University of Nebraska Medical Center

NEBRASKA'S HEALTH SCIENCE CENTER

OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
Clinical Research Center

September 15, 2019

Re: LB390 Final Annual Report
Statute: 28-468

Dear Chairs of Judiciary and Health & Human Services Committees,

On the behalf of the University of Nebraska Medical Center I respectfully submit the 2019 annual report for the Cannabidiol Pilot Study, which will serve as the final annual report. This study allowed 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.

A more detailed scientific report was submitted on January 21, 2019, but to briefly summarize:

- 31 patients were consented for evaluation for potential participation in the study.
- 27 patients qualified for and enrolled in the study. All had medically refractory epilepsy, with the majority demonstrating benefit while participating.
- 11 patients under the age of 19 were 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 included sleepiness, unsteady gait, lethargy and a drop in the platelet count. These 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 tolerated a dose between 10-20mg/kg/day, with some taking the maximum dose of 25mg/kg/day.

In June of 2018 the FDA approved the cannabidiol product used in this study, 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) rescheduled Epidiolex®, so it is no longer a Schedule I drug. Epidiolex® is now commercially available across the U.S., including in Nebraska, as a prescription medication.

Once the drug became commercially available, our access to the product at no charge for this study became limited. Due to the availability of the product commercially, as well as the large pool of data submitted to the FDA as well as published, it was decided that the study was ready to be terminated.

We worked with patients who desired to continue treatment and facilitated their transition to prescription products through their healthcare providers.

The primary objectives of LB390 were achieved. We greatly appreciate the support provided for this study on behalf of those Nebraska residents living with this chronic and debilitating condition. This study provided access to pharmaceutical grade cannabidiol, via an FDA regulated protocol, while generating information to help inform a decision by the FDA that this was a safe and effective product, which is now available commercially.

Respectfully Submitted,

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CC: Senator Crawford