February 5, 2018

The Honorable Jerry Hill
State Capitol, Room 5035
Sacramento, CA 95814

Dear Chair Hill and Members of the Senate Business, Professions and Economic Development Committee:

On behalf of the epilepsy community, we, the undersigned organizations, urge you to support Assembly Bill 710 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, as well as the many more who experience significant adverse effects from their current medication.

Our organizations represent the more than 3 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), 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), another type of rare epilepsy. We are hopeful that Greenwich Biosciences' Epidiolex will help individuals living with rare epilepsies, and urge you to pass Assembly Bill 710 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 Epidiolex and when individuals living with rare epilepsies can access this treatment options.

Since pure CBD is a Schedule I substance under most state controlled drug laws, state action to ensure proper rescheduling of FDA-approved treatments derived from CBD would need to happen before then to ensure timely access for individuals living with rare epilepsies and no treatment options. Unless Assembly Bill 710 is passed to ensure access to new treatments derived from CBD that are approved by

FDA and scheduled by DEA, Epidiolex would not be made available to individuals living with uncontrolled seizures associated with Dravet and LGS in California.

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.

We urge you to support Assembly Bill 710 which will allow therapies derived from CBD and approved by the FDA to become available to patients in California. 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 301-918-3766 or aostrom@efa.org with any questions or concerns.

Sincerely,

Epilepsy Foundation
Lennox-Gastaut Syndrome Foundation
Tuberous Sclerosis Alliance