TO: The Honorable William C. Smith, Jr., Chair
Members, Senate Judicial Proceedings Committee
The Honorable Jeff Waldstreicher

FROM: Epilepsy Foundation
TSC Alliance
LGS (Lennox-Gastaut Syndrome) Foundation
Dravet Syndrome Foundation

DATE: February 23, 2022

RE: **SUPPORT** – Senate Bill 614 – *Criminal Law – Controlled Dangerous Substances – Schedules – Adjustment*

On behalf of the Epilepsy Foundation, TSC Alliance, LGS (Lennox-Gastaut Syndrome) Foundation, and Dravet Syndrome Foundation, we submit this letter of support for Senate Bill 614.

Tuberlous sclerosis complex (TSC) is a rare genetic disease that causes non-cancerous (benign) tumors to grow in the brain and other parts of the body such as the eyes, heart, kidneys, lungs, and skin. TSC usually affects the central nervous system and can result in a combination of symptoms including seizures, developmental delay, and behavioral problems, although the signs and symptoms of the condition, as well as the severity of symptoms, vary widely. TSC affects about 1 in 6,000 people and is the leading genetic cause of epilepsy and autism.

LGS is a rare and debilitating form of early childhood-onset epilepsy that is characterized by highly treatment resistant seizures, multiple seizure types, moderate to severe cognitive impairment, and increased risk of premature death. 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, the majority of individuals living with this rare epilepsy do not achieve seizure control and experience lifelong cognitive impairments that severely limit quality 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). This condition affects 1 in 15,700 to 20,900 individuals globally.

Epidiolex, initially approved by the FDA for treatment of Dravet syndrome and Lennox-Gastaut syndrome (LGS) and subsequently approved for the treatment of TSC in individuals one year of age and older has been an extraordinary breakthrough in the ability to effectively treat these catastrophic conditions. While Epidiolex was initially designated by the DEA as a Schedule V substance. It was subsequently descheduled in July 2020 which dramatically enhanced access.

Unfortunately, Maryland's current controlled dangerous substances (CDS) scheduling system created unnecessary confusion and access to Epidiolex after it was descheduled. While Maryland generally follows the federal scheduling, they are only able to update their actual statute annually during the Legislative Session. Because Epidiolex was descheduled during the interim it resulted in confusion and access challenges. Thankfully, the Maryland Department of Health issued a letter essentially saying they would not enforce it as a scheduled drug as they planned to deschedule it when they updated their statute this Session.

Our organizations and the families we represent want to ensure that similar confusion does not occur in the future. Senate Bill 614 would amend Maryland's CDS statute to reference Federal CDS schedules as opposed to listing all of the compounds in each of the schedules. It will allow Maryland to stay current with the federal government's schedules and prevent future access and management issues for scheduled and descheduled drugs due to timing as occurred with Epidiolex.

The Epilepsy Foundation, TSC Alliance, LGS Foundation, and Dravet Syndrome Foundation request your support for Senate Bill 614 to ensure that Marylanders living with epilepsy and seizure disorders do not face future State barriers to lifechanging treatments.

For more information:
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