Recommendations Regarding HB 21-1317

April 19, 2023

Scientific Review Council

Contact:

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Submitted to:

House Finance and Public and Behavioral Health and Human Services Committees

And

Senate Finance and Health and Human Services Committees

Dear Members of the House Finance and Public and Behavioral Health and Human Services Committees & Senate Finance and Health and Human Services Committees,

We the members of the Scientific Review Council (SRC) are submitting this letter to comment on the April 2023 report submitted to the Colorado General Assembly by the Cannabis Research and Policy Team from the Colorado School of Public Health (ColoradoSPH). This report was prepared by the ColoradoSPH team in response to the mandate given to it under House Bill 21-1317 (HB 1317). The SRC, required under HB 1317, has reviewed the ColoradoSPH report during 11 open meetings and provided input both verbally and in writing. We also reviewed the evidence-based dashboard which includes data extracted from the 452 observational and randomized control trial studies selected with the inclusion criteria applied by the Cannabis Research and Policy Team (CRPT).

Overall, we acknowledge the rigorous effort of the CRPT and support the submission of this report. The Cannabis Research and Policy Team did a comprehensive and inclusive job in reviewing the current state of the literature starting with 66,000 plus study reports yielding 452 studies suitable for analysis on high-concentration Delta-9 Tetrahydrocannabinol (THC). Data from these studies have been placed in a searchable, evidence map suitable for future use by researchers and the general public. We also highlight the important discussions of the pharmacokinetics of THC and of the limitations of the research designs.

Throughout the review of the existing literature on high-concentration THC, the SRC has been keenly aware of the definitions of high-concentration THC, the heterogeneity of study designs, small and variable numbers of study participants, numerous methods of consumption, and non-standardized outcome measures across the studies. We understand the challenges of comparing the studies and the need for caution in interpretation of results. Given these challenges, the scoping review resulted in the identification of limited to modest signals of both adverse and beneficial effects of high-concentration THC that need to be further researched.

Going forward, we suggest the following recommendations.

Overall Recommendations

- Although there are some limited to moderate signals on the adverse and beneficial effects of high-concentration THC, we recommend caution in interpretation of the evidence. The limitations posed by study design, a lack of standardization for quantifying THC consumptions and exposure and other problems introduce great uncertainty. Please see the grey box in the beginning (page 12) and end of the final report (page 45) regarding the general use of THC at its implications.
- As clinicians and researchers, the available literature on high-concentration THC reveals potential adverse and limited beneficial effect. In addition, no or limited evidence does not mean that high-concentration THC is either safe or beneficial in all populations. We recommend caution for adult consumers in using high-concentration THC. We also recommend that the retail industry continue to provide education about the potential effects of high-concentration THC.

- This scoping review does not comment on the existing literature of general use of THC. We are particularly concerned about the potential to misinterpret the results and conclusions of the current scoping report addressing high-concentration THC cannabis products. See grey box in the final report.
- We recommend a call to action for improved standards for future research on THC particularly for methods for quantification of cannabis exposure. There are many research gaps identified by this scoping review that should be addressed. The potential for increased toxicity is certainly there but it's bundled up with experience, tolerance, self-titration, and target of use. What we need to understand at some point is how self-titration of products works, how decisions are made regarding product choice, method of use and how use patterns are established and maintained over time.
- If a therapeutic outcome is explored, we recommend using the FDA process of evaluation of therapeutic outcome described here: <u>https://www.fda.gov/drugs/development-approval-process-drugs</u>. Very little (if any) of the literature reviewed would meet FDA standards for approval of high-concentration THC products as therapeutics.
- In considering assessment of evidence related to adverse consequences/outcomes, we recommend including case reports available in emergency room data and poison centers.
- In addition, future high-concentration THC research should include vulnerable and marginalized populations including adolescents, pregnant women, racial and ethnic populations, and people with underlying conditions that increase their likelihood of experiencing adverse or beneficial effects of THC.
- If future high-concentration THC research is funded by the State legislature, a research committee should help define the research questions. In particular, the mental health studies highlight the limitations in research methods. Placebo-controlled randomized clinical trials (RCTs) should be prioritized for future research dollars.
- Furthermore, it may be time to consider the impact of generalized use of THC and other cannabinoids. We recommend future funding be considered to assess the health impact of THC in Colorado and other states who have legalized adult use of THC.
- Finally, we will continue to participate in the THC educational campaign.

Respectfully,

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Christopher Urbina, MD, MPH Chair of The Scientific Review Council

Member	Role on Council per HB 21-1317	Affiliation(s)
	Preventive medicine specialist (or	Pueblo Department of Public
(Chair)	preventive medicine public health	Health and Environment;
	professional)	Former Director of CDPHE
Gregory Kinney, PhD,	Epidemiologist	Colorado School of Public
MPH		Health
	Physician familiar with the	
	administration of medical marijuana	Children's Hospital Colorado;
David Brumbaugh, MD,	-	University of Colorado
MSc	experience recommending medical	School of Medicine
	marijuana to those aged zero	
	to seventeen	
Kennon Heard, MD	Madical Taxiaalagist	University of Colorado
Kennon Heard, MD	Medical Toxicologist	School of Medicine
Archana Shrestha, MD	Neurologist	University of Colorado
Archana Shiesuna, MD	Neurologist	School of Medicine
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Susan Calcaterra, MD,	Internal medicine physician (or other	University of Colorado
MPH	specialist in adult medicine)	School of Medicine
Joseph Schacht, PhD	Licensed Substance Abuse Disorder	University of Colorado
1	Specialist	School of Medicine
Kent Hutchison, PhD	Neuropsychopharmacologist	University of Colorado
·		School of Medicine
	Medical professional (or public health	
	professional) who specializes in racial	North Colorado Health
Lesley Brooks, MD	and health disparities and	Alliance; SummitStone Health
	systemic inequalities in health care and	Partners
	medicine	

Scientific Review Committee Members