

# Recent Research Findings and the Legalization of Hemp

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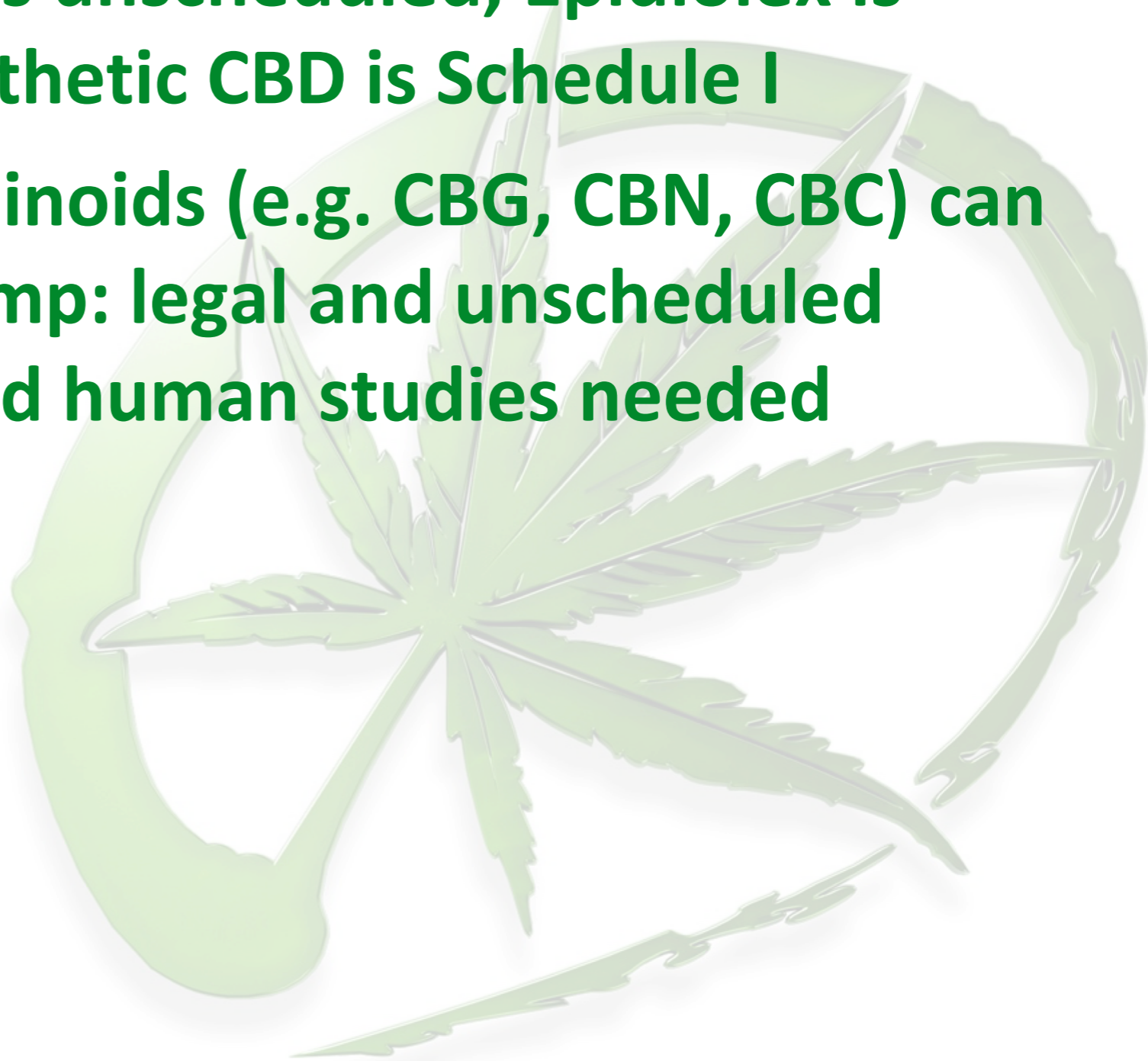
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# Regulatory Clean-up

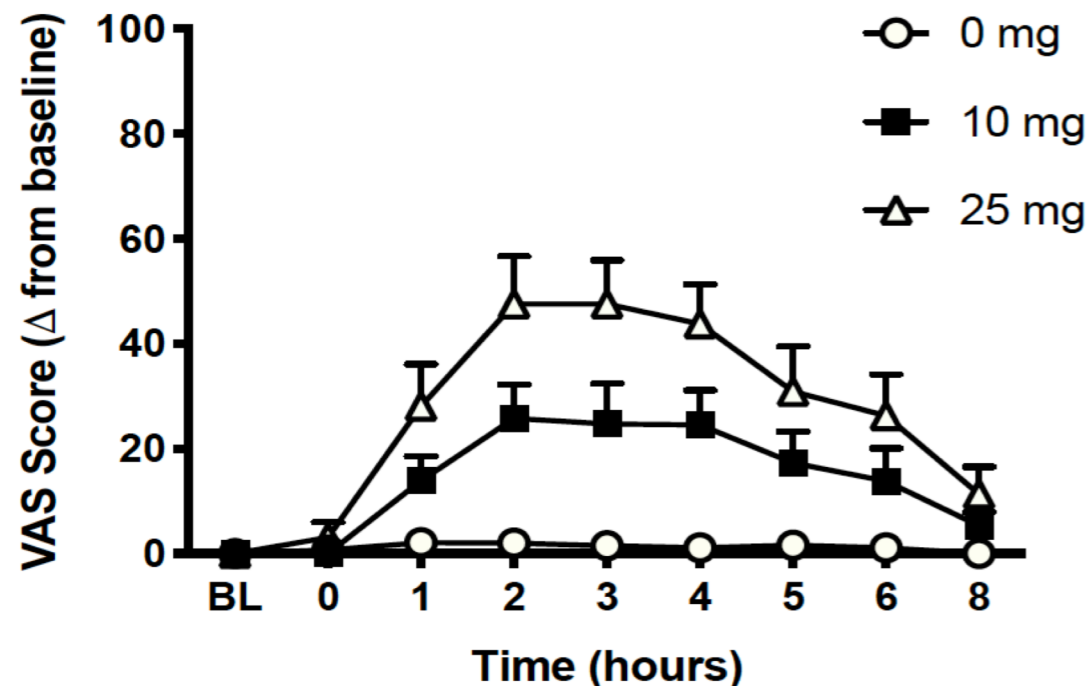
- CBD is the predominant byproduct of hemp
- Hemp-derived CBD is unscheduled, Epidiolex is Schedule V, and synthetic CBD is Schedule I
- Other minor cannabinoids (e.g. CBG, CBN, CBC) can be isolated from hemp: legal and unscheduled products – controlled human studies needed



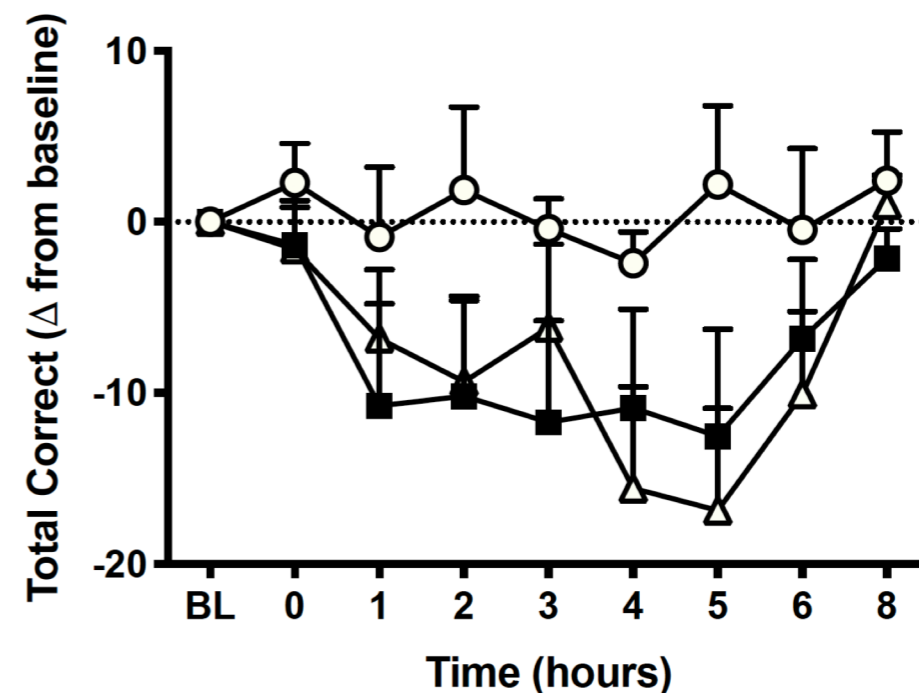
# THC Content

- Hemp is defined as having 0.3% THC or less
- CBD oils sold as hemp found to contain up to 6.4mg/mL THC <sup>1</sup>
- Oral THC doses of 10mg produce mild/moderate drug effects, and can impair cognitive performance

## Drug Effect

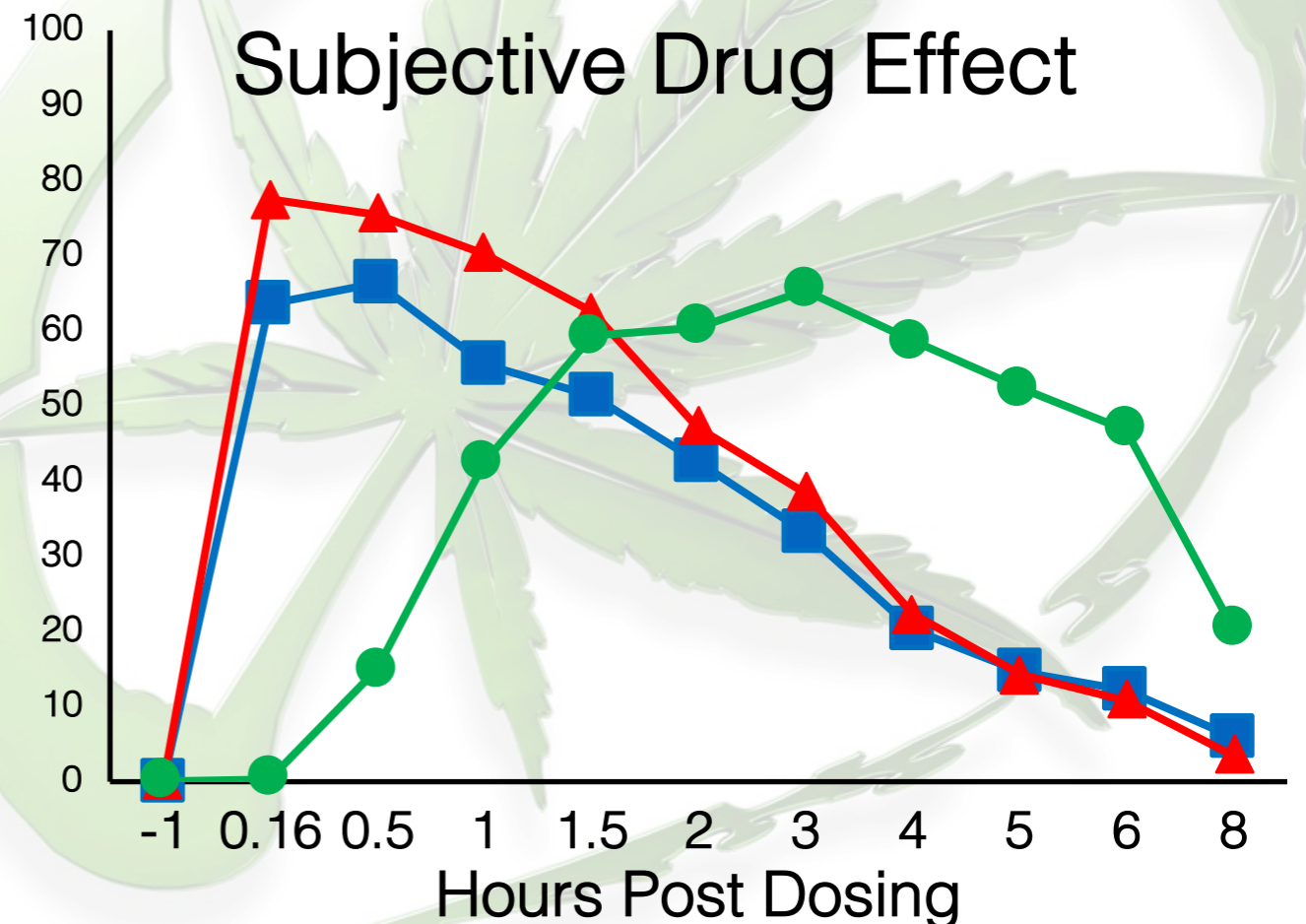
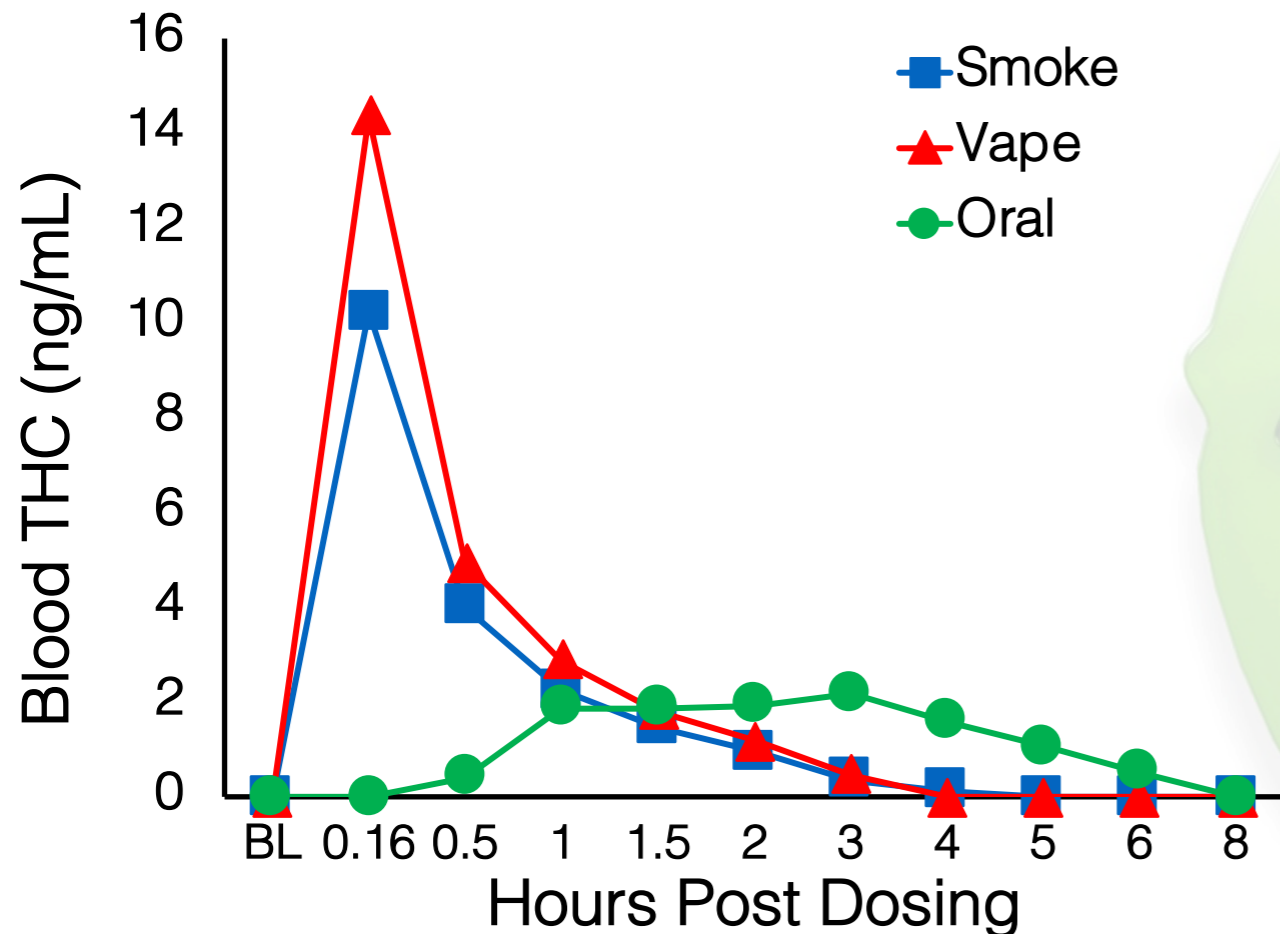


## PASAT



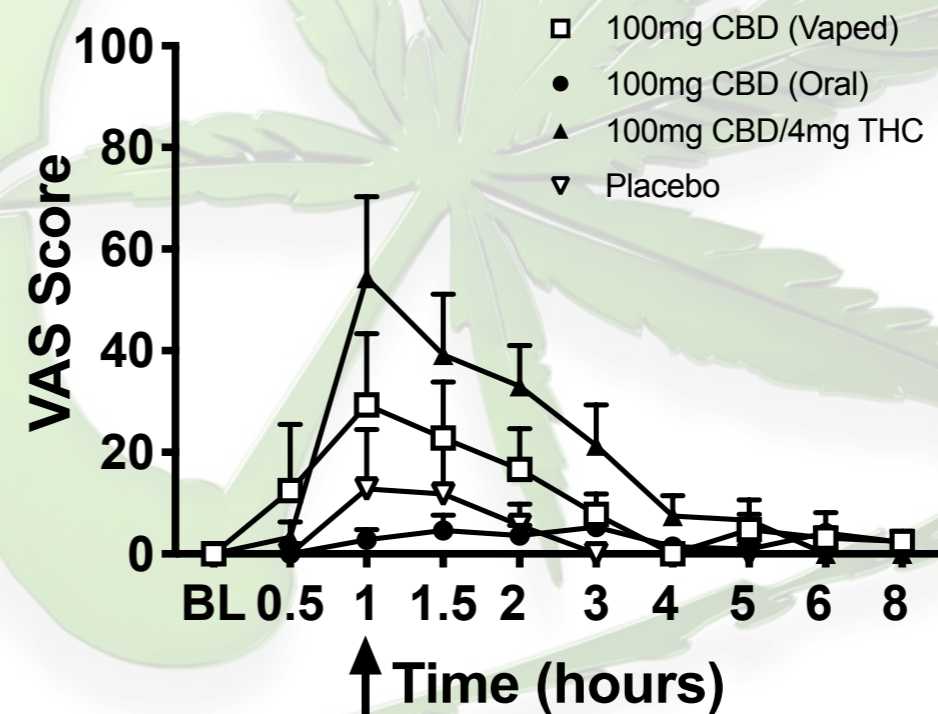
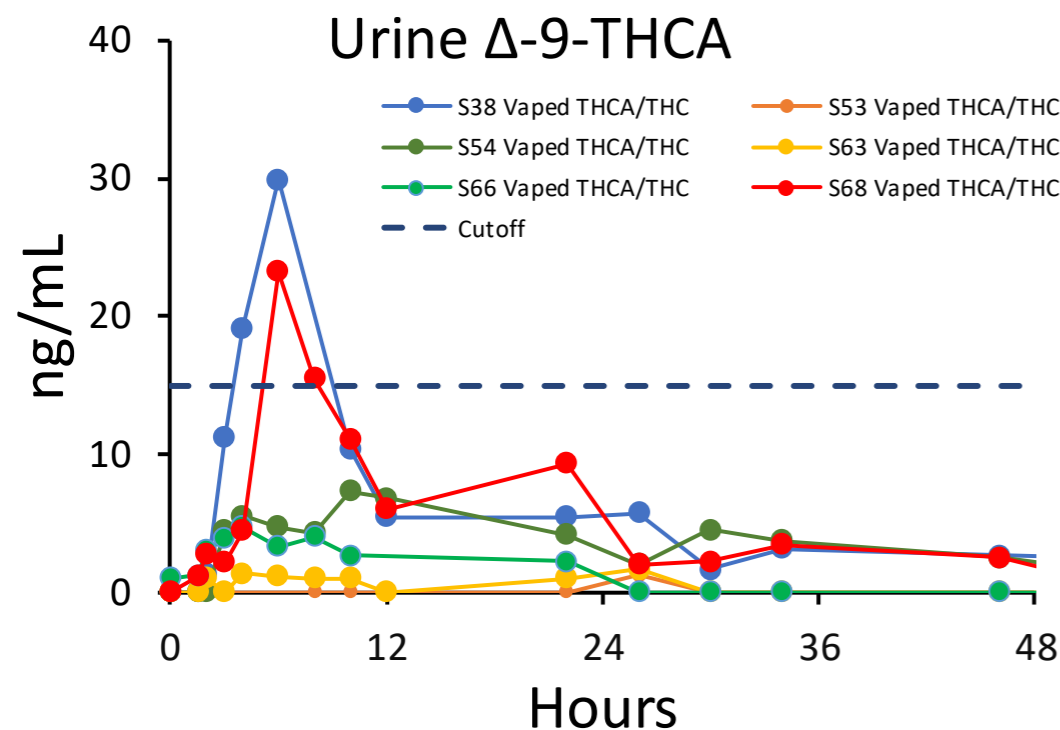
# Route of Administration

- Controlled lab studies indicate that vaporized THC produces stronger drug effects than smoked/oral<sup>2,3</sup>
- Time course differs and blood THC poorly correlates with drug effects for oral dosing<sup>2,3</sup>

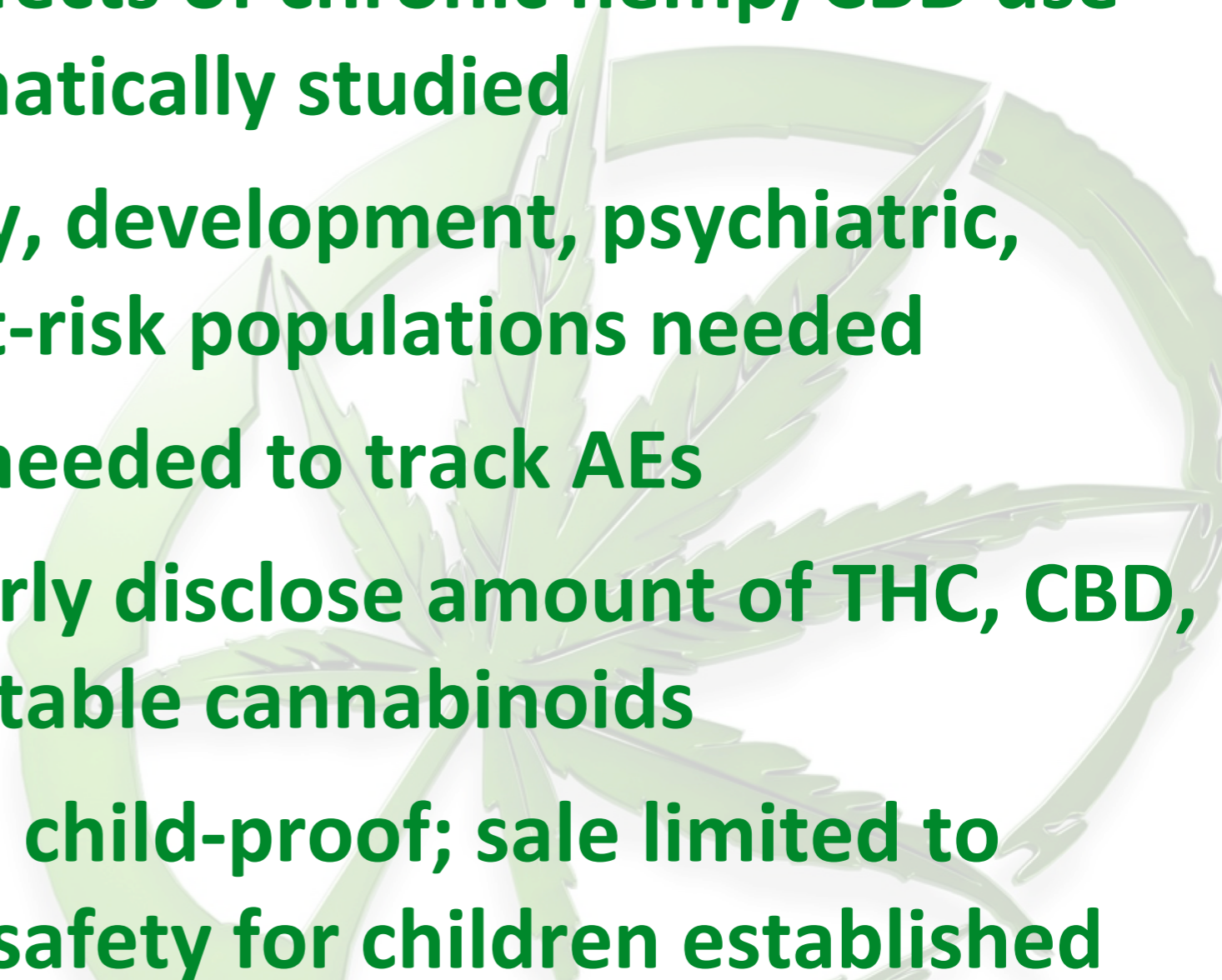


# CBD Study


- Vaporized CBD produced discriminable drug effect, but was not THC-like; no cognitive impairment
- No THC in blood after pure CBD; significant increase in blood CBD when THC present
- Two participants had 2 positive drug tests after acute inhalation of drug containing ~4mg THC



# Additional Points

- **Standards for QC testing and contaminants is urgent**
  - **Long-term health effects of chronic hemp/CBD use has not been systematically studied**
  - **Effects on pregnancy, development, psychiatric, elderly, and other at-risk populations needed**
  - **Pharmacovigilance needed to track AEs**
  - **Labeling should clearly disclose amount of THC, CBD, and any other detectable cannabinoids**
  - **Packaging should be child-proof; sale limited to adults over 18 until safety for children established**
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# Summary/Recommendations

- Variation in scheduling of cannabinoids needs to be reconciled; pathway needed to advance science
  - Total THC dose should be limited to mitigate abuse liability, AEs, and impairment
  - It is possible that use of legal hemp products can impact drug testing programs
  - Drug-drug interactions are a major concern <sup>4,5</sup>
  - **REGULATION NEEDED IMMEDIATELY FOR CONTENT, QC, AND LABELING; CONSIDER USE OF EXISTING CGMP REGULATIONS FOR DRUGS/SUPPLEMENTS; URGENT NEED TO FUND CANNABIS REGULATORY SCIENCE**
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# References

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2. **Vandrey R, Herrmann ES, Mitchell JM, Bigelow GE, Flegal R, LoDico C, Cone EJ. Pharmacokinetic Profile of Oral Cannabis in Humans: Blood and Oral Fluid Disposition and Relation to Pharmacodynamic Outcomes. J Anal Tox. 2017; 41; 83-99.**
3. **Spindle TR, Cone EJ, Schlienz NJ, Mitchell JM, Bigelow GE, Flegal R, Hayes E, Vandrey R. Acute Effects of Smoked and Vaporized Cannabis in Healthy Adults Who Infrequently Use Cannabis: A Cross-Over Trial. JAMA Network Open. 2018; 1; e184841, 1-14.**
4. **Cox EJ, Maharao N, Patilea-Vrana G, et al. A marijuana-drug interaction primer: Precipitants, pharmacology and pharmacokinetics. 2019;Pharmacol Ther. May 6. pii: S0163-7258(19)30075-0.**
5. **Alsherbiny MA and Li CG. Medicinal Cannabis-Potential Drug Interactions. Medicines. 2019;6(3):1-12.**