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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, SENATE DRAFT 1
RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.
by
Nolan P. Espinda, Director

House Committee on Health
Representative John M. Mizuno, Chair
Representative Bertrand Kobayashi, Vice Chair

Thursday, March 21, 2019; 10:00 a.m.
State Capitol, Conference Room 329

Chair Mizuno, Vice Chair Kobayashi, and Members of the Committee:

The Department of Public Safety (PSD) supports Senate Bill (SB) 1263, Senate Draft (SD) 1, 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 (C.F.R.) and to update section 329-22, HRS, to conform Hawaii law with recent changes to the federal controlled substances 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 supports SB 1263, SD 1, because its passage would permanently add Epidiolex to section 329-22, HRS, to mirror recent changes to the 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 SENATE DRAFT 1
RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT
By
Clifton Otto, MD

House Committee on Health
Representative John M. Mizuno, Chair
Representative Bertrand Kobayashi, Vice Chair

Thursday, March 21, 2019; 10:00 AM
State Capitol, Conference Room 329

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

Comment #1 – One of the purposes of this bill is to harmonize the state and federal regulation of controlled substances by making scheduling changes to Hawaii's Uniform Controlled Substances Act (UCSA) that correspond with recent changes to federal controlled substance regulation.

In this case, a new FDA-approved botanically derived Cannabidiol (CBD) oil made in England is being considered for placement in Hawaii State Schedule V, which would match the decision of the Drug Enforcement Administration (DEA) to place such approved CBD drug products on the federal Schedule V list.

Which begs the question: if FDA-approved CBD is going to be placed in Hawaii State Schedule V, then what schedule does unapproved CBD fall under ?

This is not a trivial question considering the wave of unregulated and unapproved CBD products that is flooding our health and wellness commercial markets.

From a chemistry perspective, you could say that CBD is a derivative of delta-9-tetrahydrocannabinol (THC), since both can be turned into each other with available chemical methods.

And if CBD is a derivative of THC, then CBD is a tetrahydrocannabinol, which would place unapproved CBD in Schedule I along with the other tetrahydrocannabinols.

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);"

The hemp hustlers will tell you that hemp-derived CBD is legal in all fifty states because hemp has been removed from the federal Controlled Substances Act under the Agriculture Improvement Act of 2018.

What they won't tell you is that now that CBD is an approved drug product in the United States, the Food and Drug Administration (FDA) cannot allow unapproved CBD to be sold as a food additive or marketed as a dietary supplement.

The Agriculture Improvement Act of 2018 did not open the door for the inter-state marketing of unapproved cannabinoids found in hemp. Otherwise, hemp farmers would be able to extract THC from hemp and sell this Schedule I controlled substance on the open market. Why would it be any different for CBD?

Adding an FDA-approved CBD drug product to Hawaii State Schedule V highlights the need to address the scheduling status of unapproved CBD. Please don't do one without the other.

Comment #2 – At the heart of our inability to effectively regulate the medical use of cannabis in Hawaii is the misconception that our Medical Use of Cannabis Program is violating federal law. Effective enforcement cannot occur when the state and federal regulation of medical use cannabis are at odds with each other.

The good news is that this idea that our program is violating federal law is just a mirage. State medical use is "currently accepted medical use in treatment in the United States", which demonstrates the intended impact that state law can have upon federal law under federalism.

State law says that cannabis has medical use, and federal law says that a substance cannot be in Schedule I if it has accepted medical use. It would be foolish to think that the federal regulation that still has cannabis listed as a Schedule I controlled substance supersedes both state and federal law.

The answer to this predicament is the phrase "does not apply", for which we already have several notable examples:

Exempt from federal Schedule I:
21 CFR 1307.31 - Native American Church.
"The listing of peyote as a controlled substance in Schedule I **does not apply** to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration."

Exempt from Guam Schedule I:
Section 2. The following *new* subsection (g) is added to Appendix A of Chapter 67 of Title 9 Guam Code Annotated, to read as follows:
"(g) The enumeration of marihuana, tetrahydrocannabinols or chemical derivatives of these as Schedule I controlled substances **does not apply** to the medical use of cannabis pursuant to the Joaquin Concepcion Compassionate Cannabis Use Act of 2013."

Exempt from the federal restriction on carriage aboard aircraft:
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."

Therefore, the first step towards re-harmonizing the state and federal regulation of medical use cannabis is to make the following amendment to Hawaii's UCSA:

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.

Comment #3 – 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 who have been referred by TSA, which is distracting our officers from other duties and 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.

Please do not allow this bill to pass out of your committee until these issues have been fully addressed.

THE QUEEN'S HEALTH SYSTEMS

To: The Honorable John M. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair
Members, Committee on Health

From: Victoria Wong, MD, FAES, Medical Director, Queen's Comprehensive Epilepsy Center and Neurodiagnostic Lab, The Queen's Medical Center
Alan Stein, MD, FAES, Medical Director, Epilepsy and Neurophysiology, Neuroscience Institute, The Queen's Medical Center
Paula Yoshioka, Vice President, Government Relations and External Affairs, The Queen's Health Systems

Date: March 19, 2019

Hrg: House Committee on Health Hearing; Thursday, March 21, 2019 at 10:00 AM in Room 329

Re: Support for S.B. 1263, S.D. 1, Relating to the Uniform Controlled Substances Act

The Queen's Health Systems (Queen's) is a not-for-profit corporation that provides expanded health care capabilities to the people of Hawai'i and the Pacific Basin. Since the founding of the first Queen's hospital in 1859 by Queen Emma and King Kamehameha IV, it has been our mission to provide quality health care services in perpetuity for Native Hawaiians and all of the people of Hawai'i. Over the years, the organization has grown to four hospitals, 66 health care centers and labs, and more than 1,600 physicians statewide. As the preeminent health care system in Hawai'i, Queen's strives to provide superior patient care that is constantly advancing through education and research.

Queen's appreciates the opportunity to provide testimony in support for S.B. 1263, S.D. 1, Relating to the Uniform Controlled Substances Act. This measure would update the Hawaii Revised Statutes to be consistent with federal law and allows for continued access to quality health care for our patients. The measure provides for registered medical practitioners in the state of Hawaii to prescribe Epidiolex to patients with epilepsy syndromes. Epidiolex is a cannabidiol oral solution currently approved by the U.S. Food and Drug Administration (FDA) for the treatment Dravet syndrome and Lennox-Gastaut syndrome, which typically do not respond to other anti-seizure medications.

Epidiolex is the first FDA-approved drug that contains a purified drug substance derived from marijuana and it is the first FDA approved drug for the treatment of patients with Dravet syndrome. Cannabidiol (CBD) is a component of marijuana but it is not a psychoactive substance meaning that the ingestion of CBD does not cause people to become intoxicated or euphoric (the "high") that comes from tetrahydrocannabinol. The Drug Enforcement Administration (DEA) has ordered that FDA-approved drugs containing "CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols" be placed in Schedule V rather than Schedule I. Schedule I is the most restrictive schedule and Schedule V is the least restrictive

schedule of the Controlled Substances Act. This scheduling would allow registered medical practitioners to prescribe Epidiolex. Presently in the State of Hawaii, there are only two practicing adult epileptologists (neurologists specializing in the care of patients with epilepsy) who have board certification in Epilepsy. The Queen's Comprehensive Epilepsy Center is the only National Association of Epilepsy Centers accredited epilepsy center in the state and we are accredited at Level 4, the highest level of accreditation. Passage of this bill would ensure that our epileptologists can continue to provide the best care possible for our community and ensure access to Epidiolex as a therapeutic option to treat Dravet syndrome and Lennox-Gastaut syndrome, both challenging forms of epilepsy. Thank you for your time and attention to this important issue.

KAISER PERMANENTE®

Government Relations

Testimony of
Jonathan Ching
Government Relations Specialist

Before:
House Committee on Health
The Honorable John H. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair

March 21, 2019
10:00 a.m.
Conference Room 329

Re: SB1263, SD1 RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

Chair Mizuno, Vice-Chair Kobayashi, and committee members, thank you for this opportunity to provide testimony on SB1263, SD1, which specifies that where electronic prescriptions are permitted, either words or figures, not both, may be used to indicate quantity and updates section 329-22, Hawai‘i Revised Statutes, to conform Hawai‘i law with recent changes to the federal controlled substances law.

Kaiser Permanente Hawai‘i SUPPORTS SB1263, SD1.

We take no position on Section 1.

Kaiser Permanente Hawai‘i supports Section 2, which 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.

SanHi
GOVERNMENT STRATEGIES
A LIMITED LIABILITY LAW PARTNERSHIP

DATE: March 20, 2019

TO: Representative John Mizuno
Chair, House Committee on Health
Submitted Via Capitol Website

FROM: Mihoko Ito

RE: **S.B. 1263, S.D.1 – Relating to the Uniform Controlled Substances Act**
Hearing Date: Thursday, March 21, 2019 at 10:00 a.m.
Conference Room: 329

Dear Chair Mizuno and Members of the Committee:

We submit this testimony on behalf of Walgreen Co. ("Walgreens"). Walgreens operates stores at more than 8,200 locations in all 50 states, the District of Columbia, and Puerto Rico. In Hawaii, Walgreens now has 19 stores on the islands of Oahu, Maui, and Hawaii.

Walgreens **supports section 2 of S.B. 1263, S.D.1**, which allows for electronic prescription quantities to be stated in either words or numbers, and eliminates the current requirement that both words and numbers be used to indicate quantity.

Using both words or numbers to describe prescription quantity may have served a historical purpose to reduce the risk of errors or fraud. However, electronic prescriptions do not pose the same risks of making quantity errors, and have become very widely used as a safe and convenient way to fill prescriptions. Amending the law as proposed in this measure is also consistent with existing federal law and will modernize and streamline the electronic prescriptions process.

Thank you for the opportunity to submit testimony in support of this measure.

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EPILEPSY FOUNDATION
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March 19, 2019

Aloha Chair John Mizuno and Members of the House Committee on Health,

I am writing in support of S.B. 1263 SD1 Relating to the Uniform Controlled Substances Act along with a proposed amendment to add in language necessary to reschedule the currently FDA approved Epidiolex formula to Schedule V, in conformity with federal law. 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. As of October 29, 2018, Epidiolex has been made available to patients in Hawaii under the Department of Public Safety's temporary rescheduling action.

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. **Unless Hawaii acts now individuals with Dravet and Lennox-Gastaut syndromes could experience a delay in accessing this new and innovative treatment option, a reduction in seizures, and an improved quality of life.**

The Epilepsy Foundation of Hawaii is an affiliate of the Epilepsy Foundation of America and together we are the leading national voluntary health organization that speaks on behalf of the at least 14,000 individuals in Hawaii (3.4 million Americans) and their caregivers living with epilepsy and seizures. We foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services.

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

Naomi Manuel
Executive Director

THE SENATE
THIRTIETH LEGISLATURE, 2019
STATE OF HAWAII

S.B. NO. 1263 S.D. 1

HLT - Thursday, 03-21-19 10:00AM in House conference room 329

House Committee on Health

Honorable Chairs and committee members:

Hawaii PAs propose an amendment to the proposed bill SB 1263 SD1.
The following language in the statute and proposed bill (marked in strikethrough)pertaining to PAs is outdated, restrictive, and overly broad regarding record review and initialing of prescriptions for controlled substances written by physician assistants. This language should be deleted from the bill and from HRS 329. It is inconsistent with HRS 453 which requires no co-signature requirement. Record review pertaining to physician assistants is also addressed in HAR Title 16 Chapter 85 and requires no co-signature either. This provides an excellent opportunity to revise HRS 329 so that it is consistent with HRS 453 and HAR Title 16 Chapter 85.

(4) A physician assistant registered to prescribe controlled substances under the authorization of a supervising physician shall include on all controlled substance prescriptions issued:
(A) The Drug Enforcement Administration registration number of the supervising physician; and

(B) The Drug Enforcement Administration registration number of the physician assistant.

Each written controlled substance prescription issued shall include the printed, stamped, typed, or hand-printed name, address, and phone number of both the

supervising physician and physician assistant, and shall be signed by the physician assistant. ~~The medical record of each written controlled substance prescription issued by a physician assistant shall be reviewed and initialed by the physician assistant's supervising physician within seven working days."~~

Thank you for your consideration of this proposed amendment.

Fielding Mercer, PA-C
Past president and Legislative Liaison - Hawaii Academy of Physician Assistants