



CANDESCENT[™]
CALIFORNIA

May 18, 2021

Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
P. O. Box 4010
Sacramento, California 95812-4010

Re: Proposed Amendments to Article 6: Safe Harbor Clear and Reasonable Warnings for Cannabis (Marijuana) Smoke and Delta-9-Tetrahydrocannabinol (Delta-9-THC) Exposure Warnings

To Whom It May Concern:

We write to express our concerns and reservations regarding the OEHHA's proposed changes to Proposition 65 warnings on cannabis products. First, the purported scientific basis for these proposed changes is without support in the cited literature, and either misstates or mischaracterizes the findings of deficient scholarship. Second, the recommended changes will necessarily result in an uncertain distribution of risk as it relates to Proposition 65 among producers and retailers. Third, the degree of warning proposed for cannabis products exceeds those of similarly-situated tobacco products with no basis provided for such incongruity. Fourth and finally, increased packaging and product positioning costs will further erode the viability of the legal market in favor of illicit operators that do not heed Proposition 65 requirements.

Deficiencies in the Scientific Record

The OEHHA asserts "the prevalence and frequency of cannabis use in pregnant women has increased" in the context of "[t]he legalization of the recreational use of cannabis in California."¹ In support of this assertion, the OEHHA cites two sources: a July 9, 2019 letter to the Journal of the American Medical Association,² and the OEHHA's previously-issued evidence regarding the developmental toxicity of cannabis smoke and delta-9-tetrahydrocannabinol.³

1 Office of Environmental Health Hazard Assessment, *Proposed Amendments to Article 6: Safe Harbor Clear and Reasonable Warnings for Cannabis (Marijuana) Smoke and Delta-9-Tetrahydrocannabinol (Delta-9-THC) Exposure Warnings*, p. 5 ("OEHHA Proposal (2021)").

2 Nora Volkow, M.D., Beth Han, M.D., Ph.D., M.P.H., Wilson M. Compton, M.D., M.P.E., and Elinore F. McCance-Katz, M.D., Ph.D., *Self-reported medical and nonmedical cannabis use among pregnant women in the United States* 322 *Journal of the American Medical Association* 167 (2019) ("Volkow letter").

3 Office of Environmental Health Hazard Assessment, *Evidence on the Developmental Toxicity of Cannabis (Marijuana) Smoke and Δ9-THC*, p. 17 ("OEHHA Evidence (2019)").

Regarding the Volkow letter, the data presented cannot meaningfully address the current state of cannabis consumption among pregnant California consumers. The letter in question compares usage rates in 2002 and 2017—substantially predating the implementation of MAUCRSA on January 1, 2018. While the cited letter does show that cannabis use among a nationwide cohort of pregnant women **had previously** increased, there is no evidence proffered in the Volkow letter that offers any evidence beyond supposition that cannabis use among pregnant women **continued to increase** following implementation of MAUCRSA. Further, the letter and underlying data from the 2017 National Survey on Drug Use and Health (“NSDUH”) does not meaningfully identify the rates of cannabis consumption within California, instead aggregating and generalizing rates across the United States.⁴

The Volkow letter includes further statistical weaknesses that, rather than supporting a change in Proposition 65 requirements, warrants additional scrutiny by OEHHA. The 2017 NSDUH data purportedly showing cannabis use among pregnant females aged 15 to 44 demonstrated *p* values—*i.e.*, probability of obtaining the results to the degree observed under the null hypothesis—well outside the 95% confidence interval cited in the resulting Volkow letter. For example, year-over-year cannabis use in all females age 18 to 44 corresponded to a *p* value of 0.0027, while **pregnant females in that same cohort** and time period corresponded to a *p* value of 0.1207.⁵ Even as the variance in *p* values does not necessarily warrant outright rejection of the reported data, such data is at best inconclusive as it relates to identifying degree of use across this limited demographic. Broadly speaking, the demographic data cited in the Volkow letter does not represent cannabis use among pregnant Californians specifically, and does not represent the state of cannabis use after the rollout of MAUCRSA generally. The paucity of relevant data contained within the Volkow letter, and the deficiencies in the underlying NSDUH data, undermines this portion of the OEHHA’s positing a “problem” requiring correction.

As to OEHHA’s 2019 report on the developmental toxicity of cannabis, NSDUH data from 2002 to 2014 was again cited as a basis for concluding “[a]mong pregnant women [...] cannabis use increased.”⁶ However, the underlying data demonstrates the same *p* value incongruity as shown in the 2017 NSDUH data noted *supra*. For example, the 2014 NSDUH data tables show *p* value of 0.0000 for use of “Marijuana and Hashish” use among all females aged 15 to 44 between the years 2011-12 and 2013-14,⁷ but a *p* value of 0.5887 for pregnant females of that same cohort and time period.⁸

The second study cited in OEHHA’s 2019 report is a research letter published in JAMA addressing cannabis use among pregnant women in Northern California from 2009 to 2016.⁹ Unfortunately, the conclusions drawn by the paper leave a number of ambiguities in the data that make extrapolation to

4 See, *e.g.*, Center for Behavioral Health Statistics and Quality, *2017 National Survey on Drug Use and Health: Detailed Tables*. Substance Abuse and Mental Health Services Administration (September 7, 2018).

5 *Id* at 1845.

6 OEHHA Evidence (2019), at 17.

7 We respectfully note OEHHA did not identify the difference between “Marijuana” and “Marijuana and Hashish” in these studies, and it remains unclear if there is a functional or practical difference between the impact of that terminology and data reporting.

8 Center for Behavioral Health Statistics and Quality, *2014 National Survey on Drug Use and Health: Detailed Tables*. Substance Abuse and Mental Health Services Administration, p. 1865 (September 10, 2015).

9 Kelly C. Young-Wolff, Ph.D., M.P.H., Lue-Yen Tucker, B.A., Stacey Alexeeff, Ph.D., Mary Anne Armstrong, M.A., Amy Conway, M.P.H., Constance Weisner, Dr.P.H., and Nancy Goler, M.D., *Trends in Self-reported and Biochemically Tested Marijuana Use Among Pregnant Females in California From 2009-2016*. 318 *Journal of the American Medical Association* 2490 (2017) (“Young-Wolff letter”).

the entire subset of pregnant Californians—and in particular, pregnant Californians that may benefit from the warnings required on Proposition 65 labeling—improper. As an overarching data integrity matter, the paper itself notes that “[p]renatal use before [versus] after women realized they were pregnant could not be distinguished.”¹⁰ As a preliminary matter, determining whether additional warnings are necessary to inform pregnant women of the risks inherent of consuming cannabis while pregnant should at least identify whether the subject women were aware of their pregnancy during their cannabis consumption. Further, the study does not meaningfully identify what proportion of pregnant people that used cannabis intended on maintaining such a pregnancy to term. Pregnant Californians sought abortion services at a rate of 17.4 per 1,000 women aged 15-44 in 2016.¹¹ In contrast, the Young-Wolff letter identified an aggregate fertility rate of approximately 43.7 live births per 1,000 women aged 15-44 over the length of the study.¹² Where the abortion rate amounts to nearly 40% of the observed fertility rate within the study group, and the highest rate of cannabis use of any age cohort in the study reached 21.8%, further study is clearly warranted.¹³ And finally, as with the Volkow letter, usage rates in 2016 cannot adequately address usage rates after the implementation of MAUCRSA beginning in 2018.

Given the substantial deficiencies in all of the evidence proffered by OEHHA in support of the proposed regulations, we submit that OEHHA has failed to demonstrate the assertion central to the proposed changes: namely, an increase in cannabis consumption among pregnant Californians following the legalization of recreational use. Absent meaningful data addressing this central question, the proposed changes are based on little more than supposition and conjecture.

Uncertain Compliance Landscape for Cannabis Producers

In addition to extant Proposition 65 warnings, cannabis goods for retail sale must dedicate substantial amounts of outside packaging to state-mandated warnings¹⁴ and other required consumer-facing information. Several product categories, including cannabis pre-rolls, are typically sold in packaging with limited surface area for such warnings as currently constituted. OEHHA’s proposal would necessarily force cannabis producers to choose between expensive packaging reconfigurations—including any attendant loss in sell-through due to decreased marketing opportunities per package—or operate under the assumption that due warning will be provided by retailers. Indeed, OEHHA recommends “[i]f the product packaging is too small to accommodate the proposed warning, other warning methods, such as posted signs and shelf tags, are available.”¹⁵

Despite the “availab[ility]” of posted signs and shelf tags, such a proposal does not mitigate the degree of uncertainty in compliance for cannabis producers. While the current regulations surrounding Proposition 65 warnings provide that cannabis producers “may enter into a written agreement [...]

¹⁰ *Id.* at 2491

¹¹ Rachel K. Jones, Elizabeth Witwer, and Jenna Jerman, *Abortion Incidence and Service Availability in the United States*, 2017. Guttmacher Institute (2019).

¹² Assuming demographic similarity to the larger population of California which, in 2016, counted 8.06 million women ages 15-44 of a total population of 39.17 (U.S. Census Bureau).

¹³ Notably, Proposition 65 packaging solutions are effectively beside the point when discussing the cannabis consumption rates of pregnant females under the age of 18, who cannot legally obtain either medical or adult-use cannabis in California.

¹⁴ 17 C.C.R. §§ 40404(b)(4), 40408(a)(3). Notably, these extant cannabis labeling requirements include specific warning to consumers that “CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL” (capitalization in original).

¹⁵ OEHHA Proposal (2021), 11.

allocat[ing] legal responsibility among” the parties involved “which shall supersede the [labeling] requirements.”¹⁶ As OEHHA’s recommendation itself suggests, many cannabis producers will be unable to apply the recommended Proposition 65 warning text to a number of smaller products. Such a change effectively changes the **permissive** element of existing regulations—i.e., “**may** enter into a written agreement”—into a functionally **mandatory** element: if a product’s packaging cannot be redesigned to accommodate OEHHA’s proposed language, then agreements with downstream distributors and retailers is the only viable path forward.

Notably, inter-company agreements are only be valid so long as “the consumer receives a warning that meets the requirements.”¹⁷ Consequently, cannabis producers forced to enter into such risk-allocation agreements would be entirely at the mercy of an individual cannabis retailer’s compliance with signage or shelf labeling: “consumer product manufacturers and upstream distributors who have contracted with downstream suppliers may still be liable for Proposition 65 violations if the consumer is not ultimately warned of the potential chemical exposure.”¹⁸ A lack of direct control over point-of-sale labeling leaves producers with limited remedies in the event such an agreement is violated resulting in a lawsuit, and necessarily impairs such a producer’s financial ability to pursue such remedies at law. Further, shunting responsibility to retailers as a result of impossibility or impracticability that is solely the result of OEHHA’s proposed regulations violates the purposes of the Act, which instructs agencies “to minimize the burden on retail sellers of consumer products” by “plac[ing] the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller.”¹⁹

OEHHA’s proposal will necessarily render a number of cannabis producers unable to include per-unit Proposition 65 labeling, effectively forcing them into agreements with individual retailers—agreements that, under current regulations, provide effectively no safe harbor for cannabis producers should the retailers fail in their duties to provide adequate notice to consumers. The practicability of implementing the proposed regulation falls well short of requirements made under the Act, and constitutes an impediment to commerce in the state.

Disproportionate Compared to Similarly Situated Nicotine Products

OEHHA proposes that cannabis products bear language warning that “delta-9-THC and other chemicals [] can affect your child’s birthweight, behavior, and learning ability.”²⁰ cursory review of similarly situated tobacco or tobacco-based products, including those solely containing nicotine, are not required to carry such “tailored” warnings despite the presumptively equivalent danger to public health.

Consumer and commercial information provided by OEHHA surrounding tobacco smoke indicates that prenatal exposure to tobacco smoke “can cause low birth weight, miscarriage, still birth, [] birth defects

16 27 C.C.R. § 25600.2(i).

17 *Id.*

18 Thomas M. Donnelly, Daniel L. Corbett, Alexandra N. Fries, and Lindsay N. Szymanski, *2020 Regulatory Amendments Attempt to Simplify Proposition 65 Warning Obligations*, Jones Day (July 2020), <https://www.jonesday.com/en/insights/2020/07/2020-regulatory-amendment-proposition-65>.

19 Health & Safety Code § 25249.11(f). Even if OEHHA were to contend that this burden can be minimized by requiring cannabis producers to provide the physical signage required, the logistical burden of maintaining adequate and clear warning materials on a per-supplier basis itself constitutes a burden that in no way can reasonably be described as “minimize[d]” by the proposed regulation.

20 OEHHA Proposal (2021), 9.

such as cleft palate[,] [and] also affect brain development[,] cause learning and behavior problems for children, and may increase children's risk for leukemia and liver cancer."²¹

To the extent that the proposed label changes are to ensure "consumers [...] can be made aware of the specific effects the exposures can cause to unborn children," OEHHA has not indicated why cannabis products would warrant such labeling requirements while smokable tobacco products would not. To the extent that the difference in basis is due to public awareness of tobacco smoke impact on prenatal health, we would note that such a degree of public awareness occurred **without** requiring specific enumeration of reproductive hazards on smokable tobacco products.

OEHHA has failed to identify a basis for requiring the level of specificity in the proposed regulations while other similarly situated tobacco products may suffice with other warning content found within pertinent regulations. Insofar as the proposed regulation is purportedly focused on public health, singling out cannabis smoke and delta-9-THC without attendant requirements of tobacco or nicotine product producers and retailers constitutes an arbitrary and capricious action without cognizable basis in scientific literature or existing law.

Benefit to Illicit Cannabis Producers and Retailers

California cannabis businesses are subject to myriad industry-specific regulatory burdens beyond those borne by other businesses operating within the state.²² Notably, cannabis producers are already obligated to provide warning to pregnant consumers under both Proposition 65 requirements and the Department of Public Health labeling requirements cited *supra*. These regulatory burdens come with measurable compliance costs, resulting in higher costs at point of sale for cannabis consumers.

Unfortunately, the illicit cannabis market in California does not reliably abide by either Proposition 65 requirements or other cannabis regulations. This decreased cost of operation provides substantial competitive advantage to illicit cannabis operations in the state, which remains several times larger than the regulated state market: "[o]f the roughly 14 million pounds of marijuana grown in California annually, only a fraction—less than 20 percent according to state estimates and a private research firm—is consumed in California."²³ That increased packaging, labeling, and compliance costs will ultimately divert yet more consumer money into the illicit cannabis market is indisputable, with only the degree of increase at issue.

Legal cannabis businesses will be injured twofold by the proposed changes: first, bearing the immediate costs of coming into compliance with new labeling requirements; second, competing for a smaller market as more consumers are incentivized to purchase lower-cost cannabis from the illicit market.²⁴

Conclusion

21 *Tobacco Smoke*, Office of Environmental Health Hazard Assessment, <https://www.p65warnings.ca.gov/fact-sheets/tobacco-smoke>.

22 See, e.g., 3 C.C.R. §§ 8000 *et seq.*, 16 C.C.R. §§ 5000 *et seq.*, 17 C.C.R. §§ 40100 *et seq.*

23 Thomas Fuller, 'Getting Worse, Not Better': *Illegal Pot Market Booming in California Despite Legalization*, *New York Times* (April 27, 2019).

24 Illicit market cannabis, being removed from all state regulatory requirements, may also contain levels of contaminants including pesticides that would normally warrant additional Proposition 65 labeling. Contrary to OEHHA's intention, the proposed regulatory changes may ultimately expose pregnant cannabis consumers to **more** chemicals known to the State of California to cause birth defects or other reproductive harm.

OEHHA's basis for changing existing Proposition 65 regulations lacks basis in available scientific evidence, will result in complicated apportionment of risk between cannabis producers and retailers, unreasonably places a disproportionate burden on cannabis products compared to tobacco, and ultimately stands to enrich the illicit cannabis market. As all compliantly labeled cannabis products in California already bear two warnings related to reproductive harm, we do not believe that disproportionate inclusion of specific developmental effects meaningfully accomplishes any legitimate state interest.

Sincerely,

Andrew Mochulsky
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