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 Senate 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 Senate 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 Senate 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 Senate 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