THE SENATE
THIRTY-FIRST LEGISLATURE, 2021
STATE OF HAWAII

S.B. NO. 1333 S.D. 1

A BILL FOR AN ACT

RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that recent updates to the Federal Controlled Substances Act require state action in order to be in conformance.

The legislature further finds that, on August 28, 2020, the department of public safety received notice via publication in the Federal Register of an interim final order that the following substance was deleted from Schedule V of the federal schedule of controlled substances, 21 C.F.R. § 1308.15, by the United States Drug Enforcement Administration (DEA): "Drug products in finished dosage formulations that have been approved by FDA and that contain cannabidiol (CBD) derived from cannabis and no more than 0.1 per cent (w/w) residual tetrahydrocannabinols."

The legislature additionally finds that this federal scheduling action removes the regulatory controls and the administrative, civil, and criminal sanctions applicable to

federal schedule V controlled substances on persons who handle or propose to handle the drug products listed above.

For clarity purposes, this Act specifically applies to the FDA-approved prescription drug Epidiolex and any generic versions of that drug that are FDA-approved and contain CBD derived from cannabis and no more than 0.1 per cent (w/w) residual tetrahydrocannabinols only.

The legislature also finds that Epidiolex was approved by the FDA on June 25, 2018, for the treatment of seizures associated with Lennox-Gastaux syndrome (LGS) and Dravet syndrome, two rare and difficult-to-treat forms of childhood-onset epilepsy, in patients two years of age or older. Epidiolex's effectiveness was studied in three randomized, double-blind, placebo-controlled clinical trials involving five hundred sixteen patients with either LGS or Dravet. Epidiolex, taken along with other medications, was shown to be effective in reducing the frequency of seizures when compared with placebo. On July 31, 2020, the FDA approved Epidiolex for a new indication – the treatment of seizures associated with tuberous sclerosis complex, a rare genetic disease, in patients one year

of age and older. Epidiolex is the only FDA-approved drug that contains a purified drug substance derived from cannabis.

This Act should not be construed to change the legal status of cannabis, marijuana, tetrahydrocannabinols, and other marijuana related constituents, except for the narrow application to the "approved cannabidiol drugs" listed in the notice. Furthermore, unless further notice is given, the controls under federal and state law pertaining to prescription drugs continue to apply to Epidiolex and any generic versions of that drug that are FDA approved and contain CBD derived from cannabis and no more than 0.1 per cent residual tetrahydrocannabinols.

The purpose of this Act is to update state statute to make it consistent with amendments in the federal controlled substances law as required under section 329-11, Hawaii Revised Statutes.

SECTION 2. Section 329-22, Hawaii Revised Statutes, is amended to read as follows:

"**§329-22 Schedule V.** (a) The controlled substances listed in this section are included in schedule V.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

(2) Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

(3) Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams; and

(6) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(c) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers.

(d) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide], (Vimpat);

(2) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid]; and

(3) Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]butanamide) (Other names: BRV; UCB-34714; Briviact) and its salts.

[~~(e) Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the United~~

~~States Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 per cent (w/w) residual tetrahydrocannabinols.~~]"

SECTION 3. Statutory material to be repealed is bracketed and stricken.

SECTION 4. This Act shall take effect upon its approval.

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Report Title:
Uniform Controlled Substances Act; Schedule V

Description:
Removes cannabidiol drugs that have been approved by the United States Food and Drug Administration from the list of Schedule V substances for consistency with federal laws. (SD1)

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