

Faculty Development Committee (FDC) Proposal

Trace Metal Profiling of Commercially Available Hemp Derived CBD Oils

Name of the Applicant:	Dr. Thomas J. Gluodenis, Jr.
Rank of the Applicant:	Associate Professor
Department:	Chemistry & Physics
Total Funding Requested:	\$7,500 (\$1,500 supplies, \$6,000 summer stipend)
Proposal Submission Date:	January 14, 2021

Introduction

Hemp contains the non-psychoactive ingredient, cannabidiol (CBD). In 2018, the Agricultural Improvement Act federally legalized hemp and its derivatives resulting in its use in a broad range of applications. For example, given the plant's unique properties, hemp is increasingly being used to extract heavy metal contaminants from the soil of polluted industrial sites. In another use model, CBD oil is extracted from the hemp plant and sold as a nutraceutical or dietary supplement. There is increasing concern that given hemp's affinity for concentrating heavy metals, the extraction and ingestion of CBD oil could create a public health hazard.

State regulations require the monitoring of four heavy metals in CBD oils. Additionally, in an attempt at self-regulation, a consortium of producers known as the U. S. Hemp Authority require that members conform to a strict series of agreed upon quality guidelines. Yet despite these safeguards, there have been state mandated product recalls and several lawsuits claiming contaminated CBD products.

In addition to issues regarding truth in labelling and the utility of self-regulation, the question exists as to whether current guidelines are sufficient to protect public health. In contrast to the four metals that are state regulated in hemp derived products, the U.S. Food and Drug Administration (FDA) requires monitoring of 24 metals in federally regulated dietary supplements.

Project Description

Over 20 CBD oils procured over the internet and from local smoke shops or gas stations will undergo comprehensive (i.e. entire periodic table) elemental profiling. The sources of the CBD oils will represent both producers that are members of the U.S. Hemp Authority and those that are not. Multiple samples from each source will be obtained over a 9-month timeframe to assess lot to lot variability. Any metals found at toxicologically significant concentrations will be quantitated and the results compared with both current state regulations and U.S. FDA requirements. This assessment of consumer CBD products is currently the largest and most comprehensive scientific study of its kind reported in the literature.

Measurable Goals & Objectives

In an era when CBD is being touted as a panacea for many afflictions and a component of preventative medicine, the objective of this project is to validate the safety of CBD based consumer products relative to toxic metal contamination. This will be done by answering three questions and disseminating the results thereby educating the scientific community, regulators, students and the public about the safety of CBD derived products:

- 1) Does the sample population studied support or call into suspect truth in labelling relative to the metals content reported in commercially available CBD oils?
- 2) Does the sample population studied suggest a quality difference between producers who are members of the U.S. Hemp Authority and those that are not? i.e. is there value to self-regulation?
- 3) Do current state regulations requiring certification of four metals go far enough to protect public health and safety or does the empirical data support expanding the panel of metals that should be routinely monitored?

Timeframe for the Project

The experimental work will begin in early January 2021, continue through the academic year with completion in September 2021. Data analysis, manuscript preparation, and oral dissemination of results will occur in the Fall 2021. Please see the appendix for a detailed timeline.

Enhancing Teaching and Research at Lincoln University

Cannabis/hemp research has attracted \$1.56 billion in funding since 2000 (Analytical Cannabis News, Sept 03, 2020). As a new faculty member seeking to build a student research program at the University, this study is anticipated to be the first in a series of investigations to characterize the efficacy and/or toxicity of this new class of consumer products. This study in particular aims to intertwine advancement of the scientific knowledge base, raise awareness of a potential public health issue, and educate both students and the general public. Using personal funds, a feasibility study was undertaken for this project which became the basis of a student's Biology 413 (Biology Research I) independent research project. That student has recently received a Title III mini grant from the Center for Undergraduate Research to fund her continued work on this proposed study. It is anticipated that given the importance of the work relative to public safety, educational outreach, and pharmaceutical research that this subject area will lend itself to additional outside funding sources providing more students the opportunity to perform independent research.

This project is also leverageable into the classroom. CHE 305 (toxicology) was taught for the first-time last semester (Fall 2020). One of the drug classes studied given its complexity and large number of biologically active compounds was cannabinoids. The outcome of this project would integrate directly into that module of the class further expanding knowledge dissemination throughout the student body.

Project Success & Communication

The project will have been deemed to be successful if the questions answered under "Measurable Goals and Objectives" can be satisfactorily answered. An interim report will be presented at the 2021 Lincoln University Undergraduate Research Symposium (April). The Principal Investigator has also been invited to present interim results at a Summer workshop on heavy metal contamination in cannabis organized by the American Society of Testing Materials (ASTM) D-37 Committee for Cannabis Standards (see appendix).

Final results will be shared with Lincoln University colleagues through an officially scheduled department meeting and disseminated to the international community of toxicologists (forensic & clinical) through proposed presentations at the following conferences: the 2021 Forensic Online Symposium: Current Trends in Forensic Toxicology (May), the 2021 annual meeting of the Society of Forensic Toxicologists (October), and the 2022 annual meeting of the American Academy of Forensic Scientists (February). A manuscript will be submitted to the peer reviewed Journal of Analytical Toxicology as well as to several trade magazines/journals such as The Journal of Cannabis Research and Cannabis Today in order to make growers, processors, and distributors aware of identified public health concerns, if any.

Budget Page

Funding Requested: \$7,500

Itemization & Justification

- 2 Liters, Plasma Pure Trace Metal Free Nitric Acid (see appendix) \$1,500
 - This is a high purity grade of reagent that would not normally be required by the University but is essential to this project.
- Salary supplement for summer work \$6,000
 - Given teaching loads and the extensive work required the majority of this work will need to be completed over the summer session.

Total Funding Requested: \$7,500

Appendix I
Project Timetable

Date	Description of Work Completed
Feb 2021	Method development, experimental design complete
March 2021	Sample Lot #1 acquired, prepared, analyzed, and data interpreted
April 2021	Presentation of interim results at LU Undergraduate Research Symposium
June/July 2021	Sample Lot #2 acquired, prepared, analyzed, and interpreted
July/August 2021	Sample Lot #3 acquired, prepared, analyzed, and interpreted
September 2021	Composite data analysis & interpretation
April 2021	Presentation at Lincoln University Undergraduate Research Symposium
May 2021	Presentation at Online Symposium: Current Trends in Forensic Toxicology
October 2021	Presentation at Annual Meeting of the Society of Forensic Toxicologists
February 2022	Presentation at Annual Meeting of the American Academy of Forensic Sciences
February 2022	Manuscript Submissions i.e., Journal of Analytical Toxicology

Appendix II

Cost of Specialized Reagents

SCP SCIENCE

348 Route 11
Champlain, N.Y.
12919-4816, U.S.A.

Tel: (800) 361- 6820
Fax: (800) 253- 5549
www.scpscience.com

Registered ISO 9001
Accredited ISO 17034 / ISO17025



Customer Quotation

Quotation Number: Q000121959
Salesperson: Chris Kermack
Currency: US Dollars
Quote Date: 1/1/2021
Expiration Date: 1/31/2021
Terms: Net 30 days
Ship Via: UPS Standard COLL
FOB Our Plant

Please reference the above quotation number when placing your order.

Customer: 6006866
Tom Gluodenis Lincoln University Accounts Payable P.O. Box 179 Lincoln University PA 19352 United States Phone: (484) - 365-7497 Fax:

Ship To:
Lincoln University Receiving 1570 Baltimore Pike Lincoln University PA 19352 United States

Line	Item	Description	UN Code	U/M	Quantity	Unit Price	Total Price
1	250-036-133	Nitric acid, PPP, 67 - 70% PlasmaPURE Plus	2031	L	2.00	793.00	1,586.00

A quantity discount has been applied to the purchase of Nitric acid, PPP, 67 - 70% compliments of SCP SCIENCE.

"STOCK"

Please note that the shipping charge is not included on this quote.

UNCode: 2031 Class: 8 (5.1) PackGroup: II

Items in red are classified as dangerous goods.



[Download MSDS Sheets](#)

Sale Amount:	1,586.00
Freight:	0.00
Sub Total:	1,586.00
 Total Amount:	 1,586.00

Appendix III

Invitation to Present at ASTM D-37 Committee for Cannabis Standards Summer Workshop

-----Original Message-----

From: Robert Thomas <robert.james.thomas@verizon.net>

Sent: Wednesday, December 30, 2020 2:23 PM

To: Thomas Gluodenis <tgluodenis@lincoln.edu>; Robert Thomas <robert.james.thomas@verizon.net>

Subject: ASTM Workshop/Symposium on Heavy Metals

Hi Tom,

Hope you are doing well. You might be aware that I serve on the ASTM D-37 Committee for Cannabis Standards. We had a committee meeting early last week and we are looking to hold a workshop/symposium focused on heavy metal contaminants in cannabis sometime in the summer of 2021 (no date fixed yet). So in order to gauge interest for the event, committee members are contacting key decision makers in the cannabis industry to see if they might be interested in contributing. You'll be glad to know I'm putting you in this category based on your proposed CBD study. So if you think you might have some preliminary data from your study, I think this would be great visibility for you. If interested, I could send you a draft of the invite/agenda we are putting together. The plan is to start getting abstracts in over the next few months and to make a decision on the scope and duration of the event (1-, 2- or 3-days).

Best to you and your family for the new year.

Regards, Rob

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Robert Thomas, CSci, CChem, FRSC

Principal Consultant

Scientific Solutions: Serving the Educational Needs of the Trace Element User Community

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Table 1

Name of the Applicant:	Tom Gluodenis
Rank of the Applicant:	Associate Professor
Proposal Submission Date:	January 15, 2021
Expertise Area:	Analytical Chemistry/Forensic Science/Toxicology
Prior FD Proposal Outcomes:	New faculty (8/2020) so no previous FD submissions
Proposal Submission Term:	Spring 2021 Summer 2021 Fall 2021