

DAVID Y. IGE  
GOVERNOR



STATE OF HAWAII  
**DEPARTMENT OF PUBLIC SAFETY**  
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No. \_\_\_\_\_

TESTIMONY ON HOUSE BILL 1893, PROPOSED HOUSE DRAFT 1  
RELATING TO HEALTH

by  
Nolan P. Espinda, Director  
Department of Public Safety

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

Thursday, February 15, 2018; 9:00 a.m.  
State Capitol, Conference Room 329

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

The Department of Public Safety (PSD) offers the following comments on the Proposed House Draft (HD) 1 of House Bill (HB) 1893, which would specify certain activities that shall become lawful, upon approval by the federal Food and Drug Administration (FDA) of one or more prescription drugs containing cannabidiol.

First, the bill is not necessary, because the process of approving new controlled substances, such as the drug containing cannabidiol, once approved by the FDA, is already statutorily established. Prescription drugs containing cannabidiol (cannabidiol drugs), like all other prescription drugs, must undergo an exhaustive approval process by federal agencies. Once the FDA approves a cannabidiol drug for marketing, that cannabidiol drug is then subject to the federal controlled substances scheduling process under the federal Drug Enforcement Administration (DEA). That DEA process is very thorough. At the final conclusion of the DEA scheduling process, the DEA places that FDA approved cannabidiol into a federal drug schedule within the federal Controlled Substances Act. A notice of the DEA's federal scheduling action is then provided by the publication of a "final rule" about that specific FDA approved cannabidiol drug in the

Federal Register. Upon publication in the Federal Register, the cannabidiol drug would be fully approved for public marketing at the federal level.

At our state level, section 329-11(d), Hawaii Revised Statutes (HRS) provides that if a controlled substance is added, deleted, or rescheduled under federal law and notice of that designation is given to PSD, the department shall similarly designate the substance as added, deleted, or rescheduled under chapter 329, HRS, after the expiration of thirty days from publication in the Federal Register of a final order. This is commonly referred to as “temporary designation,” and this has the effect of law temporarily, until the next legislative session, when PSD recommends to the legislature a statutory amendment to make such scheduling permanent and consistent with federal law. If in the next regular session of the state legislature, such corresponding change has not been made in chapter 329, HRS, the temporary designation shall be nullified.

In the case of a cannabidiol drug that both the FDA and DEA have approved for public marketing, and after the expiration of thirty days from publication in the Federal Register, PSD would follow the procedures required under chapter 329, HRS, and temporarily schedule that approved cannabidiol drug. This temporary designation would allow that specific cannabidiol drug to be temporarily available for administration or prescription, as well as the other authorities described in HB 1893, Proposed HD 1, pertaining to possession and transportation by patients, authorized patient representatives, pharmacies, and wholesalers. The temporary designation of that federally approved cannabidiol drug would become permanent after PSD proposes to make changes to chapter 329, HRS, and the legislature passes such a measure into law. As explained above, pursuant to section 329-11(a), HRS, PSD must comply, and has successfully and repeatedly complied, with this process to propose such statutory amendments annually.

Second, PSD believes that if HB 1893, Proposed HD 1 were to pass in its current form, the DEA scheduling process and the statutory mandates outlined in section 329-11, HRS would preclude application of this proposed measure until both the DEA and

state scheduling processes are completed. Significantly, any application of HB 1893, Proposed HD 1 before the DEA and chapter 329-11 processes are completed could subject entities who attempt to administer, dispense, prescribe, transport or possess any cannabidiol drug merely approved by the FDA, to criminal prosecution under federal and state laws.

Thank you for the opportunity to testify on this measure.



**TESTIMONY OF  
THE DEPARTMENT OF THE ATTORNEY GENERAL  
TWENTY-NINTH LEGISLATURE, 2018**

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**ON THE FOLLOWING MEASURE:**

H.B. NO. 1893, PROPOSED H.D. 1, RELATING TO HEALTH.

**BEFORE THE:**

HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES

**DATE:** Thursday, February 15, 2018      **TIME:** 9:00 a.m.

**LOCATION:** State Capitol, Room 329

**TESTIFIER(S):** Russell A. Suzuki, Acting Attorney General, or  
Jill T. Nagamine, Deputy Attorney General

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Chair Mizuno and Members of the Committee:

The Department of the Attorney General opposes the proposed House Draft 1 of this bill.

The proposed House Draft 1 of this bill deleted the contents of the original bill and inserted contents that would add a section to chapter 329, Hawaii Revised Statutes (HRS), to conform State law to prospective federal law. This bill would make it lawful to prescribe, dispense, possess, transport, and use prescription drugs containing cannabidiol if the federal Food and Drug Administration (FDA) approves of one or more prescription drugs containing cannabidiol.

There is no need for this bill. It is premature to enact a law that is contingent on a change in federal law. If and when the federal law changes, section 329-11, HRS, provides a method for the Department of Public Safety to temporarily reschedule a substance. If the federal FDA approves cannabidiol for use in one or more prescription drugs, the Department of Public Safety is already authorized to reschedule those drugs accordingly.

Proposed section 329-\_\_(c), HRS (page 3, lines 5-7), provides that "[n]othing in this section shall be construed to amend, alter, or otherwise restrict access to medical cannabis, recreational marijuana, or both, as authorized under state law." Because there is no State law that authorizes the recreational use of marijuana, the reference to

recreational marijuana should be deleted from that subsection if the Committee decides to advance this bill, to avoid any misleading interpretation.

We respectfully ask this Committee to consider our concerns and hold this bill.

**HB-1893**

Submitted on: 2/13/2018 12:22:58 PM

Testimony for HHS on 2/15/2018 9:00:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Scott Foster	Hawaii Advocates For Consumer Rights	Support	No

Comments:



## **HB1893 Treating Opioid Addiction with Cannabidiol Products**

HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES:

- Representative John Mizuno, Chair; Representative Bertrand Kobayashi, Vice Chair
- Thursday, February 15<sup>th</sup>, 2018: 9:00 a.m.
- Conference Room 329

### **HAWAII SUBSTANCE ABUSE COALITION Opposes HB1893 HD1:**

*GOOD MORNING CHAIR, VICE CHAIR AND DISTINGUISHED COMMITTEE MEMBERS. My name is Alan Johnson. I am the current chair of the Hawaii Substance Abuse Coalition (HSAC), a statewide hui of almost 40 non-profit alcohol and drug treatment and prevention agencies.*

**Doctors can use medical marijuana already to treat opioid misuse; however only treatment agencies, not doctors, treat chronic addiction, which medication-assisted treatment requires extensive testing. Additionally, such treatment centers are busy treating marijuana addiction too.**

**Doctors treat opioid misuse, not opioid addiction. They can utilize medical marijuana already as an option** when they identify opioid misuse. There is some anecdotal evidence, (not thoroughly researched) that “suggests” that medical marijuana used by doctors for opioid misuse may help to reduce overdose. This is an option at the discretion of the treating physician and patient. Patients who misuse need to slow down not necessarily stop, because there is not an uncontrollable use of narcotic drugs. If the patient demonstrates chronic addiction, which is an illness, then they refer to specialized treatment. Medical doctors do not treat their patients for chronic addiction.

**Patients with chronic addiction conditions are referred by medical doctors to specialized treatment centers.** Physical medical doctors don’t treat addiction, which is to say that primary care doesn’t treat chronic opioid use disorders. Specialty care, which is various for-profit or non-profit treatment agencies, are few in number and often have a psychiatrist or psychologist on site to oversee programs.

**Treatment centers are required to follow evidenced-based practices as mandated by international accreditation standards, federal contracts, state government licensure and 3<sup>rd</sup> party payer requirements.**

**Within specialty care for the treatment of drug addiction, marijuana addiction is a major problem.** Licensed and accredited treatment centers report that 22% of adults are there to treat their marijuana addiction. For youth, almost 60% have a problem with marijuana.

**Medications that assist treatment are well researched and have to be approved by federal agencies before using in a treatment environment** in order to minimize any harm to the patients. Unlike the general practice for pharmaceuticals, medications for treatment must first become evidenced-based practices after a preponderance of testing. Circumventing this practice exposes medication-assisted treatment to pharmaceutical practices, which can be abused for profit.

**Community based harm reduction strategies are great for outreach as well as for people that misuse addictive drugs but the preference for helping people with chronic addiction to refer them to treatment.** They operate on the principle that people should be able to use narcotic drugs if they want to, provided they can use them more safely. However the people can't slow down or use safely, then they are referred to formalized treatment services. If the patient refuses addiction treatment, they work with them to try to slow down their use to moderation or at least provide a safer environment.

**Within this approach, there is interest in recommending marijuana for people with chronic additions to opioids to move them to an addiction that is less likely to overdose. However, they can do this by having a physician help them access medical marijuana for pain or other medical issues without having to change laws for specialty treatment centers.**

**There are professional pain management clinics run by anesthesiologists who anecdotally report that they deal with marijuana addiction as well as opioid addiction.** These pain management specialists have obtained training, licensure and certification to treat pain. Treatment centers work with them. Similar to other narcotics such as opioids, marijuana is reported to be helpful in moderation but if heavily used, marijuana overuse leads to an increase in pain sensitivity. So pain management specialists (specialty doctors) require patients to wean off these drugs, including marijuana, which then lowers the patient's reported pain threshold. These powerful drugs, including marijuana, are good only in moderation while heavy use can be detrimental to their pain experience and subject patients to addiction.

**In summary, medical marijuana is already available for primary care doctors and counterproductive for specialty care treatment centers who treat a lot of marijuana addiction in their facilities as well as opioid use disorders.** Moreover, many patients with a chronic addiction disorders overuse any drug because of their brain disease. It is not conducive for evidenced-based treatment that has to meet international accreditation standards, is restricted for federal funds use (such funding is blended with state funding) and opens the door to pharmaceutical abuse in the one area that has been stringently protected from such abuse through extensive research requirements.

**Let's wait a few years for good research, which has the potential to identify certain non-toxic elements in marijuana,** such as CBD, and with good evidence bring it into specialized treatment. In the meantime, medical marijuana is available for pain and as an options for primary care to use for opioid misuse.

We appreciate the opportunity to provide testimony and are available for questions.



**Testimony of Greenwich Biosciences**  
**House Committee on Health and Human Services**  
**Hawaii State Capitol Room 329**  
**RE: HB 1893 proposed HD1**  
**Thursday, February 15, 2018**  
**9 a.m.**

Dear Representative Mizuno and Members of the Committee:

Mahalo for the opportunity to testify in **strong support of HB 1893 proposed HD1.**

- The FDA has recently fast-tracked their review of Epidiolex, a drug for rare forms of pediatric epilepsy, including Dravet Syndrome. Epidiolex contains the marijuana derivative cannabidiol or CBD, and if approved by the FDA, it will be the first and only prescription medicine approved for children with Dravet Syndrome, and the first ever botanically derived medicine containing a marijuana extract to gain FDA approval.
- Approval by the FDA could come as early as June of this year, and without this bill, severely ill epileptic kids in Hawaii may not have access to a prescription medicine approved by the FDA and prescribed by their doctors. Current Hawaii law may prohibit doctors and pharmacies from prescribing and dispensing FDA approved products that are derived from cannabis or contain marijuana extracts, like Epidiolex.
- In Hawaii, H.R.S. section 329-131 of the uniform controlled substances act prohibits prescription requirements of section 329-38 and pharmacy licensure requirements, chapter 461, from being applied to the medical use of marijuana. Therefore, as you may not apply pharmacy or prescriptive authority to marijuana, we are concerned anything under the definition of marijuana may not be prescribed or issued through a pharmacy.
- H.R.S. [§329-131] .Prescription and pharmacy requirements not applicable. Notwithstanding any other law to the contrary, the prescription requirements of section 329-38 and the board of pharmacy licensure or regulatory requirements under chapter 461 shall not apply to the medical use of marijuana under this part. [L 2015, c 241, pt of §5]
- This bill is an addition to Hawaii pharmacy law that will not affect Hawaii's existing medical marijuana laws, it simply creates an additional pathway that will allow FDA approved medicines containing marijuana or marijuana extracts to be dispensed in Hawaii pharmacies and prescribed by doctors.

- Marijuana's status as a Schedule I Drug at both the state and federal levels necessitates this bill. If the FDA approves Epidiolex or any other medicine containing marijuana extracts, by law the DEA will have to remove that particular drug formulation from Schedule I and place it in Schedules II-V, so the drug can be lawfully distributed throughout the United States. All 50 states also have their own drug schedules and as a result, any drug moving out of Schedule I and into a lower drug Schedule must also be rescheduled and/or decriminalized at the state level. In the case of Epidiolex, Greenwich Biosciences is pursuing these necessary pharmacy and criminal law changes in every state, so pediatric epilepsy patients can access this prescription medicine as soon as possible following FDA approval.

Thank you for hearing this measure, and we respectfully request your support for HB 1893 proposed HD1, to clearly and lawfully allow for the prescribing and dispensing of FDA approved products that contain CBD.

### **Additional Background Info**

- Currently Epidiolex is being studied in 5 different phase 3 clinical trials with more than 50 leading epilepsy investigators throughout the United States, involving more than 800 children with three different forms of severe and debilitating pediatric epilepsy.
- GW grows various cannabis varieties that are bred to maintain a precise chemical composition; the plants are cultivated under rigorously-controlled conditions, and the active components are extracted with liquid CO2. In the case of Epidiolex, we put the CBD extract through a purification process involving milling, decarboxylation and winterization to remove the THC.
- As you are probably aware, THC is the primary psychoactive component of the marijuana or cannabis plant, whereas CBD is non-psychoactive and possesses anti-convulsant properties that making purified CBD effective in treating severe seizure disorders without psychoactive effect.
- It is important to note that as Epidiolex was being developed, the naturally occurring THC in the GW's CBD rich cannabis strain was intentionally removed due to evidence of impaired cognition and developmental delays in children exposed to THC.
- Epidiolex has both Orphan Drug Designation and Fast Track Designation from the FDA due to the lack of effective treatment options and rarity of these severe forms of pediatric epilepsy.

- Our Fast Track status means Epidiolex could be approved and on the market by the Fall of 2018.
- The DEA has indicated upon FDA approval of a CBD based drug like Epidiolex they will reschedule cannabidiol in the exact pharmaceutical formulation approved by the FDA in Schedule IV or V, and they will not be rescheduling all of CBD, marijuana or any other derivative of marijuana;
- All marijuana related scheduling outside of a very narrow purified pharmaceutical formulation of CBD will remain, and current state level access to non- prescription marijuana, CBD and any of its derivatives will remain unchanged by this bill, including medical marijuana and CBD products obtained under the Hawaii Medical Marijuana Program.
- Even in states like Colorado with full legal marijuana, it is unlawful for a pharmacy to dispense and a provider to prescribe any prescription medication that contains marijuana or its derivatives. Epidiolex is a prescription medication that will only be prescribed by doctors, dispensed at licensed pharmacies and covered by insurance, and therefore it cannot and will NOT be sold at marijuana dispensaries or available online.
- This bill is a technical and narrow bill to provide access to a new class of medications for a very small group of children with severe epilepsy in Hawaii.
- This bill will apply to all FDA approved prescription CBD medications and not only to GW Pharma. Once GW does the hard work of achieving rescheduling at the federal and state levels, other companies developing prescription cannabis based medications will receive the benefit of our efforts.
- Currently there are two other U.S. based pharmaceutical companies, Insys and Zynerva, developing prescription cannabidiol or CBD drugs to treat a variety of conditions including epilepsy, autism, cancer pain and MS.
- **We would like to ask you again for your support of HB 1893 proposed HD 1, to ensure immediate access for Hawaii families to timely and life-saving drugs like Epidiolex upon FDA approval and DEA rescheduling. If we do not enact this bill, it is very likely families in Hawaii could have to wait until the spring or summer of 2019 to gain access to Epidiolex and that is time many of these families simply do not have. Thank you again for your time and consideration.**



February 13, 2018

The Honorable John M. Mizuno  
Hawaii State Capitol, Room 329  
Honolulu, HI 96813

Dear Chair Mizuno and Members of the House Committee on Health & Human Services:

On behalf of the Epilepsy Foundation and our local affiliate, Epilepsy Foundation of Hawaii, we urge you to support House Bill 1893 as amended by HD1, which would allow therapies derived from cannabidiol (CBD) and approved by the Food and Drug Administration (FDA) to become available to patients. Access to new therapies is particularly important for the one third of people living with epilepsy who experience intractable or uncontrolled seizures and are living with rare epilepsies, and the many more who experience significant adverse effects from their current medication.

The FDA is currently reviewing at least one CBD derived therapy that shows promise for the treatment of Dravet and Lennox-Gastaut syndromes (LGS), tuberous sclerosis complex (TSC) and potentially other rare epilepsies. This potential treatment option has both Orphan Drug Designation and Fast Track Designation from the FDA and could be approved as soon as early 2018. After FDA approval, the Drug Enforcement Administration (DEA) would schedule the therapy through administrative action and the medication would become available for patients. However, since CBD is a Schedule I substance under the state drug schedule, state action is needed to ensure proper rescheduling of FDA-approved therapies derived from CBD. Unless Hawaii acts, patients will not have access to these new therapies. This is an issue of creating access to FDA-approved, prescription drugs and we strongly urge your support of HB1893 as amended by HD1.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of the at least 3.4 million Americans, including nearly 13,000 Hawaii residents, with epilepsy and seizures. 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 for epilepsy, and about a third of people living with epilepsy suffer from uncontrolled or intractable seizures, with many more living with significant side-effects, despite available treatments. Uncontrolled seizures can lead to disability, injury, and even death.

The Epilepsy Foundation and the 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 patients gaining access to proven and potentially lifesaving treatment once they have been reviewed and approved by FDA. We urge your support of HB1893 as amended by HD1. Please do not hesitate to contact Angela Ostrom, Chief Legal Officer & Vice President Public Policy, at 301-918-3766 or aostrom@efa.org with any questions or concerns.

Sincerely,

Handwritten signature of Naomi Manuel in black ink.

Naomi Manuel  
Executive Director  
Epilepsy Foundation of Hawaii

Handwritten signature of Philip M. Gattone in black ink.

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

February 14, 2018

The Honorable Rep. John M. Mizuno  
Hawaii State Capitol, Room 439  
Honolulu, HI 96813

Dear Chair Mizuno and Members of the House Health and Human Services Committee:

On behalf of the epilepsy community, we, the undersigned organizations, urge you to support ~~HB 1093 HD1~~ ~~Senate Bill 18-1187~~ which would allow therapies derived from cannabidiol (CBD) and approved by the Food and Drug Administration (FDA) to become available in the state. Access to new therapies is particularly important for the one third of people living with epilepsy who experience intractable or uncontrolled seizures and are living with rare epilepsies, as well as the many more who experience significant adverse effects from their current medication.

Our organizations represent the more than 3.4 million Americans living with epilepsy and seizure disorders. Together we foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. We have seen firsthand the devastation that uncontrolled seizures can bring, including developmental delays, medical complications, and even death. This is why, as organizations that represent individuals living with severe forms of epilepsy and uncontrolled seizures, we are committed to exploring and advocating for all potential treatment options for epilepsy, including new and innovative treatments approved by the FDA.

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 and about one million people live with uncontrolled or intractable seizures. Uncontrolled seizures can lead to disability, injury, and even death, and many individuals living with uncontrollable seizures suffer from rare epilepsies characterized by seizures that are difficult to treat with existing treatment options. Access to new treatments is particularly important for these individuals, who live with the continual risk of serious injuries and loss of life.

Greenwich Biosciences is developing a treatment derived from CBD that shows promise for the treatment of Dravet and Lennox-Gastaut syndromes (LGS), tuberous sclerosis complex (TSC), and potentially other rare epilepsies. Epidiolex has both Orphan Drug Designation and Fast Track Designation from the FDA for Dravet syndrome and also Orphan Drug Designation for LGS and tuberous sclerosis complex (TSC). We are hopeful that Greenwich Biosciences' Epidiolex will help individuals living with rare epilepsies, and urge you to pass Senate Bill 18-1187 which would help ensure timely access to this promising treatment option if it gains FDA approval. Acting now would ensure that there are no delays between the time the FDA approves and the DEA scheduled Epidiolex, and when individuals living with rare epilepsies can access this treatment option.

Since CBD is a Schedule I substance, state action is needed to ensure proper scheduling and timely access for FDA-approved therapies derived from CBD. Unless ~~Senate Bill 18-1187~~ is

~~HB 1093 HD1~~

passed, Epidiolex would not be made available to individuals living with uncontrolled seizures associated with Dravet, LGS, and TSC in Colorado.

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). There are currently no FDA-approved treatments for Dravet, and nearly all patients continue to have uncontrolled seizures and other medical needs throughout their lifetime.

Lennox-Gastaut syndrome (LGS) 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 FDA-approved treatments for LGS, many individuals living with this rare epilepsy do not achieve seizure control and experience related cognitive impairments that severely limit quality of life.

Tuberous Sclerosis Complex (TSC) is a genetic disorder that causes several types of seizures, and the formation of tumors in many different organs, primarily in the brain, eyes, heart, kidney, skin and lungs. Infants are often diagnosed with TSC after experiencing infantile spasms, which lead to developmental delays, intellectual disability and autism. Older children and adults may develop multiple types of seizures including generalized, complex partial, and other focal seizures. Nearly 90 percent of people living with TSC have epilepsy and experience a variety of seizure types, and more than half don't respond to epilepsy medications.

We urge you to support <sup>HB 1893 CD1</sup> ~~Senate Bill 18-1187~~ which would allow therapies derived from CBD and approved by the FDA to become available to Colorado residents living with epilepsy.

Bureaucratic processes should not stand in the way of patients gaining access to proven and potentially lifesaving treatment once they have been approved and reviewed by the FDA. Please do not hesitate to contact Angela Ostrom, Chief Legal Officer & Vice President Public Policy at the Epilepsy Foundation, at 301-918-3766 or aostrom@efa.org with any questions or concerns.

Sincerely,

Dravet Syndrome Foundation  
Epilepsy Foundation  
Epilepsy Foundation of Hawaii  
Lennox-Gastaut Syndrome Foundation  
Tuberous Sclerosis Alliance

February 14, 2018

Chair Mizuno, Vice Chair Kobayashi and members of the Health Committee.

We are writing to support House Bill 1893 HD1. We live on Maui and are not able to attend in person.

Our 28 year old son has Dravet Syndrome which is a rare and catastrophic type of epilepsy. His seizures started before age 2 and have progressed, worsening over the years. He may have anywhere from 5-40+ tonic clonic (grand mal) seizures a day. We have run out of treatment options. Working with our neurologist, we have tried medications that were not FDA approved, available only in other countries, not covered by insurance, and often costing us thousands of dollars a month. Unfortunately, like other medications tried, there was little or no effect and the seizures continued.

CBD (cannabidiol) oil has been the only therapy that has had a significant impact on his seizures. A very small amount of CBD oil at night has decreased his seizures by approximately 40-50%. We get the product from a reputable source but there are always concerns about quality control, availability, and accessibility, particularly in this uncertain political environment.

We are looking forward to FDA approval of Epidiolex not just for our son but the many others who live with disabling and often life threatening seizures. We are most grateful that our son has reached his 28<sup>th</sup> birthday but we know that some will not be as lucky. About 10-20% of people with Dravet Syndrome are estimated to pass away before adulthood, with most premature deaths occurring before 10 years of age. Families like ours live with the fear of premature death such as SUDEP (sudden unexpected death by epilepsy). Epidiolex gives us hope that our son can live a long and happy life.

Please support this bill and allow Hawaii patients access to this therapy. Please remove any barriers that would get in the way between our kids and possibly life saving treatment. Thank you for this opportunity to speak on this issue.

Sincerely,  
Keith E. Tanaka, parent  
Joanne C. Tanaka, parent  
Wailuku, HI

**HB-1893**

Submitted on: 2/12/2018 10:21:13 PM

Testimony for HHS on 2/15/2018 9:00:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Jari S.K. Sugano	Individual	Support	No

Comments:

Chair Mizuno, Vice Chair Kobayashi and members of the Health committee.

Thank you for this proposal of HB1893 HD1. I apologize for not being present to personally testify on this bill.

My 9 year old daughter is one of a handful of patients living in Hawaii with a diagnosis of Dravet Syndrome. Dravet syndrome is a rare and catastrophic form of epilepsy. We are no strangers to evaluating orphan drugs or therapies that received a FDA fast track designation. However, we often have to work with physicians outside of the state to obtain access.

We are always looking for new therapies that can bring relief to her condition. Epidiolex, a cannabidiol (CBD) pharmaceutical product, was initially evaluated for patients with Dravet and Lennox-Gastaut syndrome but it has huge implications for many living with epilepsy in Hawaii.

Data from published clinical trials showed that many children with intractable seizures reaped tremendous benefit from this cannabis-derived drug currently being evaluated by the FDA.

It is expected that the FDA / DEA will approve and reschedule this new line of therapy for children with intractable seizures, however, I would hate for the state's definition of medical cannabis to prohibit or interfere with timely sales in Hawaii.

The language in HN1893 HD1 would clarify the state's position on this newly anticipated FDA option for those who desperately need access to an affordable, cannabis product, covered by insurance. I would suggest that the bill be amended to specify that patients with a legal Epidiolex prescription do not have to obtain a DOH 329 card for access.

We fought hard for Act 241 with high hopes that the dispensary system would be the solution for our child. However, the products coming out of dispensaries are not in line with what our child needs. Due to the intractable nature of her seizure disorder, quality, consistent dosing and affordability is key.



Passage of this bill would streamline access to a pharmaceutical grade, CBD product and minimize the unnecessary red tape for patients patiently waiting for an affordable and sustainable option.

Jari S.K. Sugano

Cannabis caregiver of a minor since 2013

Medical Marijuana Working Group Member

Act 230 Working Group Member

**HB-1893**

Submitted on: 2/13/2018 11:53:00 AM

Testimony for HHS on 2/15/2018 9:00:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Earl Yamamoto	Individual	Oppose	No

Comments:

Strong concerns

Hearing posted at 9:07 pm Monday, February 12th, allowing less than 12 hours before timely testimony submittal deadline of 9:00 am tuesday morning.

I recommend following amendment.

Page 3, line7

Delete "recreational marijuana, or both"

Enough attention is being spent by this legislature on medical marijuana. Don't create laws anticipating legalization of a presently illegal substance.

**HB-1893**

Submitted on: 2/13/2018 7:49:17 AM

Testimony for HHS on 2/15/2018 9:00:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Teri Heede	Individual	Oppose	No

## Comments:

The lack of understanding regarding CBD and how it works with THC components in the plant is appalling.

The legislature's impulse to run to BIG PHARMA for solutions is appalling (you know, they are the ones that are proven to have contributed to the opioid crisis).

It is time that we STOP CRIMINALIZING patients and promoting PROFITS B4 PATIENTS.

As written, this bill is unsupportable as a benefit to patients.

**HB-1893**

Submitted on: 2/13/2018 8:12:18 AM

Testimony for HHS on 2/15/2018 9:00:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Stuart Coleman	Individual	Support	No

Comments:

Mahalo for your consideration and support of this bill.

Aloha, Stuart Coleman

**LATE**

**HB-1893**

Submitted on: 2/14/2018 5:09:50 PM

Testimony for HHS on 2/15/2018 9:00:00 AM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Shari R. Lynn	Individual	Oppose	No

Comments:

Now that using marijuana medically is legal, it appears it is the magic cure for everything. (So was Snake-oil at one time). In thinking about using marijuana as a MAT component, I am scratching my head because it seems a lot like it might have been if we were using alcohol (also with many positive and negative brain function interactions) to treat another drug addiction. Just because it's legal, does not make it appropriate. In my opinion, it's still like trading seats on the Titanic. More research with longitudinal studies is imperative before uncapping this magic cure.

**LATE**

**HB-1893**

Submitted on: 2/14/2018 8:49:02 PM

Testimony for HHS on 2/15/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
William Haning, MD	Hawai`i Society of Addiction Medicine	Oppose	No

Comments:

Testimony OPPOSING HB1893:

Respected Members of the Committee:

I testify on behalf of the Hawai`i Society of Addiction Medicine, a chapter of the American Society of Addiction Medicine, in opposition to this measure. Any of the commentary in my name below may be included in submissions from other individuals or organizations, in an effort to assure timely submission. If so, I apologize for any duplication.

HB1893 seeks to amend Hawaii revised statute 329 – 121, definitions, which relate specifically to the prescription of cannabis (“marijuana”). The emendation is specifically to add opioid use disorders to the list of indications for prescription of cannabis. The added indication is described as, “opioid use disorder.” “*Cannabis*” in other versions of this bill has been modified to, “...various forms of non-psychoactive, high cannabidiol products...that do not contain a significant amount of tetrahydrocannabinol.”

The implications of this amendment are as follows: 1. Cannabis may or even should be used in the management of opioid use disorder, whether in the withdrawal phase or at other points on the timeline of recovery. 2. Cannabis efficacy has been demonstrated in such treatment. 3. Cannabis is implicitly safe for use in the management of substance use disorders.

Contrary concerns:

1. None of these implications above has been convincingly shown to be true.

2. While not stated, there is a higher moral purpose imputed by this

bill coming before the Legislature, relief of suffering. While that

purpose is commendable, its achievement must include procedures

for validating both efficacy and safety. The history of medicine is replete with examples of raw plants (slippery elm, cinchona bark, foxglove, *papaver somniferum*) which contain therapeutically useful substances (aspirin, quinine, digitalis, morphine) but which are themselves toxic and inconsistent in content. A medication's dynamics, effects, safe therapeutic range and route of delivery, and adverse effects must be known before it is used. Otherwise it is unregulated research with an uninformed subject.

3. By acknowledging substance use disorders, and specifically opioid use disorders, as chronic or debilitating diseases does not automatically qualify them for management with cannabis. This is equally true of other chronic, disabling illnesses. The indications for treatment with a pharmaceutical agent are efficacy and demonstrated safety.

4. There is no body of evidence that compellingly supports the use of cannabis or its components in the management of opioid use disorders. The requirements of such research are: respect for persons; beneficence; and justice.

a. In the absence of adequate studies supporting such use, and without any formal research proposals seeking justification, this legislative proposal constitutes uncontrolled and unregulated research in humans.

b. Human subjects research must conform to The Common

Rule, which addresses in detail the requirements for ethical research. The Common Rule provides guidance for the federal Health Resources and Services Administration (HRSA) in its determination of safe research practices.

c. The representation of a substance as a “medication” obliges a long journey, from basic bench research, animal trials, human trials, determination of toxicological limits, through the hands of a trained and licensed pharmacist, to a physician. Anything less by way of process risks reacting to a need with a fantasy. *My patients with substance use disorders – your friends and relatives – have an illness, and deserve the same respect in meeting their needs as those with diabetes or cancer.* That respect includes offering medications that meet the same standards of development and testing as insulin and chemotherapy.

d. Finally, our foremost objection is this: Use of an unvalidated treatment approach will reliably derail those seeking care from receipt of appropriate and validated medications, based on our experience with many other such substitutions (in oncology, in behavioral health, others). Those with substance use disorders are particularly vulnerable to offers of a quick fix, particularly one with the possibility of euphoria. For opioid use disorders, these medications with known effectiveness include methadone, buprenorphine, and naltrexone.

1. note that even the modification of *cannabis* to "...various forms of non-psychoactive, high cannabidiol products...that do not contain a *significant* [italics mine – wfh] amount of tetrahydrocannabinol," is not meaningful without a quantitative specification of “significant”. The monitoring of this quantity, whatever it should prove to be, creates complications that only underscore the complexity of the task of safely creating and monitoring medications for usefulness. Treatment of substance use disorders in any case is not a matter of solely giving medication, but obliges consideration of psychosocial, behavioral, and even spiritual approaches. It is a discipline of medicine and not a casual undertaking.



In separate submissions, the legislature has been encouraged to support research which determine both the safety and efficacy of the component chemicals within cannabis. That encouragement should be preserved even while declining to enact this bill.

Very respectfully,

W. F. Haning, III, MD, DFASAM, DFAPA