SENATE COMMITTEE ON PUBLIC SAFETY

Senator Nancy Skinner, Chair
2017 - 2018 Regular

Bill No:	AB 845	**Hearing Date:**	June 20, 2017
Author:	Wood		
Version:	June 7, 2017		
Urgency:	Yes	**Fiscal:**	Yes
Consultant:	SJ		

Subject: ***Cannabidiol***

HISTORY

Source: Epilepsy Foundation of Greater Los Angeles

Prior Legislation: SB 643 (McGuire) Ch. 719, Stats. of 2015
AB 266 (Bonta) Ch. 689, Stats. of 2015
AB 243 (Wood) Ch. 688, Stats. of 2015

Support: California Life Sciences Association; Dravet Syndrome Foundation; Epilepsy Foundation; Epilepsy Foundation of Northern California; LGS Foundation; Tuberous Sclerosis Alliance; two individuals

Opposition: None known

Assembly Floor Vote: 76 - 0

PURPOSE

The purpose of this bill is to permit specified health care practitioners to prescribe, furnish, or dispense a product composed of cannabidoil (CBD) under state law, if CBD is excluded from Schedule I of the Federal Controlled Substances Act (Act), or if it is approved by the Federal Food and Drug Administration (FDA) and either placed on a schedule other than Schedule I or is exempted from the Act.

Existing federal law establishes the Controlled Substances Act which regulates the manufacture, importation, possession, use and distribution of controlled substances such as hallucinogens, narcotics, depressants, and stimulants. Categorizes drugs into five schedules or classifications based on their potential for abuse, status in international treaties, and any medical benefits they may provide. Specifies that Schedule I drugs are considered the most harmful with no medical benefits, and includes marijuana in this schedule. Indicates that Schedule V substances are the least restricted. (21 U.S.C. § 812.)

Existing law establishes the California Uniform Controlled Substances Act (UCSA) which regulates controlled substances. (Health & Saf. Code §§ 11000 *et seq*.)

Existing law classifies controlled substances in five schedules according to their danger and potential for abuse. (Health & Saf. Code §§ 11054-11058.)

Existing law authorizes only a physician, dentist, podiatrist, veterinarian, naturopathic doctor, a registered nurse acting, a certified nurse-midwife, a nurse practitioner, a physician assistant, or an optometrist to write or issue a prescription. (Health & Saf. Code § 11150.)

Existing law specifies that a prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. Establishes responsibility for proper prescribing of controlled substances upon the prescribing practitioner, and a corresponding responsibility with the pharmacist who fills the prescription. Provides that any person who knowing violates this provision shall result in imprisonment for up to one year, or a fine of up to $20,000, or both. (Health & Saf. Code § 11153.)

Existing law, the Compassionate Use Act of 1996, exempts certain patients and their primary caregivers from criminal liability under state law for the possession and cultivation of marijuana. (Health & Saf. Code § 11362.5.)

Existing law, the Medical Cannabis Regulation and Safety Act (MCRSA), regulates medical cannabis in California, including its cultivation, transportation, storage, distribution, and sale. (Bus. & Prof. Code §§ 19300 *et seq.*)

Existing law establishes the Bureau of Marijuana Control (Bureau) within the Department of Consumer Affairs for the licensure and regulation of cannabis. (Bus. & Prof. Code § 26010.)

Existing law, the Adult Use of Marijuana Act (AUMA), permits adults 21 years of age or older to legally grow, possess, and use cannabis for non-medical purposes, as specified. Authorizes, beginning January 1, 2018, the selling and distributing of cannabis through a regulated business. (Bus. & Prof. Code §§ 26000 et seq.)

Existing law prohibits an individual who possesses a license in good standing to practice medicine or osteopathy, as specified, from recommending medical cannabis to a patient, unless that person is the patient's attending physician. (Bus. & Prof. Code § 2525.2.)

This bill makes Legislative findings and declarations that both children and adults with epilepsy are in desperate need of new treatment options, and that CBD is showing potential as one of these treatments. If federal laws prohibiting the prescription of medications composed of CBD are repealed or if an exception from the general prohibition is enacted permitting the prescription of drugs composed of CBD, patients should have rapid access to this treatment option. The availability of this new prescription medication is intended to augment, not to restrict or otherwise amend, other cannabinoid treatment modalities currently available under state law.

This bill states that a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense CBD is in compliance with state law if CBD is removed from Schedule I of the Act and placed on a different schedule, or if a product composed of cannabidiol is approved by the federal FDA and either placed on a schedule of the Act other than Schedule I, or exempted from one or more provisions of the Act.

This bill states that, upon the effective date of CBD's exclusion or exemption from the Act, the prescription, furnishing, dispensing, transfer, possession, or use of a product composed of cannabidiol in accordance with federal law is authorized pursuant to state law, as specified.

This bill contains an urgency clause.

COMMENTS

1. Need for This Bill

According to the author:

> Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime. There is no "one size fits all" treatment option and about one million people live with uncontrolled or intractable seizures. Uncontrolled seizures can lead to disability, injury, and even death, and many individuals living with uncontrolled seizures suffer from rare epilepsies characterized by seizures that are difficult to treat with existing treatment options. Access to new treatments is particularly important for these individuals, who live with the continual risk of serious injuries and loss of life.
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> The FDA is currently reviewing at least one CBD derived therapy that shows promise for the treatment of rare epilepsy conditions. This potential treatment option has both "Orphan Drug Designation" and Fast Track Designation from the FDA. Given the Fast Track Designation, this potential treatment option could be available as soon as early 2018.
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> Currently, any product that contains any material, compound, mixture, or preparation, which contains any quantity of marijuana is considered a Schedule I Controlled Substance unless specifically exempted. Under current law, should a product derived from CBD, like Epidiolex, be approved and rescheduled, it would still be considered a Schedule I substance under California statute and therefore could not be prescribed by a physician unless specifically exempted. Individuals suffering from these rare forms of epilepsy and those living with uncontrolled seizures would not be able to access the medication. AB 845 will ensure Californians with uncontrolled seizures have continued access to FDA approved epilepsy treatments derived from CBD.

2. Cannabidiol

Cannabinoids are chemical components of cannabis that produce pharmacologic effects throughout the body, including the central nervous system and the immune system. The primary active cannabinoid in cannabis is delta-9-tetrahydrocannabinol (THC). Another active cannabinoid is CBD which may provide relief for pain, anxiety, seizures, and other conditions without causing the "high" of THC. Cannabinoids can be taken by mouth, inhaled, or sprayed under the tongue. Two cannabinoids, dronabinol and nabilone, are FDA-approved drugs used for the prevention or treatment of chemotherapy-related nausea and vomiting.

3. FDA Approval Process

The FDA reviews drug applications to determine whether they are safe and effective through scientific investigations, including adequate and well-controlled clinical trials.

The FDA has several programs to facilitate the approval of drugs for certain conditions. The Orphan Drug Act grants special status to a drug or biological product to treat a rare disease or condition which qualifies the sponsor for various development incentives, including tax credits for qualified clinical testing. "Fast track" is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

The drug Epidiolex, referenced by this bill's sponsors, is a CBD drug candidate by GW Pharmaceuticals and is currently in clinical trials with the FDA. CBD has long been used as a treatment for Dravet syndrome, a rare and severe form of epilepsy in children, and GW Pharmaceuticals sees Epidiolex as useful in treating both Dravet and Lennox-Gastaut syndrome (LGS), another rare form of childhood epilepsy. This bill is intended to facilitate the prescription of any FDA-approved CBD products by stating that federal reclassification or exemption from Schedule I triggers the safe prescription, furnishing, dispensing, transfer, possession, or use of a product composed of CBD in accordance with federal and state law.

4. Related Legislation

SJR 5 (Stone) requests that Congress pass a law to reschedule cannabis, marijuana, and its derivatives from a Schedule I drug, and that the President of the United States sign such legislation. The bill is pending in the Assembly.

5. Proposed Amendment

In December 2016, the Drug Enforcement Agency (DEA) finalized a rule adding "marihuana extracts" to the list of Schedule I controlled substances under the federal Controlled Substances Act. (21 C.F.R. § 1308, 81 Fed.Reg. 90194 (Dec. 12, 2016) <https://www.federalregister.gov/documents/2016/12/14/2016-29941/establishment-of-a-new-drug-code-for-marihuana-extract> [as of Jun. 12, 2017].) "Marihuana extract" is defined as "an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant." Cannabidiol is considered a "marihuana extract" by the DEA.

Because cannabidiol itself is not explicitly listed under Schedule I, Legislative Counsel has advised that cannabidiol's removal from Schedule I—the language in the current version of the bill—may be an unascertainable event. As a result, Legislative Counsel suggested an amendment to replace the word "removed" with "excluded" on page 2, line 15 of the bill, and the author intends to make this amendment. The bill as amended would read:

11150.2 (a) "Notwithstanding any other law, if cannabidiol is **excluded** from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I…"

6. Argument in Support

California Life Sciences Association supports this bill stating:

> This bill would benefit patients in California by allowing access [to] controlled substances containing cannabidiol (CBD) if and when federal law permits such access.

As clinical evaluations of CBD continue, evidence grows of CBD's anti-seizure effects, though studies have also suggested potential anti-inflammatory, anti-anxiety, anti-psychotic, and analgesic benefits to the compound. One of the most promising applications of CBD is for the prevention and treatment of seizures in children with forms of drug-resistant epilepsy. While legal and regulatory hurdles to CBD access for patients remain at the federal level, we are hopeful that U.S. Food and Drug Administration (FDA) approval of a purified CBD extract for the treatment of pediatric epilepsy could ensure safe and effective access to this compound. With enactment of AB 845, the state will have done its part to facilitate patients/ access to the benefits of safe and effective CBD-based medicines.

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