August 31, 2016

Cody C. Widberg
Executive Director
Minnesota Board of Pharmacy
2829 University Ave. SE Suite 530
Minneapolis, MN 55414-3251

Dear Mr. Widberg,

On behalf of the epilepsy community, we, the undersigned organizations, urge you to support changes to state law to ensure access to Food and Drug Administration (FDA) approved therapies. The changes are necessary for timely access to medications derived from cannabidiol (CBD) once approved by the FDA and scheduled by the Drug Enforcement Agency (DEA).

We are hopeful that CBD derived therapies will help individuals living with rare epilepsies, and urge the Minnesota Board of Pharmacy to begin to explore changes in state law that may be necessary to ensure access to these promising treatment options once approved by the FDA. Acting now would protect patients and families. If the state fails to act, individuals would not be able to access these newly approved FDA therapies at pharmacies in the state or through their health insurance plan.

Our organizations represent the 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 uncontrolled 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.

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 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 the 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.

The FDA is currently reviewing at least one CBD derived therapy (Epidiolex) that shows promise for the treatment of Dravet syndrome, Lennox Gastaut syndrome, Tuberous Sclerosis Complex (TSC), and other rare epilepsies. This potential treatment option has both Orphan Drug Designation and Fast Track Designation from the FDA for Dravet syndrome and also Orphan Drug Designation for LGS and TSC. Given the Fast Track Designation, this potential treatment option could be available as soon as early 2018. Since pure CBD is a Schedule I substance under most state schedules, state action is needed to ensure proper rescheduling of FDA-approved treatments derived from CBD.

Unless the Minnesota Board of Pharmacy acts to ensure access to new treatments derived from CBD that are approved by the FDA and scheduled by the DEA, these therapies would not be made available to individuals living with uncontrolled seizures in Minnesota. Therefore, we urge you to begin to explore how the Minnesota Board of Pharmacy can take steps to ensure access to this potentially lifesaving treatment option if approved by the FDA.

We urge you to support the epilepsy community and begin to explore how Minnesota can remove barriers that would prevent access to FDA approved medications derived from CBD so that individuals living with uncontrolled seizures can have timely access to innovative and lifesaving treatments. We welcome the opportunity to discuss this issue further with you. Please contact Angela Ostrom, Chief Legal Officer and Vice President of Public Policy at the Epilepsy Foundation, at aostrom@efa.org with any questions or concerns.

Sincerely,

Epilepsy Foundation
Epilepsy Foundation of Minnesota
Aicardi Syndrome Foundation
Citizens United for Research in Epilepsy (CURE)
Danny Did Foundation
Dravet Syndrome Foundation
DUP15q Alliance
FACES at NYU Langone Medical Center
Gillette Children's Specialty Healthcare
Hope for hypothalamic hamaryomas
ICE Epilepsy Alliance
LGS Foundation
PCDH19 Alliance
Phelan-McDermid Syndrome Foundation
The Brain Recovery Project
Tuberous Sclerosis Alliance