University of Nebraska Medical Center

NEBRASKA'S HEALTH SCIENCE CENTER

OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
Clinical Research Center

September 14, 2018

Re: LB390 Annual Report
Statute: 28-468

Dear Chairs of Judiciary and Health & Human Services Committees,

On the behalf of the University of Nebraska Medical Center and Deepak Madhavan, MD, we respectfully submit the 2018 annual report for the Cannabidiol Pilot Study. This study allows access to cannabidiol oil for patients who suffer from intractable or treatment-resistant seizures. The catalyst for the study was LB390 introduced by Senator Sue Crawford.

We would like to take this opportunity to present the current state of the Cannabidiol Study and provide you with an update regarding the study based upon data collected by the research team, including reports from the participants and families helping us to evaluate the use of cannabidiol oil.

To date:

- 31 patients were consented for evaluation for potential participation in the study.
- 27 patients qualified and enrolled in the study, with 23 currently taking study drug. The majority have demonstrating benefit, particularly those with either Lennox Gastaut Syndrome or Dravet Syndrome.
- 11 patients under the age of 19 have been included.
- 4 patients withdrew from the study due to:
    - Elevated liver enzymes
    - Parent concerns of potentially worsening seizures
    - Moved out of state
    - Parents concerns of lack of seizure improvement
- Common adverse side effects have included sleepiness, unsteady gait, lethargy and a drop in the platelet count. These have generally resolved with adjusting the dosage of the study drug and/or their other seizure medications. These are consistent with other national data collected to date.
- Most have tolerated a dose between 10-20mg/kg/day, with some taking the maximum dose of 25mg/kg/day.

In June of this year the FDA approved the cannabidiol product used in this study, to be branded under the name Epidiolex® (cannabidiol) oral solution for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age and older. As part of the approval process, the Drug Enforcement Agency (DEA) is in the process of rescheduling

Epidiolex® before it is made commercially available to patients. GW/Greenwich plans for Epidiolex® to be commercially available by late Fall of 2018.

Once the drug is commercially available, our access to the product at no charge for this study will likely be limited, We are currently in discussions with GW Pharmaceuticals and are requesting to continue to receive cannabidiol for patients who may not have access through insurance to receive this product, either due to lack of insurance or lack of approval for their specific indication.

We greatly appreciate the support provided for this study on behalf of those Nebraska residents living with this chronic and debilitating condition.

Respectfully Submitted;

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