

Interim Joint Committee on Health Services October 23, 2024



Highlights: Center Progress



NIH Grant Funding

NIH GRANTS AWARDED:

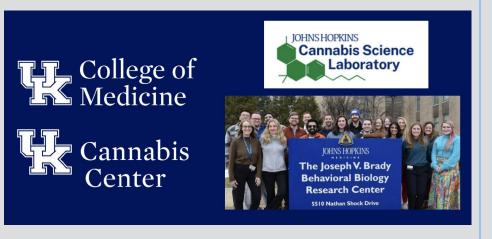
- <u>\$2.8 million NIH grant</u> for an inpatient trial to examine cannabis for opioid use disorder
- **<u>\$128,000 NIH grant</u>** in collaboration with the Cannabis, Cannabinoids and Addiction Center at Indiana University

NIH GRANTS SUBMITTED:

• **<u>\$2.87 million NIH grant submitted</u>** – will be reviewed October 30



Collaboration: Johns Hopkins University



- The Johns Hopkins team is recognized as the international leader in clinical cannabis research
- We held a 2-day research collaborative meeting at UK in May 2024
- The UK/JHU team designed and planned a collaborative NIH R01 grant (Feb 2025)
- 5-year project, \$3 million budget
- UK will serve as the lead site/investigator



DEA Growing License Submitted

- Submitted DEA Schedule I cannabis growing application
 - Established indoor growing facility with full security
 - Collaboration with UK College of Agriculture
 - Awaiting on DEA response, hope to know more by the end of the month
- The final DEA decision on cannabis scheduling anticipated in early December (i.e., remain Schedule I or become less restrictive Schedule III)



Clinical Trials: Cancer, Metabolic Health

- We are conducting two clinical trials one with cancer patients and one with patient who have metabolic disease (type 2 diabetes, high BMI, insulin resistance)
- All federal, state and local research permissions received (approx. 15-20 regulatory approvals required per study)
- We had long delays due to federally-regulated Schedule I drug supply shortage (affected nearly all cannabis researchers)
- Drug manufacturing is now complete
- We are only waiting on DEA approval hope to hear by the end of the month
- Planning for enrollment in November
- First studies of their kind, first studies to explore controlled daily dosing for 4+ months
- Several NIH grants planned, including with Markey Cancer Center





Completed 10+ Cannabis Projects

- Human laboratory trial: interaction of inhaled cannabis and intranasal opioids
- Human laboratory trial: cannabis impact on simulated driving performance
- **IU collaboration**: endocannabinoid expression in substance use disorder
- Granted 5 UK Faculty Seed Grants: all completed, manuscripts in development
 - one NIH proposal submitted, several in development
- Analytical chemistry projects: all completed
- In addition, we have held symposia and webinar series on cutting-edge cannabis science, open to the public





Top Line Data: Two Exemplar Studies



Cannabis: Fetal and Maternal Health



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CANNABIS: MATERNAL AND CHILD HEALTH

Rationale: In states that allow cannabis use, use during pregnancy has increased

UK researchers conducted a UK HealthCare chart review:

- examined data from live birth pregnancies over the past 5 years (n = 24,281 infants)
- 7.8% of pregnant patients screened positive for THC
- plan to continue to track and monitor to determine how changes in cannabis policy impact rates of maternal use







CANNABIS: MATERNAL AND CHILD HEALTH

- Enrolled 57 pregnant women who reported recently using cannabis
- 60% continued to use cannabis during pregnancy
- Most common reported motivations:
 - nausea/morning sickness
 - sleep aid
 - fear/anxiety
 - stress
 - physical pain
 - emotional pain



CANNABIS: MATERNAL AND CHILD HEALTH

Of those who continued to use during pregnancy:

- 85% used at least 15/30 days of the month
- 54% used daily or multiple times per day
- 50% smoked cigarettes, 58% vaped nicotine
- 76% rated cannabis as safer than rx antiemetics
- most reported never hearing any cannabis information from their physician
- most did not understand current KY cannabis legislation

Next Steps: NIH grant applications, continue to monitor cannabis policy impact, series of studies exploring cannabis impact on maternal and infant health outcomes



Drug Misuse: Opioid and Cannabis Trial



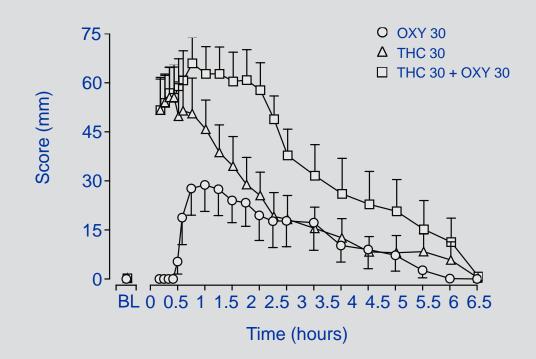
DRUG INTERACTION TRIAL: OPIOIDS & CANNABIS

- **Rationale:** Animal studies have indicated cannabinoids enhance opioid analgesia and either decrease or do not alter opioid rewarding effects
- 5-week inpatient study (*n*=9) examining the effects of opioids, cannabis and their combination in a human trial
- Double-blind, placebo-controlled, randomized study
- Participants with a history of opioid misuse received a wide dose range of inhaled cannabis and intranasal opioids



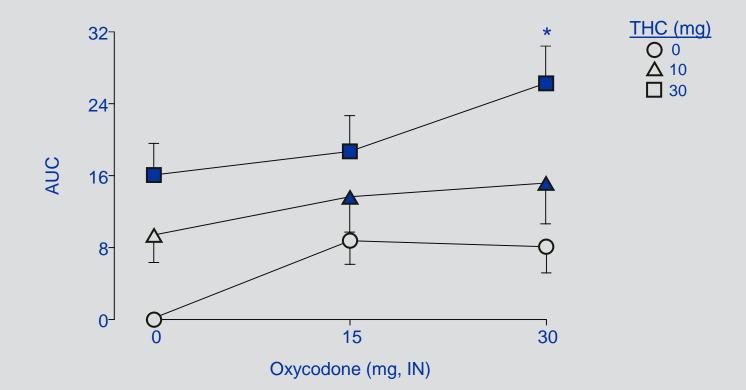


"How much do you LIKE the drug effects?"





"How HIGH are you?"





KEY TAKEAWAYS

- Cannabis did not alter the physiological safety of opioids did not increase opioidinduced respiratory depression, miosis
- Cannabis did not produce analgesia alone and did not increase opioid analgesia
- Cannabis increased the abuse potential of opioids increased the peak effects and duration of the euphoric-like effects of opioids - particularly with high dose combinations
- Next steps: Now enrolling those with severe OUD to determine the effects of cannabis on opioid withdrawal and safety and abuse potential of higher doses of opioids



Future Directions

1) Clinical trials: areas of interest: autism, substance use disorder, lung inflammation, multiple sclerosis, lupus and other autoimmune diseases, palliative care

2) NIH grants: continue to apply and conduct our federally-funded studies; next submission Feb 2025

3) Pediatric cannabis poisonings: accidental ingestion of THC-edibles (gummy bears, cookies)

- Delta-8 THC poisonings in children are increasing (some requiring intubation, ICU) reports from UK Emergency Dept; will need to brace for further spikes when KY dispensaries open
- 4) Public health impact of KY Medical Cannabis: opioid overdose, cannabis impaired driving crashes, cannabis hyperemesis syndrome, rx drug use and misuse, workplace impairment
- **5)** Characterizing the KY Medical Cannabis Program: population-level data on reasons for patient use, number of refills, quantity rx and dispensed, types of products used, concomitant opioid use





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