SB1263

Measure Title:	RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.
Report Title:	Uniform Controlled Substances Act
Description:	Updates section 329-38(i), Hawaii Revised Statutes, to be consistent with federal law under Title 21 of the Code of Federal Regulations to allow for the use of either words or figures, not both, to indicate quantity where electronic prescriptions are permitted.
Companion:	HB1037
Package:	Governor
Current Referral:	CPH
Introducer(s):	KOUCHI (Introduced by request of another party)

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STATE OF HAWAII
DEPARTMENT OF PUBLIC SAFETY
919 Ala Moana Boulevard, 4th Floor
Honolulu, Hawaii 96814

No. _____

TESTIMONY ON SENATE BILL 1263
RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.
by
Nolan P. Espinda, Director

Senate Committee on Commerce, Consumer Protection, and Health
Senator Rosalyn H. Baker, Chair
Senator Stanley Chang, Vice Chair

Wednesday, February 20, 2019; 9:15 a.m.
State Capitol, Conference Room 229

Chair Baker, Vice Chair Chang, and Members of the Committee:

The Department of Public Safety (PSD) supports Senate Bill (SB) 1263, which proposes to amend chapter 329-38(i), Hawai'i Revised Statutes (HRS), to be consistent with Title 21 of the Code of Federal Regulations. PSD also proposes an amendment to SB 1263 to amend section 329-22, HRS, by adding subsection (e) to make it consistent with amendments in federal controlled substances law as required under section 329-11, HRS.

Currently, section 329-38(i), HRS, requires that both words and figures (e.g., alphabetically and numerically) be used to indicate quantity on all prescriptions for controlled substances, including electronic prescriptions. Title 21 of the Code of Federal Regulations requires only that the quantity be indicated on the prescription, with no specification as to how the quantity should be stated, allowing for the use of words or figures. The local healthcare community has informed PSD that many electronic prescription programs do not have the capability to use both words and figures because many of these computer

programs were created to comply with the quantity regulations in federal law. As a result, if the Hawaii prescriber's electronic software does not allow for the use of both words and figures to indicate a quantity, then that software cannot be used to prescribe controlled substances in Hawaii. Practically speaking, the result is that electronic prescriptions are rejected, and prescriptions are reissued in written form, by fax, or telephonically. SB 1263 would allow for consistency with federal regulations and efficiency. Prescribers would be able to increase of use electronic prescriptions, improving convenience and timeliness for patients to receive their medication.

As a further amendment to the Chapter 329, HRS, Uniform Controlled Substances Act, PSD would propose adding the following amendment to this measure:

"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 U.S. 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 ~~2~~3. New statutory material is underscored.

SECTION ~~3~~4. This Act shall take effect upon its approval. "

This additional amendment would update section 329-22, HRS, by adding subsection (e) to make it consistent with amendments in federal controlled substances law as required under section 329-11, HRS. Such

wording would incorporate an amendment to the federal Controlled Substances Act that was temporarily permitted in Hawaii by temporary designation of a new controlled substance by PSD in 2018. Under section 329-11(d), HRS, PSD's temporary designation of a new controlled substance shall be nullified if the next regular session of the state legislature has not made the corresponding changes to law.

The controlled substance specified in this proposed amendment was scheduled by the Federal Government in 2018. This specific federal scheduling action was to include what is known as EPIDIOLEX, a Schedule V controlled substance. As explained by Greenwich Biosciences, EPIDIOLEX was approved by the Federal Food and Drug Administration on June 25, 2018 for the treatment of seizures associated with two rare and difficult-to-treat forms of childhood-onset epilepsy in patients two years of age and older. PSD proposes this amendment to section 329-22, HRS, to mirror recent changes to federal Controlled Substances Act, thereby eliminating differences between federal and state law.

Thank you for the opportunity to testify on this measure.

Akamai Cannabis Clinic
3615 Harding Ave, Suite 304
Honolulu, HI 96816

TESTIMONY ON SENATE BILL 1263
RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT
By
Clifton Otto, MD

Senate Committee on Commerce, Consumer Protection, and Health
Senator Rosalyn H. Baker, Chair
Senator Stanley Chang, Vice Chair

Wednesday, February 20, 2019; 9:15 AM
State Capitol, Conference Room 229

Thank you for the opportunity to provide testimony on this measure. Please consider the following comments related to this bill:

1 - If the reason for annually updating Hawaii's Uniform Controlled Substances Act is to harmonize the state and federal regulation of controlled substances, then the Drug Enforcement Administration (DEA) Marijuana Extract rule needs to be considered:

https://www.federalregister.gov/documents/2016/12/14/2016-29941/establishment-of-a-new-drug-code-for-marihuana-extract

21 CFR 1308.11(d)
(58) Marihuana Extract - 7350

"Meaning 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."

https://www.deadiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html

2 - A controlled substance with accepted medical use cannot have the highest degree of danger. The following amendment needs to be made to Hawaii's Uniform Controlled Substances Act in order to harmonize the accepted medical use of cannabis in Hawaii with state scheduling regulations:

Section 329-14, Hawaii Revised Statutes, is amended by adding the following subsection:
(f) The enumeration of cannabis, tetrahydrocannabinols or chemical derivatives of these as Schedule I controlled substances does not apply to the medical use of cannabis pursuant to Section 329, Part IX, and Section 329D, Hawaii Revised Statutes.

3 – It is still unclear whether Cannabidiol (CBD) is a controlled substance in Hawaii, and whether the unregulated CBD products that are flowing into our state are safe or legal for human consumption. The Legislature is currently considering an amendment to our Uniform Controlled Substances Act that would place FDA-approved CBD products, such as Epidiolex, into state Schedule V, the least restrictive of our controlled substance schedules.

However, our Department of Public Safety (PSD) still has not told us the scheduling status of non-FDA approved CBD, which makes it impossible to regulate the imported CBD products that are being sold in smoke shops, health food stores, and ink cartridge stores throughout the state. Even imported dried hemp flowers with questionable levels of THC are being sold in our smoke shops without any oversight.

While the unresolved situation with CBD in Hawaii continues to put our residents at risk, states like California are starting to take action. In July of 2018, the California Department of Public Health issued a FAQ on Industrial Hemp and CBD in food products based on federal law, which clearly prohibits the use of hemp-derived CBD as a food additive or dietary supplement in that state.

New York's Department of Health and Mental Hygiene has also started prohibiting the addition of CBD to food products, a signal that other states are starting to recognize that regulation in this area is necessary in order to protect consumers and comply with federal law.

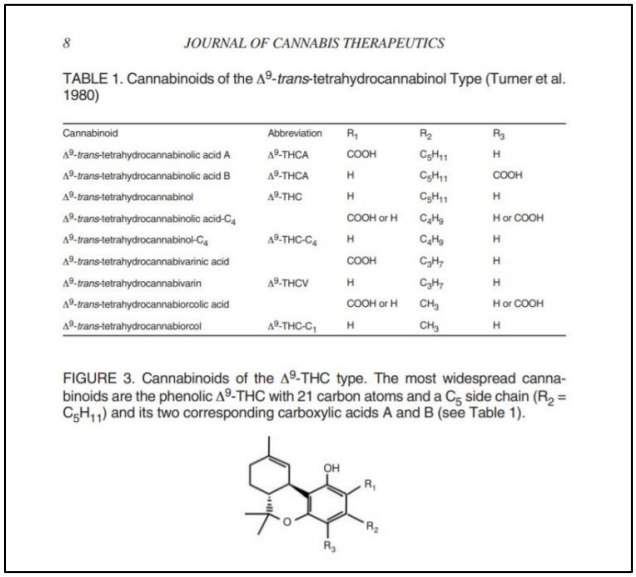
The Food and Drug Administration (FDA) is very clear about the status of CBD and THC as food additives or dietary supplements:
"Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug."

Perhaps a good place to start is by requiring that PSD provide testimony on this matter in order to answer the following question before this bill passes through your committee:

Is CBD a tetrahydrocannabinol or a derivative of a tetrahydrocannabinol ?

HRS 329-14. Schedule I. (a) The controlled substances listed in this section are included in Schedule I.
(g) Any of the following cannabinoids, their salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:
(1) Tetrahydrocannabinols; meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, **derivatives**, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following: Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers; Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers; and Delta 3,4 cis or trans tetrahydrocannabinol, and its optical isomers (since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions, are covered);

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6154432/pdf/can.2018.0030.pdf
Delta-8-THC (Delta-6-THC):
https://pubchem.ncbi.nlm.nih.gov/compound/2977#section=Top
Delta-9 THC (Delta-1-THC):
https://pubchem.ncbi.nlm.nih.gov/compound/Dronabinol#section=Top



8 JOURNAL OF CANNABIS THERAPEUTICS

TABLE 1. Cannabinoids of the Δ^9-*trans*-tetrahydrocannabinol Type (Turner et al. 1980)

Cannabinoid	Abbreviation	R_1	R_2	R_3
Δ^9-*trans*-tetrahydrocannabinolic acid A	Δ^9-THCA	COOH	C_5H_{11}	H
Δ^9-*trans*-tetrahydrocannabinolic acid B	Δ^9-THCA	H	C_5H_{11}	COOH
Δ^9-*trans*-tetrahydrocannabinol	Δ^9-THC	H	C_5H_{11}	H
Δ^9-*trans*-tetrahydrocannabinolic acid-C_4		COOH or H	C_4H_9	H or COOH
Δ^9-*trans*-tetrahydrocannabinol-C_4	Δ^9-THC-C_4	H	C_4H_9	H
Δ^9-*trans*-tetrahydrocannabivarinic acid		COOH	C_3H_7	H
Δ^9-*trans*-tetrahydrocannabivarin	Δ^9-THCV	H	C_3H_7	H
Δ^9-*trans*-tetrahydrocannabiorcolic acid		COOH or H	CH_3	H or COOH
Δ^9-*trans*-tetrahydrocannabiorcol	Δ^9-THC-C_1	H	CH_3	H

FIGURE 3. Cannabinoids of the Δ^9-THC type. The most widespread cannabinoids are the phenolic Δ^9-THC with 21 carbon atoms and a C_5 side chain (R_2 = C_5H_{11}) and its two corresponding carboxylic acids A and B (see Table 1).

https://cannabis-med.org/data/pdf/2003-01-1.pdf

4 – The inter-island transportation of cannabis for personal medical use continues to be an issue that is requiring significant amounts of local law enforcement time due to the processing of patients at our state airports who have been referred by TSA, which is threatening the safety of our airports. Local law enforcement officers are also telling patients that they cannot travel with their medicine because it is against federal law, which is beyond the authority of a state law enforcement agency, and not entirely true because of the federal aviation regulation that specifically exempts the carriage of cannabis aboard aircraft if authorized by state law or state agency.

Therefore, in order to clarify the existing provisions for inter-island transport within Hawaii's Medical Use of Cannabis Act and to protect the right of patients to transport legal amounts of cannabis for personal medical use to other islands under state law and the Americans with Disabilities Act, the following amendment needs to be made to the Medical Use of Cannabis section of Hawaii's Uniform Controlled Substances Act:

HRS 329-122(f):

"For purposes of interisland transportation, "transport" of cannabis, usable cannabis, or any manufactured cannabis product, by any means is allowable only by a qualifying patient or qualifying out-of-state patient for their personal medical use, or between a production center or retail dispensing location and a certified laboratory for the sole purpose of laboratory testing pursuant to section 329D-8, as permitted under section 329D-6(m) and subject to section 329D-6(j), and with the understanding that state law and its protections do not apply outside of the jurisdictional limits of the State. The Department of Transportation and the Department of Public Safety shall adopt rules to provide compliance with this section.

14 CFR 91.19 Carriage of narcotic drugs, marihuana, and depressant or stimulant drugs or substances.

(a) Except as provided in paragraph (b) of this section, no person may operate a civil aircraft within the United States with knowledge that narcotic drugs, marihuana, and depressant or stimulant drugs or substances as defined in Federal or State statutes are carried in the aircraft.
(b) Paragraph (a) of this section **does not apply** to any carriage of narcotic drugs, marihuana, and depressant or stimulant drugs or substances **authorized by** or under any Federal or **State statute** or by any Federal or **State agency**.

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Government Relations

Testimony of
Jonathan Ching
Government Relations Specialist

Before:
Senate Committee on Commerce, Consumer Protection, and Health
The Honorable Rosalyn H. Baker, Chair
The Honorable Stanley Chang, Vice Chair

February 20, 2019
9:15 a.m.
Conference Room 229

Re: SB1263, RELATING TO HEALTH

Chair Baker, Vice-Chair Chang, and committee members, thank you for this opportunity to provide testimony on SB1263, which specifies that where electronic prescriptions are permitted, either words or figures, not both, may be used to indicate quantity.

Kaiser Permanente Hawai‘i SUPPORTS SB1263.

Kaiser Permanente Hawai‘i is the state’s largest integrated health system that provides care and coverage for 255,000 members. Each day, over 4,500 dedicated employees and more than 600 Hawai‘i Permanente Medical Group physicians come to work to care for our members at Moanalua Medical Center and 27 other clinic locations, providing high-quality care and delivering on our commitment to improve the health of the 1.4 million people in the communities we serve.

SB1263 clarifies the Uniform Controlled Substances Act (Title 21 of the Code of Federal Regulations) for electronic prescriptions by confirming that electronic prescriptions do not need to indicate quantity in *both* figures and words. This will simplify the process for these electronic prescriptions without posing the risks that quantity indications in both words and figures were intended to address when prescriptions are hand-written.

The requirement of both numeric and alphabetic quantity for prescriptions is intended to address two primary risks. First, requiring both numeric and alphabetic quantity reduces the risk of misreading quantities when the prescriber’s handwriting is illegible. Second, the requirement is intended to prevent fraud by eliminating the possibility that a quantity could be increased by adding digits to a numeric quantity – e.g., turning 5 into 50 by adding 0. These issues are not present with electronic prescriptions placed in secure systems, which require multiple authentications before transmittal and cannot be modified once authenticated and transmitted. Therefore, the requirement for both numeric and alphabetic quantity in secure electronic prescriptions is not necessary.

The proposed amendments to HRS Section 329-38(i) to be consistent with the Uniform Controlled Substances Act will simplify Kaiser Permanente Hawai‘i’s electronic prescription process without exposing our patients to any increased risk of error or fraud.

Thank you for the opportunity to provide testimony on this important measure.

TESTIMONY OF NAHELANI WEBSTER ON BEHALF OF GREENWICH BIOSCIENCES IN SUPPORT OF S.B. 1263

LATE

To: Chair Baker and Members of the Committee on Commerce, Consumer Protection, and Health.

My name is Nahelani Webster and I am presenting this testimony on behalf of Greenwich Biosciences in **support** of S.B. 1263 Relating to the Uniform Controlled Substances Act **with a proposed amendment**.

We previously testified on a measure, S.B. 1266 that was heard in your committee on February 12, and was deferred due to concerns. We'd like to offer the comments below addressing any concerns and respectfully ask the committee to add in the language attached as a new Section 2, rescheduling the Epidiolex formula to Schedule V, in conformity with federal law.

In review of the testimony submitted on S.B. 1266, the Department of Public Safety, the Democratic Party of Hawaii, and Greenwich Biosciences were in support. Comments were offered by Akamai Cannabis Clinic. Opposition was received from 16 individuals and 4 individuals in support. The concerns raised from those opposed to the measure were writing to oppose the **banning of Cannabidiol (CBD), which the bill does not do.** The testimony received in opposition was not applicable to the language in the bill which would permit the state to be in line with federal law that re-scheduled a specific formula that applies to currently only one product, Epidiolex, and would apply to any future generic versions developed with the same narrowly described formula. **The language does not ban CBD.**

The purpose of the language is to update our state statute to make it consistent with amendments in the federal controlled substances law as required under Hawaii Revised Statutes ("HRS") section 329-11. This will allow for Epidiolex to be available to the public in the State of Hawaii.

Epidiolex was approved by the U.S. Food and Drug Administration (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 is a Schedule V drug, the lowest DEA restriction classification, based on its low abuse potential. By adding Epidiolex to current treatment, seizures are significantly reduced in those with Dravet and LGS who were not previously helped with various epilepsy medicines

As of October 29, 2018, Epidiolex has been made available to patients in Hawaii under the Department of Public Safety's temporary rescheduling action. If this language does not pass, dozens of patients in Hawaii currently using Epidiolex under the care of their neurologists for catastrophic forms of epilepsy will lose access to this important new therapy. This is a hugely important measure to ensure state law is in line with the federal law. We respectfully urge you to support this language and amend S.B. 1263 to add in the language below making the re-scheduling to Schedule V permanent.

Thank you for the opportunity to present this testimony. Please contact me if you have any questions.

Language to be added:

"SECTION 2. Section 329-22, Hawaii Revised Statutes, is amended by 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;

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(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:

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(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. [L 1972, c 10, pt of §1; am L 1978, c 68, §6; am L 1985, c 150, §4; am L 2003, c 151, §6; am L 2008, c 119, §6; am L 2010, c 123, §4; am L 2017, c 155, §3].

"(e) Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the U.S. 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."”