

**Model comments on the California Department of Food and Agriculture Proposed
Text of Regulations
*Getting it Right from the Start: Regulation of Recreational Marijuana***

A project of the Public Health Institute

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(with appreciation to UCSF's Center for Tobacco Control Research and Education for helpful input)

Notes on submission:

Comments can be submitted three ways:

- 1) Through **email**: Write in the email subject line: Comments on Cannabis Cultivation Regulations. Address the email to: CalCannabisRegs@cdfa.ca.gov

2) By **mail** to:

California Department of Food and Agriculture

Attn: Amanda Brown

CalCannabis Cultivation Licensing Division

Proposed Cannabis Cultivation Regulations

P.O. Box 942871 Sacramento, CA 94271

3) Or by **attending a public hearing**.

Tuesday, August 28 1pm-3pm California Department of Food & Agriculture Auditorium 1220 N
Street Sacramento, CA 95814

Mailed or emailed comments are due by 5pm PST on **August 27, 2018**

Highlighted, bracketed text indicates sections that need to be filled in by the submitting organization.

This Instructions Page Should be Deleted prior to Submission.

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[INSERT DATE]

To:
California Department of Food and Agriculture
Attn: Amanda Brown
CalCannabis Cultivation Licensing Division
Proposed Cannabis Cultivation Regulations
P.O. Box 942871 Sacramento, CA 94271

Comment on California Department of Food and Agriculture Proposed Regulations in
CALIFORNIA CODE OF REGULATIONS, TITLE 3. FOOD AND AGRICULTURE, DIVISION 8. CANNABIS
CULTIVATION, CHAPTER 1. CANNABIS CULTIVATION PROGRAM

Comment Summary:

CDFA's PROPOSED REGULATIONS, WHILE CREATING IMPORTANT SYSTEMS FOR MANAGING LEGALIZED CANNABIS CULTIVATION, FAIL TO ADDRESS TWO KEY THREATS TO PUBLIC HEALTH AND EQUITY, SPECIFICALLY THE GROWING PROPORTION OF CANNABIS SOLD IN THE UNITED STATES THAT IS HIGH POTENCY, WITH GREATER RISKS OF NEGATIVE HEALTH IMPACTS SUCH AS ADDICTION AND PSYCHOSES, AND THE NEED TO ASSURE THAT INDIVIDUALS WHO HAVE BEEN HISTORICALLY VICTIMIZED BY THE WAR ON DRUGS HAVE THE OPPORTUNITY TO PARTICIPATE IN THE LEGALIZED CANNABIS INDUSTRY. WE ALSO RECOMMEND A GREATER DISTANCE FROM INSTITUTIONS SERVING CHILDREN AND YOUTH.

About the Submitting Organization:

[INSERT ORGANIZATION NAME AND DESCRIPTION OF WORK]

General Comments: The creation and government endorsement of a legal cannabis industry that will span both medical and recreational use **presents risks that such an industry may seek to drive up demand and addiction, exploit problem use to increase profit, and exert powerful influence over the regulatory environment** as other industries have done, most notably tobacco, or that such other industries may seek to enter and dominate the new cannabis markets.

Ample evidence exists which supports a measured precautionary approach.¹ The 2017 National Academies of Sciences, Engineering and Medicine report *The Health Effects of Cannabis and Cannabinoids* found “substantial evidence” of association of cannabis use with development of substance use disorders when use begins early, with schizophrenia and other psychoses, with low birth weight when used during pregnancy, increased respiratory problems with smoking, and motor vehicle crashes.¹ A growing body of literature suggests that cannabis smoking is associated with cardiovascular disease, stroke, and impairment of endothelial function.^{1,2,3,4} Even secondhand exposure to marijuana smoke has negative cardiovascular effects; a recent study in rats found that one minute of exposure impaired normal functioning of arteries (endothelial function) for at least ninety minutes.⁵ Changes in endothelial function are associated with development of heart disease and triggering heart attacks.^{6,7} Cannabis smoke shares a similar toxicity profile to tobacco smoke,⁸ and California has identified cannabis smoke as a known human carcinogen since 2009.^{9,10} **Daily cannabis use by youth has been associated with more than halving high school graduation rates and other negative effects of cognition.**^{11,12} Cannabis consumption has been associated with altered or decreased cognition among adolescents,^{13,14} and cyclic vomiting syndrome.¹⁵ Evidence for cannabis’ negative health effects (and medical efficacy) is still under study and evidence will continue to emerge in the coming years, owing largely to longstanding barriers to research stemming from illegality.¹⁶

¹ National Academies. (2017). *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*. The National Academies Press: Washington, DC.

² Yankey, B.A., et al., (2017). Effect of marijuana use on cardiovascular and cerebrovascular mortality: A study using the National Health and Nutrition Examination Survey linked mortality file. *Eur J Prev Cardiol*, 24(17):1833-1840.

³ Mittleman, M.A., et al., (2001). Triggering myocardial infarction by marijuana. *Circulation*. 103(23):2805-9.

⁴ Wang, X., et al., (2016). One Minute of Marijuana Secondhand Smoke Exposure Substantially Impairs Vascular Endothelial Function. *J Am Heart Assoc*. 5(8). pii: e003858.

⁵ Wang, X., et al., (2016). One Minute of Marijuana Secondhand Smoke Exposure Substantially Impairs Vascular Endothelial Function. *J Am Heart Assoc*. 5(8). pii: e003858.

⁶ Widlandky ME, Gokce N, Keaney JF Jr, Via JA. (2003). The clinical implications of endothelial dysfunction. *J Am Coll Cardiol*, 42(7): 1149-60.

⁷ Yeboah J, Folsom AR, Burke GL, et al. (2009). Predictive Value of Brachial Flow-Mediated Dilation for Incident Cardiovascular Events in a Population-Based Study: The Multi-Ethnic Study of Atherosclerosis. *Circulation*, 120(6): 502-509. doi: 10.1161/CIRCULATIONAHA.109.864801.

⁸ Moir, D., et al., (2008). A comparison of mainstream and sidestream marijuana and tobacco cigarette smoke produced under two machine smoking conditions. *Chem Res Toxicol*. 21(2):494-502.

⁹ California Environmental Protection Agency. (2017). *Chemicals Known to the State to Cause Cancer or Reproductive Toxicity*, Office of Environmental Health Hazard Assessment, Editor: <https://oehha.ca.gov/media/downloads/proposition-65/p65single01272017.pdf>

¹⁰ Tomar, R.S., Beaumont, J. and Hsieh, J.C.Y. (2009). *Evidence on the Carcinogenicity of Marijuana Smoke*, California Environmental Protection Agency Office of Environmental Health Hazard Assessment Reproductive and Cancer Hazard Assessment Branch, Editor.

¹¹ Silins E, et al. Cannabis Cohorts Research Consortium. (2014). Young adult sequelae of adolescent cannabis use: an integrative analysis. *Lancet Psychiatry*. 1(4):286-93. doi: 10.1016/S2215-0366(14)70307-4

¹² Sagar KA, Gruber (2018) Marijuana matters: reviewing the impact of marijuana on cognition, brain structure and function, & exploring policy implications and barriers to research, International Review of Psychiatry, DOI: [10.1080/09540261.2018.1460334](https://doi.org/10.1080/09540261.2018.1460334)

¹³ Lorenzetti V, et al. (2016). Cannabis Use: What is the Evidence for Functional Brain Alteration? *Curr Pharm Des*. 22(42): 6353-6365.

¹⁴ Sagar KA, Gruber SA (2018) Marijuana matters: reviewing the impact of marijuana on cognition, brain structure and function, & exploring policy implications and barriers to research, International Review of Psychiatry, DOI: [10.1080/09540261.2018.1460334](https://doi.org/10.1080/09540261.2018.1460334)

¹⁵ Blumentrath CG, Dohrmann B, Ewald N. (2017). Cannabinoid hyperemesis and the cyclic vomiting syndrome in adults: recognition, diagnosis, acute and long-term treatment. *Ger Med Sci*, 15:Doc06

¹⁶ National Academies. (2017). *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*. The National Academies Press: Washington, DC.

Protecting the public health requires that both medical and recreational cannabis markets be well controlled and designed to prevent the emergence of a powerful industry that resembles the tobacco or alcohol industries. Unless the State of California clearly adopts a public health framework for regulating this new legal market,¹⁷ **normal profit-maximizing behavior by business is likely to impose excessive and growing health costs on the people of California** similar to those imposed by the tobacco and alcohol industries, including designing products to capture and addict clients from the youngest possible age, using their political power to oppose effective regulatory, tax, and public education policies that would reduce consumption and profits. It is the duty of the State to act now, not to promote the unfettered growth of the cannabis industry, but rather to act effectively to protect public health while executing a prudent and cautious approach to allow transition to a legal market.

Specific Recommendations:

Problematic areas:

There are at least three significant areas of omission in the proposed regulations that need to be addressed:

1) Issue: Vast Increases in Potency of Cultivated Cannabis (No reference section)

In 2007, Judge Gladys Kessler, in a landmark decision in *US v Philip Morris*,¹⁸ held the tobacco companies liable for violating RICO by fraudulently covering up the health risks associated with smoking and for marketing their products to children. She recognized that the tobacco industry had tailored nicotine content and delivery in tobacco products for decades to better addict those initiating smoking.

“As demonstrated in the previous Section, Defendants have long known that nicotine creates and sustains an addiction to smoking and that cigarette sales, and ultimately tobacco company profits, depend on creating and sustaining that addiction. Section V(B)(3), supra. Given the importance of nicotine to the ultimate financial health of Defendants, they have undertaken extensive research into how nicotine operates within the human body and how the physical and chemical design parameters of cigarettes influence the delivery of nicotine to smokers. Using the knowledge produced by that research, Defendants have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction. At the same time, Defendants have concealed much of their nicotine-related research, and have continuously and vigorously denied their efforts to control nicotine levels and delivery.”¹⁹

Tragically, we are seeing a very similar process underway in the cannabis industry, where the concentration of tetrahydrocannabinol, the main psychoactive component of cannabis, has been

¹⁷ Barry RA, Glantz SA. A Public Health Framework for Legalized Retail marijuana Based on the US Experience: Avoiding a New Tobacco Industry. *PLoS Med* 2016;13(9): e1002131. doi: [10.1371/journal.pmed.1002131](https://doi.org/10.1371/journal.pmed.1002131)

¹⁸ Kessler, G. Amended Final Opinion in *US. V Philip Morris USA Inc.* United States District Court for the District of Columbia. Civil Action No. 99-2496 (GK) 449 F.Supp.2d 1 (D.D.C. 2006)

¹⁹ Kessler, G. Amended Final Opinion in *US. V Philip Morris USA Inc.* United States District Court for the District of Columbia. Civil Action No. 99-2496 (GK) 449 F.Supp.2d 1 (D.D.C. 2006)

rapidly increased over the past quarter century from approximately 3% to levels as high as 28% or more in flower. Whether this is a conscious policy to deepen addiction, or merely an attempt to provide a stronger high, the net effect is the same. Agricultural production of cannabis, whether legal or illegal, has been rapidly and massively shifting from traditional plants to more harmful high potency ones, unbalanced by cannabidiol, with a complete absence of public policy discussion or action on the associated public health risks. El Sohly *et al* note:

“Between January 1, 1995, and December 31, 2014, 38,681 samples of cannabis preparations were received and analyzed. The data showed that although the number of marijuana samples seized over the last 4 years has declined, the number of sinsemilla samples has increased. Overall, the potency of illicit cannabis plant material has consistently increased over time since 1995 from ~4% in 1995 to ~12% in 2014. The cannabidiol content has decreased on average from ~.28% in 2001 to <.15% in 2014, resulting in a change in the ratio of Δ^9 -tetrahydrocannabinol to cannabidiol from 14 times in 1995 to ~80 times in 2014.”²⁰

This transition to higher potency has been particularly dramatic **post-legalization of recreational cannabis**, with a recent study by RAND of the legalized market in the state of Washington demonstrating the rapid disappearance of traditional cannabis with concentrations of THC below 10% and the extraordinarily rapid growth of high potency flower with over 15% and 20% in the short period between 2014-2016:

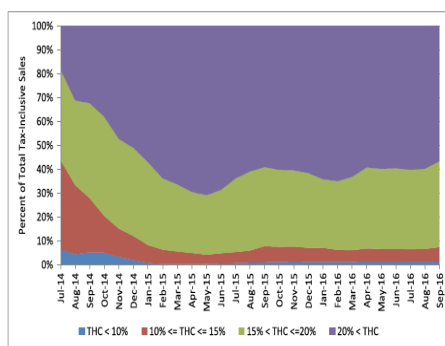


Figure 3 Market shares for cannabis flower products sold, by delta-9-tetrahydrocannabinol (THC) % category. Market share is calculated as a percent of total cannabis flower expenditures (excise-tax-inclusive). [Colour figure can be viewed at wileyonlinelibrary.com]

*“Among flower products, the market share of strains with greater than 15% THC has grown to 92.5% of flower sales (Fig. 3), and (not shown) an even greater share of THC consumption. Flowers with less than 10% THC now account for less than 2% of flower expenditures, and market share for flower products with 10–15% THC has declined significantly by 60.4% since October 2014 (linear trend $P = 0.007$);. In contrast, **the market share of flower products with more***

than 20% THC has increased by 48.4% since October 2014, now accounting for 56.5% of retail expenditures on cannabis flower....” (See Figure)²¹

The potential health effects of these shifts are of great concern. According to Sagar and Gruber:

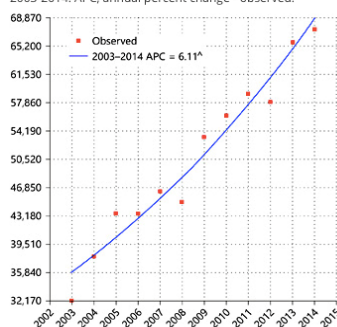
²⁰ El Sohly, M. A., Mehmedic, Z., Foster, S., Gon, C., Chandra, S., & Church, J. C. (2016). Changes in Cannabis Potency Over the Last 2 Decades (1995-2014): Analysis of Current Data in the United States. *Biological Psychiatry*, 79, 613–619. doi:[10.1016/j.biopsych.2016.01.004](https://doi.org/10.1016/j.biopsych.2016.01.004)

²¹ [Smart B, C,aulkins JP, Kilmer B, Davenport S, Midgette G](https://doi.org/10.1111/add.13886). Variation in cannabis potency and prices in a newly legal market: evidence from 30 million cannabis sales in Washington state. *Addiction*. 2017 Dec;112(12):2167-2177. doi: 10.1111/add.13886. Epub 2017 Jul 4

“Although one study showed that individuals who smoke high potency MJ flower titrate their use to receive less THC, some suggest that, despite attempts to titrate high potency products, users are still exposed to higher amounts of THC than those using lower potency products,²² while still other studies have shown that individuals do not adjust their use when using higher potency products.²³ Increased exposure to THC has also been associated with increased symptoms of cannabis use disorders,^{24,25} increased risk for of psychosis,^{26,27} and, as observed in acute administration studies, impaired cognition.^{28,29,30} In addition, one study assessing the relationship between brain structure and potency of MJ flower products, classified as either ‘high’ or ‘low’ potency by self-report, noted alterations in corpus callosum white matter microstructure in high-potency MJ users compared to low-potency users and controls.³¹

Fig. 1

Trends in the number of first-time cannabis treatment admission in Eu-22 - joinpoint regression outcome, 2003-2014. APC, annual percent change - observed.



seeking care (See Figure).³³ At a time when the U.S. is in the throes of a major opioid epidemic,

In the United Kingdom, Freeman found high-potency cannabis use to be associated with an increased severity of dependence, especially in young people. While its profile was strongly defined by negative effects such as memory impairment and paranoia, it was also perceived as offering “best high” or “preferred.”³² Consumption of higher potency products also corresponds over time to major upsurges in care seeking behavior for cannabis dependency in Europe, now the leading substance of abuse for

²² van der Pol et al., 2014 van der Pol, P., Liebrechts, N., Brunt, T., van Amsterdam, J., de Graaf, R., Korf, D. J., ... van Laar, M. (2014). Cross-sectional and prospective relation of cannabis potency, dosing and smoking behaviour with cannabis dependence: an ecological study. *Addiction*, 109, 1101–1109. doi:[10.1111/add.12508](https://doi.org/10.1111/add.12508)

²³ Chait, L. D. (1989). Delta-9-tetrahydrocannabinol content and human marijuana self-administration. *Psychopharmacology (Berl)*, 98, 51–55. Retrieved from <https://www.ncbi.nlm.nih.gov/ucsf.idm.oclc.org/pubmed/254301810>

²⁴ Freeman & Winstock, 2015 Freeman, T. P., & Winstock, A. R. (2015). Examining the profile of high-potency cannabis and its association with severity of cannabis dependence. *Psychological Medicine*, 45, 3181–3189. doi:[10.1017/S0033291715001178](https://doi.org/10.1017/S0033291715001178)

²⁵ Van der Pol, ibid

²⁶ Di Forti, M., Marconi, A., Carra, E., Fraitetta, S., Trotta, A., Bonomo, M., ... Murray, R. M. (2015). Proportion of patients in south London with first-episode psychosis attributable to use of high potency cannabis: a case-control study. *The Lancet Psychiatry*, 2, 233–238. doi:[10.1016/s2215-0366\(14\)00117-5](https://doi.org/10.1016/s2215-0366(14)00117-5)

²⁷ Large, M., & Nielssen, O. (2017). Daily use of high-potency cannabis is associated with an increased risk of admission and more intervention after first-episode psychosis. *Evidence-Based Mental Health*, 20, 58. doi:[10.1136/eb-2017-102630](https://doi.org/10.1136/eb-2017-102630)

²⁸ D'Souza, D.C., Perry, E., MacDougall, L., Ammerman, Y., Cooper, T., Wu, Y. T., ... Krystal, J. H. (2004). The psychotomimetic effects of intravenous delta-9-tetrahydrocannabinol in healthy individuals: implications for psychosis. *Neuropsychopharmacology*, 29, 1558–1572. doi:[10.1038/sj.npp.1300496](https://doi.org/10.1038/sj.npp.1300496)

²⁹ Kowal, M. A., Hazekamp, A., Colzato, L. S., van Steenberghe, H., van der Wee, N. J., Durieux, J., Hommel, B. (2015). Cannabis and creativity: highly potent cannabis impairs divergent thinking in regular cannabis users. *Psychopharmacology (Berl)*, 232, 1123–1134. doi:[10.1007/s00213-014-3749-1](https://doi.org/10.1007/s00213-014-3749-1)

³⁰ Ramaekers, J. G., Kauert, G., van Ruitenbeek, P., Theunissen, E. L., Schneider, E., & Moeller, M. R. (2006). High-potency marijuana impairs executive function and inhibitory motor control. *Neuropsychopharmacology*, 31, 2296–2303. doi:[10.1038/sj.npp.1301068](https://doi.org/10.1038/sj.npp.1301068)

³¹ Rigucci et al., 2016 Rigucci, S., Marques, T. R., Di Forti, M., Taylor, H., Dell'Acqua, F., Mondelli, V., Dazzan, P. (2016). Effect of high-potency cannabis on corpus callosum microstructure. *Psychological Medicine*, 46, 841–854. doi:[10.1017/S0033291715002342](https://doi.org/10.1017/S0033291715002342)

³² Freeman TP, Winstock AR. *Psychol Med*. Examining the profile of high-potency cannabis and its association with severity of cannabis dependence. 2015 Nov;45(15):3181-9. doi: [10.1017/S0033291715001178](https://doi.org/10.1017/S0033291715001178). Epub 2015 Jul 27.

³³ Montanari L, Guarita B, Mounteney J, Zipfel N, Simon R, Cannabis Use among People Entering Drug Treatment in Europe: A Growing Phenomenon? *Eur Addict Res* 2017;23:113-121

and our mental health and substance abuse services are strained to bursting, it makes little sense to facilitate this dangerous trend in a new and heavily regulated industry.

While the Netherlands tolerates cannabis sales, cannabis above 15% THC content are proposed as Schedule I.³⁴ Recent recommendations for legalization in the United Kingdom endorse restricting legalization to products below 15% THC.³⁵ Canada's Task Force on Cannabis Legalization and Regulation recognized increasing potency as a fundamental public health challenge that needs to be addressed. Inexplicably, the regulatory framework under development in California has completely omitted any effort to, or even discussion of how to, address this important challenge to date.

As the lead agency responsible for regulating agricultural production in the State of California, it is essential that CDFA act now to slow this rapid and dangerous trend in cannabis agriculture. While there is still much debate about the best approach to be used, for example optimal potency maxima for cultivation *versus* taxation policy, the policy of doing nothing, in use to date, has clearly not been successful. We recommend that the State contract with the University of California Office of the President to bring together an expert panel to produce a study of the public health risks of increasing cannabis potency, decreasing THC:CBD (as well as of flavored cannabis products), and an analysis of regulatory and fiscal options to address these issues by mid-2019. Until such time as that assessment is available, we strongly recommend a limit on the potency of allowable cannabis cultivation for sale as flower or pre-rolls to below 20% THC content.

2) Issue: Promotion of Equity in Licensing

Article 2. Applications § 8100 – 8115 :

Absent from the proposed text of regulations is any effort to promote equity to ensure that residents of communities that suffered high rates of incarceration and other social ill effects from unequal enforcement of cannabis laws are able to benefit from legalization. This will have the effect of consolidating cultivation and processing supported by wealthy investors in favorable locations before low-income community members who have historically been incarcerated for engaging in the same activities, can feasibly develop locations. Requirements for advance leasing of premises and fees are all obstacles.

To avoid transfer of wealth from low-income communities to wealthy investors, we strongly recommend that a category of equity applicant be defined, related to majority ownership by person(s) with long term residence in communities with high rates of cannabis-related incarceration, or who have been categorized as equity applicants by their local jurisdiction, and that at least 50% of all state licenses be reserved for and issued to applicants from these categories. Applications who have been categorized as equity applicants by their local jurisdiction should receive priority status. The ability to defer fees by one year, and to use a staged licensing process that allows preliminary approval pending confirmation of premises, as is being considered in some jurisdictions, would allow lower income applicants to secure an expensive

³⁴ http://www.emcdda.europa.eu/countries/drug-reports/2017/netherlands/drug-laws-and-offences_en

³⁵ IEA Discussion Paper No.90 JOINT VENTURE Estimating the Size and Potential of the UK Cannabis Market Christopher Snowdon June 2018

premise or land only when there is a reasonable basis to believe that a license would be forthcoming.

3) Issue: Distance from youth serving facilities

§ 8102. (x) An attestation that the proposed location is at least a six-hundred (600) foot radius from a school providing instruction in kindergarten or any grades one (1) through twelve (12), or a day care center or youth center as defined in section

26001 of the Business and Professions Code, that is in existence at the time the application is submitted, or that the premises complies with a local ordinance specifying a different radius. The distance shall be measured in the same manner as provided in subsection (c) of section 11362.768 of the Health and Safety Code unless otherwise provided by law;

Since sales of cannabis are prohibited to individuals under age 21, and neurological development is not mature until closer to age 25, the prohibition on location of premises licensed under this division should be increased to 1,000 feet, which is a mere 3 blocks, and extended to include community colleges and universities, given that a large part or even the majority of students may be under age 21. We also recommend that the distance requirement apply to distance from existing substance abuse treatment centers.

Further, this rule, as written, is subject to a more expansive interpretation wherein any local jurisdiction is given carte blanche to issue a permit for a premises located within a 600-foot radius of the listed youth serving institutions. While it is certainly reasonable to provide exceptions for premises that licensed prior to January 1, 2017, the ambiguous wording of this provision risks exploitation and resultant widespread exposure of youth to cannabis licensees. We strongly urge adding a criteria that the local license must have been issued prior to January 1, 2017 to allow an exception to the 600 foot buffer.

Conclusion

In summary, while the science surrounding the potential harms and benefits of medical cannabis is evolving, clearly identified risks during pregnancy, of dependency, motor vehicle accidents, pulmonary disease, and to mental health, as well as growing concern for cardiovascular health and youth neurological outcomes, amongst other concerns require **a far more cautious approach to rolling out legalization**. In particular, the rapid shift in agricultural production to high potency plants is of deepest concern.

CDFA's proposed regulations are an important step in the process of bringing the cannabis industry into the light and away from its status as an illegal or under-regulated industry. While some of the provisions adopt best practices, they fall short in other areas. The proposed text of regulations will allow the large-scale shift to higher potency, more addictive and more dangerous cannabis to continue unabated, and fails to advance any proposals to assure greater equity in access to licenses. Addressing these issues will be essential to promote a functional and well-

regulated cannabis system that prioritizes protection of public health over business interests in the State of California.

Thank you for considering these recommendations, which we believe should be corrected in your proposed regulation.

Sincerely,

[INSERT SIGNATURE(S)]