at **$32,500 annually**, comparable to other seizure medications on the market. The cost depends on the weight of the patient. For a **25-pound child** with LGS or Dravet syndrome dosed at 10 mg/kg /day, the cost will be about **$5,052** per year before insurance. For a **150-pound teen**, the cost will be about **$30,312** per year before insurance. It will be covered under most Medicaid and insurance plans.

VS

ARTISANAL CBD OIL

Prices, potency, quantity, and purity are variable, and depend on the manufacturer. A brand of CBD recommended by the Realm of Caring has a product with 3600 mg of CBD per 120 ml bottle. The recommended dose of CBD for an adult to treat seizure disorders is 1500-2000 mg of CBD per day, which would equal about a half of that $249 bottle per day, or **$44,820 per year**. These products are not covered by insurance.

> "Based on the doses we are using in the Epidiolex studies and given the concentration differences, **people hoping to get an anti-seizure effect from 2% CBD oil would have to consume a liter of oil per day**. That's even assuming that the suppliers can ensure stability of dose from batch to batch - something they cannot do. **Nor can they guarantee their products are free of psychoactive doses of THC**. Even a "pure" product with a CBD to THC ratio of 20:1,when doses at concentrations likely to provide a medical benefit (1000 mg to 2000 mg of CBD per day) would yield between 50 mg and 100 mg of THC per day (the "recommended" recreational THC "dose" on some Colorado websites is 25 mg of THC, equivalent to one "joint")."

Robert T. Wechsler, MD, PhD, FAES, FAAN
Owner, Consultants in Epilepsy & Neurology, PLLC
Medical Director, Idaho Comprehensive Epilepsy Center
(2/20/2018)

2018 FARM BILL

Removes Hemp as defined under section 297A of the Agricultural Marketing Act of 1946 from the Controlled Substances Act by excluding Hemp from the term marihuana and exempting THC in Hemp. Hemp is now defined under section 297A of the Agricultural Marketing Act of 1946 as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." Therefore, any cannabis plant that contains more than 0.3 percent THC would be considered non-hemp cannabis—or marijuana—under Federal law and would thus face no legal protection under this new legislation.

Allows hemp cultivation broadly, not simply pilot programs for studying market interested in hemp-derived products. However there are restrictions. Under section 10111 of the Farm Bill, state departments of agriculture must consult with the state's governor and chief law enforcement officer to submit a plan to the USDA Secretary. This plan must include, among other things, a procedure for testing THC concentration levels of hemp produced in the State. Not later than 60 days after receipt the USDA Secretary must approve or disapprove the plan.

The Bill identifies actions that are considered negligent violations of federal law, the requirement for a corrective action plan, and the result of negligent violations. Violations include, but are not limited to, failing to obtain a license or other required authorization from the State Department of Agriculture and producing Cannabis sativa L. with a THC content of more than 0.3% on a dry weight basis. Hemp producers that violate the State plan three times in a 5-year period will be ineligible for a period of 5 years beginning on the date of third violation.

Hemp products produced in accordance with the Farm Bill Section 10113, not all hemp products, can be transported across state lines. The Farm Bill states in section 10114 "No State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the Agricultural Marketing Act of 1946 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable."

Expands research related to development of commercial products derived from hemp. Under section 7125, the Farm Bill allows for fundamental and applied research related to the development of new commercial products derived from natural plant material, including hemp, for industrial, medical, and agricultural applications under the The Department of Agriculture's research project program for the development of supplement and alternative crops. Section 7401 amends the Critical Agricultural Materials Act to specifically identify hemp as within the scope of the research and development program lead by the Department of Agriculture and
Section 7415 amends Section 7606 of the 2014 Farm Bill to add that the Secretary must conduct a study of agricultural pilot programs to determine the economic viability of the domestic production and sale of industrial hemp.

Hemp farmers are now protected under the Federal Crop Insurance Act.

The Farm Bill does not legalize all cannabidiol. Section 12608 does remove hemp-derived products from Schedule I of the Federal Controlled Substances Act, but it does not legalize cannabidiol (CBD) generally. CBD, like THC, is a component of any species of the genus Cannabis, including Cannabis *sativa L.* The Farm Bill ensures that any cannabinoid that is derived from hemp will be legal *if and only if* that hemp is produced in a manner consistent with the Farm Bill and associated state regulations. The one exception is pharmaceutical-grade CBD products that have been approved by FDA, currently only Epidiolex which was rescheduled to Schedule V of the Controlled Substances Act in September 2018.

The Farm Bill did not amend the Federal Food, Drug, and Cosmetic Act. The Farm Bill did not alter the approval process for new drug applications, the requirements for the conduct of clinical or nonclinical research, the oversight of marketing claims, or any other authorities of the FDA as they are set forth in that Act.

The U.S. FDA still considers the interstate commerce of foods and dietary supplements containing CBD to be illegal because CBD is now an approved active ingredient in a prescription drug—Epidiolex—and it is illegal to introduce such ingredients into the food supply or market them as dietary supplements.

TESTING LABORATORIES[1]

ACCREDITED LABS:

- Abide by a list of management, quality, testing, and reporting standards established by an accrediting organization or governmental body
- Have management and testing procedures that are evaluated by an independent third party
- Have testing and reports routinely assessed and audited by an independent third party
- Use instrumentation that is appropriate for the testing, validated, and have quality control measures in place
- Have validated methods that fit within a publicly available scope of testing
- If in their accreditation scope, may produce test reports that substances are free from toxins, poisons, molds, or fungus

UNACCREDITED LABS:

- No assurances that industry, governmental, or international standards are being followed
- No third-party assurances of the management system, testing procedures, instrumentation, or quality control
- Generally, no way to determine if the lab has been independently assessed by a competent third party
- No way to ensure the product labels are accurate

[1] Matthew Gamette, M.S., C.P.M. Laboratory System Directory. Idaho State Police Forensic Services. March 2019.