EPILEPSY FOUNDATION

February 21, 2017

The Honorable Brad Zaun
Iowa State Senate
State Capitol
1007 East Grand Ave
Des Moines, IA, 50319

Dear Senator Zaun:

On behalf of the Epilepsy Foundation and the Epilepsy Foundation of North/Central Illinois, Iowa and Nebraska, we would like to thank you for introducing Senate File 282 and for your leadership on the creation of a state pathway for therapies approved by the Food and Drug Administration (FDA) and derived from cannabidiol (CBD). We look forward to working with you on an amendment to the bill that would ensure access for FDA-approved therapies derived from CBD at any schedule, not just Schedule II.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of more than three 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 uncontrolled or intractable seizures, with many more living with significant side-effects, despite available treatments. Uncontrolled seizures can lead to disability, injury, and even death.

The Epilepsy foundation is supporting legislation across the country that would allow therapies derived from CBD and approved by the FDA to become available to patients. Access to new therapies is particularly important for the epilepsy community due to the significant unmet need and often debilitating side-effects to the currently available medications.

While we support the introduction of Senate File 282, we seek to amend the bill because it only triggers state action if the federal Drug Enforcement Administration (DEA) schedules a product as a Schedule II, which would significantly limit access. We would like the state to adopt the federal schedule assigned to the FDA-approved therapy by the DEA.

The FDA is currently reviewing at least one CBD derived therapy that shows promise for the treatment of Dravet and Lennox Gastaut syndromes (LGS), tuberous sclerosis complex (TSC) and potentially other rare epilepsies. This potential treatment option has both Orphan Drug Designation and Fast Track Designation from the FDA and could be approved as soon as early 2018. After FDA approval, the DEA would schedule the therapy through administrative action and the medication would become available for patients. However, since CBD is currently a Schedule I substance under the Iowa state

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drug schedule, state action is needed to ensure proper rescheduling of FDA-approved treatments derived from CBD. Unless Iowa acts, patients will not have access to these new treatments, which would be available in neighboring states that have taken action. This is an issue of creating access to FDA-approved therapies.

The Epilepsy Foundation and the Epilepsy Foundation of North/Central Illinois, Iowa and Nebraska 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 proven and potentially lifesaving treatment once they have been reviewed and approved by FDA. We thank you for your leadership to create a state pathway for FDA approved therapies derived from CBD. Please reach out to Roxanne Cogil with the Epilepsy Foundation of North/Central Illinois, Iowa, Nebraska at rcogil@epilepsyiowa.org or (515) 238-7660 with any questions or concerns.

Sincerely,

Ben Slack
Executive Director
Epilepsy Foundation of North/Central Illinois, Iowa & Nebraska

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