# RESEARCH PROGRESS REPORT SUMMARY 

Grant 02930: A Dose Finding Study of Cannabidiol in Dogs with Idiopathic Epilepsy
Principal Investigator: Stephanie McGrath, DVM, MS
Research Institution: Colorado State University
Grant Amount:
Start Date: 5/1/2021 End Date: 10/31/2024
Progress Report:
Mid-Year 3
Report Due: 10/31/2023
Report Received: 11/15/2023
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## Original Project Description:

Affecting approximately $5 \%$ of the canine population, idiopathic epilepsy is a widespread disease that is often frustrating and, at times, debilitating to both dogs and their owners. About one-third of dogs afflicted by epilepsy are refractory to the standard drugs available to treat the disease so finding a replacement or adjunctive medication is imperative. Recently, the anticonvulsive properties of cannabidiol (CBD) have been demonstrated in human and canine patients. The primary objective of this study is to find an effective dose of CBD for idiopathic epilepsy in client-owned dogs with uncontrolled seizures ( $\geq 2$ seizures per month). Aim 1 of this study is to determine the dose of oral CBD that will reduce average monthly seizure activity in client-owned refractory idiopathic epileptic dogs by $50 \%$ or more when added to standard anticonvulsive therapy. Aim 2 of this study is to evaluate the safety and tolerability of CBD in dogs with idiopathic epilepsy. Investigators hypothesize that, at the appropriate dose, CBD will be effective in lowering the average monthly seizure frequency by $50 \%$ in at least $50 \%$ of uncontrolled epileptic dogs and that CBD, even at high doses, will be well tolerated. An effective agent with limited side effects has the potential to improve the quality of life of epileptic dogs, and ultimately afflicted humans, as dogs serve as an ideal surrogate for human epileptic conditions.

## Publications:

None at this time.

## Presentations:

A dose-finding study of cannabidiol in dogs with idiopathic epilepsy; presented at AAVMC-NIH Veterinary Scholars Research Symposium 2023

## Report to Grant Sponsor from Investigator:

The preparations for the CBD dose finding epilepsy study were started in May 2021, including creating the study documents necessary for the trial, creating an announcement for Colorado veterinarians and pet owners, the start of patient recruitment and medical record review to determine eligibility. We began enrolling patients for Phase I of the study at the end of the summer of 2021. Enrollment has been completed for Phase I; however, several dogs are still actively enrolled in the 3 month study period. Several modifications have been made to the study design/dosing groups. First, we eliminated the third dosing group ( $20 \mathrm{mg} / \mathrm{kg}$ BID) due to adverse events in all dogs in this group. Second, we added two dosing groups, which made for a total: Group 1: $5 \mathrm{mg} / \mathrm{kg}$ BID Full Spectrum CBD oil; Group 2: $5 \mathrm{mg} / \mathrm{kg}$ BID Distillate CBD oil; Group 3: $10 \mathrm{mg} / \mathrm{kg}$ BID Full Spectrum CBD oil; and Group 4: $10 \mathrm{mg} / \mathrm{kg}$ BID Distillate CBD oil. Due to the adverse events we observed with the $20 \mathrm{mg} / \mathrm{kg}$ group, including ataxia, lethargy, inappetence, and diarrhea/vomiting, we wanted to have two CBD products tested in each group (one with and one without THC) to distinguish CBD vs THC effects on dogs. We were successful in completing Phase I this summer and have started enrollment for Phase II. The results of Phase I were analyzed by a statistician immediately upon completion. The most effective dose and CBD formulation was $10 \mathrm{mg} / \mathrm{kg}$ twice daily of the distillate, which is the dose and product that was employed for Phase II. Phase II began in July 2022. We have enrolled 17 dogs, which means 5 more dogs need to be enrolled to complete the study.

