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

No. _____

TESTIMONY ON HOUSE BILL 1040
RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.
By
Nolan P. Espinda, Director

House Committee on Judiciary
Representative Chris Lee, Chair
Representative Joy A. San Buenaventura, Vice Chair

Monday, February 4, 2019; 2:05 p.m.
State Capitol, Conference Room 325

Chair Lee, Vice Chair San Buenaventura, and Members of the Committee:

The Department of Public Safety (PSD) **supports** House Bill (HB) 1040, which updates chapter 329 of the Hawaii Revised Statutes (HRS), to incorporate an amendment made to the federal Controlled Substances Act that was temporarily permitted in Hawaii by the temporary designation of a new controlled substance by PSD in 2018. Under chapter 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.

Chapter 329-11, HRS, provides that if a substance is added, deleted, or rescheduled under federal law, then PSD shall recommend to the Legislature that a corresponding change in Hawaii law be made.

The following substance was scheduled by the Federal Government in 2018:

> 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 percent (w/w) residual tetrahydrocannabinols.

To avoid such nullification of the controlled substance that was temporarily designated by PSD in 2018, PSD supports the passage of HB 1040. Equally important, PSD supports SB 1040 as it amends chapter 329, 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.

EPILEPSY FOUNDATION

LATE

February 4, 2019

Representative Chris Lee
Hawaii State Capitol, Room 302
Honolulu, HI 96813

Dear Chair Lee and Members of the House Judiciary Committee:

On behalf of the Epilepsy Foundation and our local affiliate, Epilepsy Foundation of Hawaii, we write to urge your support for House Bill 1040 which would amend Hawaii's controlled substances list to allow for timely access to medications derived from cannabidiol (CBD) approved by the Food and Drug Administration (FDA) that have now been scheduled by the Drug Enforcement Agency (DEA).

On June 25, 2018, the FDA approved Epidiolex, a medication derived from cannabis for the treatment of seizures in two rare epilepsy conditions known as Dravet and Lennox-Gastaut (LGS) syndromes in individuals 2 years of age or older. There are ongoing clinical trials to assess the effectiveness of Epidiolex for Tuberous Sclerosis Complex (TSC), another rare epilepsy syndrome. This treatment option received Orphan Drug Designation for LGS and TSC. On September 27, 2018, the DEA designated Epidiolex as Schedule V. However, since CBD is a Schedule I substance under the state drug schedule, state action is needed to properly re-schedule Epidiolex to ensure timely access to this new treatment option. Unless Hawaii acts now in passing HB 1040, individuals with Dravet and Lennox-Gastaut syndromes could experience a delay in accessing this new and innovative treatment option.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of the at least 3.4 million Americans living with epilepsy and seizures. Together with the Epilepsy Foundation of Hawaii, we foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. 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 for epilepsy, and about a third of people living with epilepsy suffer from uncontrollable or intractable seizures, with many more living with significant side effects, despite available treatments. Uncontrolled seizures can lead to accident, injury, increased hospitalization costs, and even early death.

Dravet syndrome is a rare and catastrophic form of intractable epilepsy that begins in infancy and is highly treatment-resistant. It is a debilitating, life-long condition characterized by frequent and prolonged seizures, poor seizure control, and developmental delays, as well as an increased risk of premature death including sudden unexpected death in epilepsy (SUDEP). Epidiolex is the first ever FDA-approved treatment for Dravet and represents hope for individuals living with Dravet syndrome who continue to have uncontrolled seizures and other medical needs throughout their lifetime.

Lennox-Gastaut syndrome is a rare and often debilitating form of childhood-onset epilepsy that is highly treatment-resistant. It is characterized by multiple seizure types, and moderate to severe cognitive impairment. Individuals living with LGS experience an increased risk of serious injury because of frequent falls associated with uncontrolled seizures. Despite other FDA-approved treatments for LGS,

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EPILEPSY FOUNDATION

many individuals living with this rare epilepsy do not achieve seizure control and experience related cognitive impairments that severely limit quality of life.

The Epilepsy Foundation and Epilepsy Foundation of Hawaii are committed to supporting physician-directed care, and to exploring and advocating for all potential treatment options for epilepsy. Bureaucratic processes should not stand in the way of individuals gaining access to clinically proven treatments once they have been reviewed and approved by the FDA. We urge your support for HB 1040 which would re-schedule Epidiolex in Hawaii to ensure timely access for the individuals who need it. Please do not hesitate to contact Laura Weidner, Esq., Vice President, Government Relations & Advocacy, at our National Office, at 301-918-3766 or lweidner@efa.org with questions or concerns.

Sincerely,

Naomi Manuel
Executive Director
Epilepsy Foundation of Hawaii

Philip M. Gattone, M.Ed.
President & CEO
Epilepsy Foundation

TESTIMONY OF NAHELANI WEBSTER ON BEHALF OF GREENWICH BIOSCIENCES IN SUPPORT OF H.B. 1040

LATE

To: Chair Lee and Members of the House Judiciary Committee.

My name is Nahelani Webster and I am presenting this testimony on behalf of Greenwich Biosciences in **support** of H.B. 1040 Relating to the Uniform Controlled Substances Act.

Greenwich Biosciences, along with parent company GW Pharmaceuticals plc ("GW"), is the world leader in advancing the therapeutic potential of cannabinoids, naturally occurring compounds found in the cannabis plant. Leveraging over 20 years of pioneering research, the company is the first and only one to develop an FDA-approved, plant-derived prescription cannabinoid product, EPIDIOLEX (cannabidiol or CBD) oral solution, Schedule V. This means it has met the rigorous evaluation standards of the FDA for safety and efficacy.

The purpose of this bill 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 were significantly reduced in those with Dravet and LGS who were not previously helped with various epilepsy medicines. The company is always seeking solutions that will transform lives, and this is why GW continues to advance cannabinoid science and study new medications to help meet serious unmet patient and caregiver needs. For GW, EPIDIOLEX is just the first step toward transforming the treatment of epilepsy in one's lifetime.

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

House Committee on Judiciary

Rep. Chris Lee (Chair), Rep. Joy San Buenaventura (Co-chair)

Testimony for HB1040 – Relating to the UCSA

Clifton Otto, MD - Comments

Public Hearing - Monday, February 4, 2019, 2:05 pm, Room 325

Thank you for considering the following comments regarding this bill:

1 - If the goal of annually updating Hawaii's Uniform Controlled Substances Act is to harmonize the state and federal regulation of controlled substances, then the DEA's Marijuana Extract rule needs to be included:

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

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 added:

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 - We need to know the state scheduling status of Cannabidiol (CBD) so that the current influx of unregulated and unlicensed CBD products can be addressed.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6154432/pdf/can.2018.0030.pdf

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HB-1040
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Testimony for JUD on 2/4/2019 2:05:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing
Bryan Houston	Individual	Oppose	No

Comments:

My name is Bryan Houston, I am a college student currently working on a masters degree in social work. I am not in support of HB1040.

Monday, February 4, 2019

One of my best friends was born missing part of a vertebrae. During his young adult life, while trying to lift something, the other portion of that vertebrae was crushed. He has since lived disabled and having to deal with extreme amounts of pain. For over a decade I've witnessed my friend struggling to manage this pain as best as he could. Fentanyl was the medication that had the greatest effect for reducing his pain, but he didn't like the side effects and dependancy risks of that medication.

A couple years ago my friend discovered cannabidiol. It was amazing to see the change in my friends life from this discovery. His pain became better managed than it had been with fentanyl, and I began to realize that there were aspects of my friend that I had never gotten to know previously. The combination of better managed pain and removal of fentanyl side effects allowed my friend greater freedom to experience and express himself. It was really wonderful to see. I am concerned that placing cannabidiol as a schedule five controlled substance could reduce its availability for my friend and others in similar situations.

Also, I've noticed that several small businesses including local ones here in Hawaii have been producing and selling cannabidiol. I have a concern that making cannabidiol a schedule five substance could make it much more difficult for small businesses to navigate. I think it would be disappointing if these small businesses were unable to continue buisness and were replaced by large corporations and pharmaceutical companies.

Due to the concerns mentioned above, I oppose HB1040.