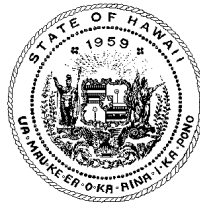


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No. _____

TESTIMONY ON HOUSE BILL 1032, HOUSE DRAFT 1
RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

By
Max N. Otani, Director

Senate Committee on Judiciary
Senator Karl Rhoads, Chair
Senator Jarrett Keohokalole, Vice Chair

Tuesday, March 30, 2021; 9:50 a.m.
Via Videoconference

The Department of Public Safety (PSD) **supports** House Bill (HB) 1032, House Draft (HD) 1, which updates Chapter 329 of the Hawaii Revised Statutes (HRS), to incorporate amendments made to the federal Controlled Substances Act that were permitted in Hawaii by the temporary designation of several new controlled substances by PSD in 2020. Under Section 329-11(d) and (e), HRS, PSD's temporary designation of new controlled substances shall be nullified if the next regular session of the State Legislature has not made the corresponding changes to state law.

Sections 329-11(d) and (e), HRS, provides that if a substance is added, deleted or rescheduled under federal law, or by an emergency scheduling action taken by PSD, then PSD shall recommend to the Legislature to make the corresponding changes in Hawaii law.

In 2020, PSD temporarily designated several substances as controlled substances and placed those substances on the schedules contained in Chapter 329, HRS. These temporary designations were made to correspond to several similar changes made to the federal controlled substances schedules by the United States Drug Enforcement Administration (DEA). This measure lists those substances and proposes to make the temporary designations permanent.

The Department supports HB 1032, HD 1 because it amends Chapter 329, HRS, to mirror recent changes to the federal Controlled Substances Act, thereby eliminating differences between federal and state law. Additionally, PSD supports the passage of HB 1032, HD 1 to avoid nullification of the controlled substances that were temporarily designated in 2020.

The Department notes that HB 1032, HD 1, also seeks to remove certain approved cannabidiol drugs (CBD) drugs from controlled substances regulation in alignment with recent federal action. Specifically, this proposal would remove the new drug Epidiolex, and any future generic equivalent of Epidiolex, from regulation as a controlled substance. Epidiolex is a drug derived from CBD (a chemical contained in cannabis) that is used to treat seizure disorders in children. By removing controlled substance regulations over Epidiolex, it would simply become a normal prescription drug that can be dispensed upon the order of a prescriber. Importantly, this proposal specifically applies to Epidiolex and any future generic equivalent. This proposal does not seek to regulate CBD products commonly found in stores, gas stations, or shopping malls.

Thank you for the opportunity to testify on this measure.

LATE

**TESTIMONY OF NAHELANI WEBSTER ON BEHALF OF
GREENWICH BIOSCIENCES IN SUPPORT OF H.B. 1032 HD1**

To: Chair Karl Rhoads and Members of the Senate Judiciary Committee.

My name is Nahelani Webster and I am presenting this testimony on behalf of Greenwich Biosciences in **support** of H.B. 1032 HD1 Relating to the Uniform Controlled Substances Act. This testimony pertains to Section 4, beginning on page 20, deleting language from Schedule V to conform with federal law..

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 company to develop an FDA-approved, plant-derived prescription cannabinoid product, EPIDIOLEX (cannabidiol or CBD) oral solution. This means it has met the rigorous evaluation standards of the FDA for safety and efficacy.

The purpose of Section 4 is to update Hawaii state statute to make it consistent with amendments in the Federal Controlled Substances Act as required under Hawaii Revised Statutes (“HRS”) section 329-11. This bill will benefit patients who have been prescribed Epidiolex in 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 Gastaut syndrome (LGS) and Dravet syndrome, two rare and difficult-to-treat forms of childhood-onset epilepsy, in patients two years of age or older.

In September 2018, the DEA placed Epidiolex in Schedule V of the Controlled Substances Act (CSA). Shortly after the DEA’s scheduling of Epidiolex, the Hawaii Department of Public Safety added Epidiolex to Schedule V of Hawaii’s Controlled Substances Act. HRS § 329-22(e); Haw. Dept. of Public Safety, Narcotics Enforcement Division, Notice of Federal Scheduling Action (Oct. 1, 2018).

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.

On March 20, 2020, Greenwich received correspondence from the DEA—confirming that, as a result of the federal 2018 Agricultural Improvement Act (“AIA”), Epidiolex has been descheduled under the CSA. As a consequence of the DEA’s letter, the FDA removed the Schedule V designation from the Epidiolex Prescribing Information Label.

On August 21, 2020, the DEA issued Interim Final Rule, removing Epidiolex from Schedule V under the CSA and making Epidiolex a descheduled drug.

EPIDIOLEX is prescribed for the treatment of seizures and is an additional medication for children and adults with Dravet, LGS, and Tuberous Sclerosis Complex, who were not previously helped with various epilepsy medicines. Greenwich is seeking solutions that will transform lives, and this is why Greenwich continues to advance cannabinoid science and study new medications to help meet serious unmet patient and caregiver needs.

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



LATE

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TESTIMONY ON HOUSE BILL 1032 HOUSE DRAFT 1
RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT
By
Clifton Otto, MD

Senate Committee on Judiciary
Senator Karl Rhoads, Chair
Senator Jarrett Keohokalole, Vice Chair

Tuesday, March 30, 2021; 9:50 AM
State Capitol, Videoconference

Thank you for the opportunity to provide testimony in **SUPPORT WITH CHANGES** on this measure.

For the sake of establishing consistency between the state and federal regulation of cannabis, please add the following amendment to this bill:

SECTION 4b. The following section is added to read as follows:

"§329-5 Recognizing the State Authorized Use of Cannabis.

The department of public safety shall submit to the administrator of the United States Department of Justice, Drug Enforcement Administration, Diversion Control Division:

[1] An application for immediate relief pursuant to title 21 Code of Federal Regulations section 1307.03 to the Office of Diversion Control. This application shall state that part IX of chapter 329, Hawaii Revised Statutes, and chapter 329D, Hawaii Revised Statutes, create an exemption from federal drug laws and

do not create any positive conflict pursuant to title 21 United States Code Annotated section 903; and that the federal scheduling of marijuana does not apply to the state authorized use of cannabis. The application shall also include a proposed rule containing the following: "The listing of marijuana as a controlled substance does not apply to the state authorized use of marijuana, and persons using marijuana in compliance with state law are exempt from registration"; and

[2] A petition for permanent relief pursuant to title 21 Code of Federal Regulations section 1308.43. This petition shall state that part IX of chapter 329, Hawaii Revised Statutes, and chapter 329D, Hawaii Revised Statutes, create an exemption from federal drug laws and do not create any positive conflict pursuant to title 21 United States Code Annotated section 903; and that the federal scheduling of marijuana does not apply to the state authorized use of cannabis. The petition shall also include a proposed rule containing the following:

"The listing of marijuana as a controlled substance does not apply to the state authorized use of marijuana, and persons using marijuana in compliance with state law are exempt from registration."

Thank you for considering this amendment proposal. Aloha.