Talking Points

Children in Vermont suffering from devastating, life threatening forms of epilepsy, such as Dravet and Lennox Gastaut Syndrome, deserve to have the opportunity to try a new FDA-approved medicine as soon as it is available without state barriers to access.

- Intractable childhood epilepsies begin early in life and most often result in persistent seizures, intellectual impairment and significant morbidity.
- As many as 80-90% of patients with Dravet and LGS do not respond to available medications, and there are currently no FDA approved treatments for Dravet Syndrome.
- Twenty percent of patients with Dravet Syndrome die before the age 18.

Cannabidiol (CBD) is being developed for the treatment of intractable childhood epilepsies and the results have been very encouraging.

- This product is being developed as a *prescription medication* for the treatment of seizures in four types of rare, intractable, childhood-onset epilepsies—Dravet syndrome, Lennox-Gastaut syndrome, Tuberous Sclerosis Complex, and Infantile Spasms.
- It is being studied in large, well-controlled clinical trials at academic centers across the country.
- These clinical trials will produce a robust body of safety and efficacy data which will undergo rigorous review by the FDA.
- Such data is critically important to help physician, caregivers and patients make informed treatment decisions.

Patients with catastrophic, medication resistant seizure disorders deserve an opportunity to try a new FDA-approved anticonvulsant as soon as it is available.

- In some cases, minimizing seizures significantly improves the cognitive and behavioral outcome for the child.
- Should an investigational CBD product receive FDA approval, the DEA would reschedule the medicine in an appropriate controlled drug schedule, thus acknowledging its demonstrated therapeutic utility- and making it legally available at the Federal level.
- Almost all states, including Vermont, have their own state controlled drug laws. Vermont's Regulated Drug Rule designates drugs and other chemical substances that are controlled or illegal because they are potentially fatal or harmful for human consumption. Amendments to the Regulated Drug Rule take approximately 6-7 months.
- Because CBD is regulated under Vermont's Regulated Drug rule, this product would not be available to patients following FDA approval.
- This amendment ensures that patients would have immediate access following FDA approval and DEA scheduling while the Vermont Department of Health goes through its rule making process.