

ON THE FOLLOWING MEASURE:

S.B. NO. 1333, S.D. 2, H.D. 1, RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

BEFORE THE:

HOUSE COMMITTEE ON CONSUMER PROTECTION AND COMMERCE

DATE: Thursday, April 1, 2021 **TIME:** 2:00 p.m.

LOCATION: State Capitol, Room 329, Via Videoconference

TESTIFIER(S): Clare E. Connors, Attorney General, or

Michelle M.L. Puu, Deputy Attorney General

Chair Johanson and Members of the Committee:

The Department of the Attorney General (Department) supports the intent of this bill but notes the following legal concerns.

The purpose of this bill is to update the Uniform Controlled Substances Act (CSA), chapter 329 of the Hawaii Revised Statutes (HRS), to maintain consistency with amendments to federal law. Specifically, the bill will: (1) exempt hemp from the CSA; and (2) remove cannabidiol drugs that have been approved by the United States Food and Drug Administration from the list of Schedule V substances. Additionally, the bill seeks to amend certain provisions of the Hawaii Penal Code in light of these updates.

The proposed revisions to the CSA are consistent with federal law. However, the proposed revisions to the Hawaii Penal Code in this bill violate section 14 of article III of the Constitution of the State of Hawaii, which provides in part that "[e]ach law shall embrace but one subject, which shall be expressed in its title." Because the single subject of this bill as expressed in its title is "Uniform Controlled Substances Act," the provisions of this bill that apply to the "Hawaii Penal Code" are in violation of the single-subject requirement of section 14 of article III of the Constitution of the State of Hawaii.

The Department respectfully recommends that this Committee amend this bill consistent with earlier drafts that did not include proposed revisions of the Hawaii Penal Code.

GREENWICH BIOSCIENCES IN SUPPORT OF S.B. 1333 SD2 HD1

To: Chair Aaron Johanson and Members of the House Committee on Consumer Protection and Commerce.

My name is Nahelani Webster and I am presenting this testimony on behalf of Greenwich Biosciences in **support** of S.B. 1333 SD2 HD1 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 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 this bill 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 an 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.

<u>SB-1333-HD-1</u> Submitted on: 3/30/2021 12:14:55 PM

Testimony for CPC on 4/1/2021 2:00:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing	
John D. Smith	Individual	Support	No	

Comments:

I support.