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

ON THE FOLLOWING MEASURE:
H.B. NO. 1893, H.D. 1, RELATING TO HEALTH.

BEFORE THE:
SENATE COMMITTEE ON PUBLIC SAFETY, INTERGOVERNMENTAL, AND MILITARY AFFAIRS

DATE: Tuesday, March 13, 2018 **TIME:** 1:30 p.m.

LOCATION: State Capitol, Room 229

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

Chair Nishihara and Members of the Committee:

The Department of the Attorney General opposes this bill.

This bill would add a section to chapter 329, Hawaii Revised Statutes (HRS), to conform State law to prospective federal law. It 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.

At the hearing on this bill in front of the House Committee on Health and Human Services, questions arose whether section 329-131, HRS, would prohibit the Department of Public Safety from approving the medical use of cannabidiol if that substance is approved by the federal FDA, and whether that section would prohibit a pharmacy from dispensing a cannabis-derived product, even if it is FDA-approved and appropriately scheduled in Hawaii. The answer to both of those questions is no. Section 329-131, HRS, provides:

> 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 cannabis under this part.

The referenced "part" is chapter 329, part IX, the medical use of cannabis. Section 329-131, HRS, does not exempt or prohibit the use of cannabis or marijuana products under other parts of the law. Its effect is specifically limited to the medical use of cannabis under part IX of chapter 329, and it means that the medical use of cannabis pursuant to chapter 329, part IX, is not subject to prescription requirements or pharmacy licensure or regulatory requirements found elsewhere in the law.

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

DAVID Y. IGE
GOVERNOR

NOLAN P. ESPINDA
DIRECTOR

Cathy Ross
Deputy Director
Administration

Jodie F. Maesaka-Hirata
Deputy Director
Corrections

Renee R. Sonobe Hong
Deputy Director
Law Enforcement

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

No. _____

TESTIMONY ON HOUSE BILL 1893, HOUSE DRAFT 1
RELATING TO HEALTH
by
Nolan P. Espinda, Director
Department of Public Safety

Senate Committee on Public Safety, Intergovernmental, and Military Affairs
Chair Clarence K. Nishihara, Chair
Chair Glenn Wakai, Vice Chair

Tuesday, March 13, 2018; 1:30 p.m.
State Capitol, Conference Room 229

Chair Nishihara, Vice Chair Wakai, and Members of the Committee:

The Department of Public Safety (PSD) offers the following comments on House Bill (HB) 1893, House Draft (HD) 1, 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, 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, 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, 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.

EPILEPSY FOUNDATION

March 12, 2018

The Honorable Clarence K. Nishihara
Hawaii State Capitol, Conference Room 229
Honolulu, HI 96813

Dear Chair Nishihara and Members of the Committee on Public Safety, Intergovernmental, and Military Affairs:

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 (LSC) 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 summer 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 for House Bill 1893, as amended by HD 1.

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 House Bill 1893, as amended by HD 1. 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,

Naomi Manuel
Executive Director
Epilepsy Foundation of Hawaii

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

8301 Professional Place East, Suite 200
Landover, MD 20785-2353
1-800-332-1000
301-459-3700
FAX: 301-577-2684
epilepsy.com

March 12, 2018

The Honorable Clarence K. Nishihara
Hawaii State Capitol, Conference Room 229
Honolulu, HI 96813

Dear Chair Nishihara and Members of the Committee on Public Safety, Intergovernmental, and Military Affairs:

On behalf of the epilepsy community, we, the undersigned organizations, 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 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 House Bill 1893 as amended by HD1 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 House Bill 1893 as amended by HD1 is passed, Epidiolex would not be made available to individuals living with uncontrolled seizures associated with Dravet, LGS, and TSC in Hawaii.

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 House Bill 1893 as amended by HD1 which would allow therapies derived from CBD and approved by the FDA to become available to Hawaii 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

Testimony of Greenwich Biosciences
Senate Committee of Public Safety, Intergovernmental, and Military Affairs
Tuesday, March 13, 2018
1:30 p.m.

Dear Chair Nishihara and Members of the Committee:

My name is Stacy Evensen testifying on behalf of Greenwich Biosciences. Thank you for the opportunity to testify in **support of HB 1893 HD 1 with a proposed amendment.**

Greenwich Biosciences is a biopharmaceutical company that has developed a new cannabis-derived therapy used in treating children with intractable epileptic seizures. This drug, Epidiolex, is currently in the final phase of clinical trials and is expected to be approved by the federal Food and Drug Administration (FDA) for use this summer. The Drug Enforcement Agency (DEA) has indicated they will reschedule the drug in Schedule IV or V. We expect that Hawaii will follow suit. When this occurs, Epidiolex will be the first CBD prescription drug product to be so approved and scheduled. There are many other drug formulations in the pipeline that are also expected to be approved. While this is wonderful news for the families of these severely ill epileptic children, without a change in Hawaii law, there is a concern that children in Hawaii may still not have access to these new drugs.

The concern stems from the provision in HRS section 329-131 of the Uniform Controlled Substances Act that prohibits the prescription requirements of section 329-38 and pharmacy licensure requirements, Chapter 461, from being applied to the medical use of cannabis.

At the hearing in the House Health Committee, the Attorney General's office was asked to opine on whether the statutes referenced above **exempted** or **prohibited** access to an FDA-approved cannabis-derived prescription drug. Their analysis was that it did neither. However, the Attorney General's office recognized that there may be a "question as to the impact of section 329-131, HRS, on the ability to market, approve, prescribe, and use, in Hawai`i, a federally approved drug containing marijuana or a marijuana derivative." The Attorney General's opinion proposed an amendment to address this concern: "We suggest adding the following sentence to the definition of "cannabis" found in section 329-121:

> ***This definition of cannabis does not include drugs that are specifically approved for marketing to the public by the appropriate federal government agencies."***

We believe this amendment is an elegant remedy to the conundrum that exists in statute currently and **respectfully request that the committee amend HB 1893 HD 1 by replacing its contents with the language suggested in the Attorney General's opinion letter (attached) to make clear that prescribing and dispensing FDA approved products that contain CBD is lawful once appropriately scheduled in Hawaii.** Mahalo for the opportunity to testify.

DAVID Y. IGERUSSELL A. SUZUKI
GOVERNORACTING ATTORNEY GENERAL
STATE OF HAWAII
DEPARTMENT OF THE ATTORNEY GENERAL
425 QUEEN STREET
HONOLULU, HAWKI 96813
(808) 586-1500

February 21, 2018

The Honorable John M. Mizuno
Chair, House Committee on Health and Human Services
The Twenty-Ninth State Legislature State
Capitol, Room 439
415 Beretania Street
Honolulu, Hawai'i 96813

Re: Committee Questions Related to
H.B. No. 1893, Relating to Health,
Considered on February 15, 2018

Dear Chair Mizuno:

Your Committee on Health and Human Services posed two questions to the Department of the Attorney General as referenced in its Standing Committee Report No. 727, dated February 16, 2018, regarding H.B. No. 1893. We also received a third clarifying question by email, through your committee clerk, Charles St. Sure. We answer all three questions, as they are slightly different. The questions and short answers are as follows:

(1) Does section 329-11, Hawaii Revised Statutes (HRS), authorize the Department of Public Safety (PSD) to approve the medical use of cannabidiol upon U.S. Food and Drug Administration (FDA) approval?

Short Answer: As with any drug approved by the FDA, section 329-11, HRS, provides the procedure by which PSD would schedule an FDA-approved drug for prescriptive use, including a drug that contains

cannabidiol. However, approval by the FDA is not the only approval that is needed before scheduling can occur, as explained further below.

(2) Does section 329-1[3]1, HRS, prohibit the Department of Public Safety from approving the medical use of cannabidiol?

Short Answer: No, PSD is not prohibited from approving, or more properly "scheduling," a product containing cannabidiol for medically prescribed use, provided that the requirements set forth in section 329-11, HRS, are followed.

(3) Does section 329-131, HRS, merely exempt cannabisderived products from the requirement of the prescription and pharmacy dispensing laws or do they actually prohibit a pharmacy from dispensing a cannabis-derived product, even if it is FDA-approved and appropriately scheduled in Hawai'i?

Short Answer: Section 329-131, HRS, does neither. Section 329-131 merely provides that for cannabis provided under part IX, chapter 329, the prescription requirements of section 329-38 and the board of pharmacy licensure or regulatory requirements of chapter 461, HRS, do not apply.

ANALYSIS:

In Hawai'i, there are two ways to allow the use of a product containing cannabidiol (a marijuana derivative) or any other marijuana[1], as that term is defined in section 329-1, HRS. Those methods are found in chapter 329, HRS. The older, traditional method, which follows federal laws, rules, and regulations, is generally found in parts I through VIII of chapter 329, HRS. Federal law requires approval by both the FDA and the U.S. Drug Enforcement Administration (DEA) before a drug can be scheduled for prescriptive use, prescribed, and dispensed under those parts of chapter 329. Versions of these laws have been adopted nationwide.

Part IX of chapter 329, HRS, regarding medical use of cannabis, allows for a different method to be followed for the use of products

containing marijuana for certain medical conditions. Section 329-131, HRS, which is the last statute in part IX, states:

> 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 cannabis under this part. [Emphasis added.]

We note that the term "marijuana" is used for the purposes of parts I through VIII of chapter 329, HRS, while part IX of chapter 329 uses the term "cannabis." The definition of "cannabis" in part IX refers to the definition of "marijuana" in section 329-1 , HRS. The terms "marijuana" and "cannabis" are thus references to the same thing. For the purpose of this letter we use the term referenced in the section of the law we discuss.

We read "under this part" to mean that the requirements of section 329-38 and chapter 461, HRS, are not required, if the requirements set forth in part IX of chapter 329, HRS, are followed. This wording does not exempt or prohibit the use of marijuana products under other parts of the law. Its effect is specifically limited to medical use of cannabis under part IX of chapter 329.

Despite the foregoing, we appreciate that some may continue to question the impact of section 329-131, HRS, as some already have, on the ability to market, approve, prescribe, and use, in Hawai'i, a federally approved drug containing marijuana or a marijuana derivative. To address this concern, we suggest adding the following sentence to the definition of "cannabis" found in section 329-121:

> This definition of cannabis does not include drugs that are specifically approved for marketing to the public by the appropriate federal government agencies.

The effect of this provision would be to require the application of parts I through VIII of chapter 329 to the marketing, approval, prescription, and use of federally approved drugs containing cannabidiol or any other marijuana derivatives. The process established for the medical use of cannabis set forth in part IX would not apply. The provisions of part IX do not satisfy the strict regulations required by the FDA and DEA. We, therefore, do not believe that the carving out of federally approved drugs from part IX would impact those involved in the certification for, or use of, marijuana under the State's current medical use of cannabis laws.

We hope that the foregoing answers the questions of the Committee. If there are any further questions, please do not hesitate to contact me at 5872978.

Very truly yours,

Diane R. Taira
Deputy Attorney General

APPROVED:

Russell A. Suzuki
Acting Attorney General

c: Representative Scott Y. Nishimoto
Chair, House Committee on Judiciary
Members, House Committee on Health and Human Services

719848_3 DOC

March 11, 2018

Chair Nishihara, Vice Chair Wakai and members of the Public Safety, Intergovernmental and Military Affairs.

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 28th 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

Testimony for HB 1893 HD 1 – Naomi Manuel, Executive Director, Epilepsy Foundation of Hawaii

- My name is Naomi Manuel and I am the Executive Director for the Epilepsy Foundation of Hawaii, which represents approximately 13,000 Hawaiian residents living with epilepsy and seizures.
- I come before the committee today to express support for House Bill 1893, as amended by HD 1, which would allow therapies derived from cannabidiol (CBD) and approved by the Food and Drug Administration to become available to patients in a timely manner.
- Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions.
    - Nearly 3 million Americans live with epilepsy, and 1 in 26 Americans will develop epilepsy at some point in their lifetime.
    - For the majority of them, epilepsy medications are the most common and most cost-effective treatment for controlling and/or reducing seizures, and they must have meaningful and timely access to physician directed care.
- 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.
    - Uncontrolled seizures can lead to disability, injury, and even death. This is why people living with uncontrolled seizures look to every newly approved FDA therapy with hope.
- Therapies derived from CBD show promise for people living with uncontrolled seizures and rare epilepsies, and we are encouraged that there are at least two potential therapies pursuing FDA approval.
    - If and when these therapies are approved by the FDA, it will be established that they are safe and effective for some epilepsy types. It will then be an issue of access to a prescription drug—no different than all other FDA-approved therapies.
- The issue lies with state drug schedules that will not automatically change even with FDA approval. Hawaii needs to implement changes to these state scheduling laws for the therapies to become available in the state. In many states, this change can be accomplished through administrative action; however, Hawaii law requires that a law be enacted to make the change.
- If Hawaii does not take action, Hawaiian residents living with epilepsy will not have access to FDA approved therapies derived from CBD.

    - This delay could mean an FDA approved therapy for a rare epilepsy available in other states would not be available here in Hawaii. Also, families currently obtaining the medication as part of a clinical trial would lose access to the medication.
- 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 the legislature to support House Bill 1893, as amended by HD 1, and begin now to take steps to eliminate any barriers that would delay the entry for an FDA approved therapy derived from CBD into the marketplace.
- We are hopeful that new therapies derived from CBD will help individuals living with uncontrolled seizures and rare epilepsies, and hope the state will ensure there is a pathway for access to all FDA approved therapies.
- Please stand with the epilepsy community and approve House Bill 1893, as amended by HD 1, to help us gain timely access to FDA-approved therapies.