



October 9, 2018

Dr. James McDonald, Medical Director
Rhode Island Department of Health
3 Capitol Hill
Providence, RI 02908

Dear Medical Director McDonald:

On behalf of the Epilepsy Foundation and our local affiliate, Epilepsy Foundation New England, we write to urge swift issuance of emergency regulations that will allow for timely access to medications derived from cannabidiol (CBD) approved by the Food and Drug Administration (FDA) that have now been scheduled by the Drug Enforcement Agency (DEA).

On June 25, 2018, the FDA approved Epidiolex, a medication derived from cannabis for the treatment of two rare epilepsy conditions known as Dravet and Lennox-Gastaut (LGS) syndromes in individuals 2 years of age or older. There are ongoing clinical trials to assess the effectiveness of Epidiolex for Tuberous Sclerosis Complex (TSC), another rare epilepsy syndrome. This treatment option received Orphan Drug Designation for LGS and TSC. On September 27, 2018, the DEA designated Epidiolex as Schedule V. However, since CBD is a Schedule I substance under the state drug schedule, state action is needed to properly re-schedule Epidiolex to ensure timely access to this new treatment option. Unless Rhode Island acts now, patients with Dravet or Lennox-Gastaut syndrome could experience a delay in accessing this new and innovative treatment option.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of the at least 3.4 million Americans 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 uncontrollable or intractable seizures, with many more living with significant side effects, despite available treatments. Uncontrolled seizures can lead to accident, injury, increased hospitalization costs, and early death.

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). Epidiolex is the first ever FDA-approved treatment for Dravet and represents hope for individuals living with Dravet syndrome who 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 other 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.

The Epilepsy Foundation and Epilepsy Foundation New England 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 clinically proven treatments once they have been reviewed and approved by the FDA. We urge swift regulatory action to re-schedule Epidiolex in Rhode Island to ensure timely access for the individuals who need it. Please do not hesitate to contact Laura Weidner, Esq., Vice President Government Relations & Advocacy, at our National Office at 301-918-3766 or lweidner@efa.org with questions or concerns. Locally, you may contact Bill Murphy, Director of Advocacy & Public Policy at Epilepsy Foundation New England at 617-851-7585 or wmurphy@epilepsynewengland.org.

Sincerely,

A handwritten signature in black ink that reads "Susan Linn".

Susan Linn
President/CEO
Epilepsy Foundation New England

A handwritten signature in black ink that reads "Philip M. Gattone".

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