Model comments on the BCC 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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Notes on submission:

Comments can be submitted three ways:

1) Through **email** to bcc.comments@dca.ca.gov with subject line "BCC Proposed Text of Regulations"

2) Through **physical mail** to
Lori Ajax, Chief
Bureau of Cannabis Control
P.O. Box 419106
Rancho Cordova, CA 95741

3) Or by **attending a public hearing**.
Hearing schedule can be found on the BCC website at https://cannabis.ca.gov/cannabis-regulations/

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

Highlighted, bracketed text indicate sections that need to be filled in by the sender.

The content contained herein is offered as a public service and does not constitute provision of legal advice nor create an attorney-client relationship.

[INSERT DATE]

To:
Lori Ajax, Chief
Bureau of Cannabis Control
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Rancho Cordova, CA 95741
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Comment on Bureau of Cannabis Control Proposed Text of Regulations
CALIFORNIA CODE OF REGULATIONS TITLE 16, DIVISION 42
BUREAU OF CANNABIS CONTROL

Comment Summary:

WHILE THE REGULATIONS CONTAIN CERTAIN IMPORTANT ADVANCES SUCH AS REQUIRING SPECIALIZATION OF CANNABIS BUSINESSES, BCC'S PROPOSED REGULATIONS AS WRITTEN CONTINUE TO PERMIT EXCESSIVE LICENSING AND DENSITY OF RETAILERS, GIVES NO CONSIDERATION TO EQUITY IN LICENSING, FALLS SHORT OF EFFECTIVELY CONSTRAINING HARMFUL MARKETING PRACTICES, AND PROPOSES EXCESSIVE DAILY SALES LIMITS, ALL OF WHICH IMPOSE UNNECESSARY RISKS ON THE HEALTH OF CALIFORNIANS. TO AVOID IRREVERSIBLE HARM, AN IMMEDIATE CAP SHOULD BE PLACED ON NUMBER OF RETAILERS LICENSED BY THE STATE AND PROVISIONS FOR GREATER EQUITY INSTITUTED UNDER THE PROPOSED REGULATIONS.

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, exploit abusive 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 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 and motor vehicle crashes.[1] Cannabis smoking has been associated with respiratory health harms, stroke, and cardiovascular disease as well as secondhand smoke risks.[1,2,3,4] Cannabis smoke shares a similar toxicity profile to tobacco smoke,[5] and California has identified cannabis smoke as a known human carcinogen since 2009.[6,7] **Daily cannabis use by youth is associated with more than halving high school graduation rates.[8]** Cannabis consumption has also been associated with altered or decreased brain function among adolescents,[9] cyclic vomiting syndrome,[10] and manifestation of psychotic disorders.[11] 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.[12] Changes in endothelial function are associated with development of heart disease and triggering heart attacks.[13,14] Evidence for cannabis's negative health effects

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[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] 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.

[6] 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

[7] 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.

[8] 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

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

[10] 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

[11] 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.

[12] 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.

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

[14] 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.

(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.[15]

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,[16] **normal profit-maximizing behavior by business is likely to impose health costs on the people of California** similar to those imposed by the tobacco and alcohol industries, including 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:

Positive changes:

The proposed text of regulations contains certain important and valuable provisions for structuring the process of legalization. Including:

- *§ 5040. Advertising Placement*
  (a)(2) Shall not use any depictions or images of minors under 18 years of age.
  (3) Shall not contain the use of objects, such as toys, inflatables, movie characters, cartoon characters, or include any other display, depiction, or image designed in any manner likely to be appealing to minors under 18 years of age; and
  (4) Shall not advertise free cannabis goods or giveaways of any type of products.
  (b) In addition to the requirements for advertising and marketing in subsection (a) of this section, all outdoor signs, including billboards, must be affixed to a building or permanent structure.

The revised framework for advertising strengthens the regulations' ability to protect youth and communities, and makes some progress in catching up to other states which have more actively limited outdoor advertising, billboards, radio and television advertising. The addition of an explicit definition of advertising content appealing to minors gives marketers clear instruction and enables objective assessment of compliance. This definition contains a number of elements also identified by a systematic review of the literature on specific content features to which minors are particularly susceptible in advertising for alcohol, tobacco and food.[17] A subsequent analysis found a positive association between the use of such features in alcohol brand advertisements and youth consumption of those

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[15] 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.
[16] Barry RA, Glantz SA. (2016). A Public Health Framework for legalized Retail marijuana Based on the US Experience: Avoiding a New Tobacco Industry. *PLoS Med. 13*(9): e1002131. doi: 10.1371/journal.pmed.1002131
[17] Padon, A., Rimal, R., DeJong, W., Siegel, M., Jernigan, D. (2018). Assessing Youth-Appealing Content in Alcohol Advertisements: Application of a Content Appealing to Youth (CAY) Index. *Health Commun. 33*(2):164-173. doi:10.1080/10410236.2016.1250331

brands, and no association with adult alcohol consumption of those brands, suggesting that they have particular appeal to youth.[18]

- *§ 5407. Sale of Non-Cannabis Goods on Premises. In addition to cannabis goods, a licensed retailer may sell only cannabis accessories and any licensee's branded merchandise or promotional materials*

We strongly support the important decision to require specialization of cannabis businesses. Allowing cannabis retailing to occur in other commercial settings, for instance, food service establishments or pharmacies that would serve youth under other circumstances, would contribute to normalization of cannabis use. This change aligns with laws of other states, such as Colorado, Washington, Nevada and Maine, that use a model of specialized cannabis commerce.

- *§ 5415. Delivery Employees (f) Prior to providing cannabis goods to a delivery customer, a delivery employee shall confirm the identity and age of the delivery customer as required by section 5404 of this division, and place the cannabis goods in a resealable child-resistant opaque exit package.*

The emergency draft delivery regulations in §5414-5421 did not contain an explicit requirement for delivery drivers to verify the age and identity of the recipient who has purchased the cannabis using a delivery platform. This change is essential to ensure compliance and dissuade diversion to youth or illicit markets. Local governments have already adopted such a provision in some cases, for instance LA City (Ordinance 185344, *Regulation No. 10. (E) Delivery for Retailer Commercial Cannabis Activity; part (4)),* but it should be uniformly required across the state if delivery is allowed.

- *§ 5025. Premises (c)(3) No cannabis goods shall be sold and/or delivered by any means or method to any person within a motor vehicle.*

Mobile locations or allowing the customer to enter a mobile vehicle for delivery present serious obstacles to enforcement of not vending to youth or any other provisions. Section 5025 is a positive addition to the proposed regulations.

Problematic areas:
There are, however, several problematic areas in the proposed text of regulations that still need to be revised or strengthened:

- *§ 5005. Personnel Prohibited from Holding Licenses*

The proposed regulations prohibit state and local law enforcement officers and other government officials with job duties related to enforcement of cannabis laws and regulations from holding licenses or cannabis business ownership interests (§ 40116).

[18] Padon, A., Rimal, R., Siegel, M. DeJong, W., Naimi, T. & Jernigan, D. (2018). Alcohol brand use of youth-appealing advertising and consumption by youth and adults. *Journal of Public Health Research.* 7(1): 1269. Doi: 10.4081/jphr.2018.1269

We would recommend clarifying that this prohibition extends to persons employed by public health departments or environmental health departments, as these are likely to be involved in oversight or inspection. We would further recommend that, in order to fully effectuate CDPH's goal of "ensur[ing] that those who are responsible for enforcement of the laws are not in a position to benefit from enforcement or lack thereof," CDPH should extend this prohibition to prohibit licensure or ownership for a defined period (e.g., one year) following separation from a government agency or office.

This modification would further reduce the potential for conflicts of interest not otherwise prohibited by the proposed regulations, such as giving preferential treatment to a business entity that has made arrangements to hire the official at a future date. Such "revolving door" prohibitions are commonplace for government officials in many states, such as legislators leaving public service to enter lobbying positions.[19]

We further recommend that the regulations also explicitly prohibit licensees from maintaining a financial relationship with a physician or other prescriber involving prescribing of cannabis, including working on the premises of the licensee or in a business agreement with a licensee. **Nor should a prescriber making recommendations for medical cannabis be an applicant, owner, director or manager of a licensed retailer.** Cannabis prescriber conflict of interest regulations, already broadly in use in the practice of medicine, have been adopted in Berkeley, Blythe, Hayward, the City of Los Angeles, Mono County, Pasadena, City of San Diego and the City and County of San Francisco.

- *§ 5016. Priority Licensing*

Absent from the proposed text of regulations are any effort to promote equity to insure that residents of communities that suffered high rates of incarceration and other social ill effects from unequal enforcement of cannabis possession laws are able to benefit from legalization. This will have the effect of consolidating commerce supported by wealthy investors in favorable locations before low-income community members who have historically been incarcerated for plying the same trade, can feasibly develop locations. Requirements for advance licensing of premises, surety bonds and fees are all obstacles. It appears to be required to declare even juvenile convictions for alcohol, dangerous drugs or controlled substances (§5002). Applications are only prioritized in the proposed regulations if from military veterans or existing dispensaries. The State Cannabis Advisory Committee adopted a number of recommendations on equity in licensing including the creation of state level equity licensing program, fee waivers, installments and deferrals, research support, access to property and premises, data collection, and local program models. None of these recommendations appear to have been incorporated into the proposed regulations.

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) in communities with high rates of cannabis related incarceration, or who have been categorized as equity applicants by their local jurisdiction, and that at

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[19] National Conference of State Legislatures. Revolving Door Prohibitions. *Conflict of Interest* 2017; http://www.ncsl.org/research/ethics/50-state-table-revolving-door-prohibitions.aspx. Accessed July 20. 2018.

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

Continuing failure to address the fundamental issue of equity is another reason why large numbers of licenses should not be rapidly issued pursuant to these proposed regulations, if unchanged.

- *§ 5019. Excessive Concentration.*

There is no limit set on the number of retailers that can be licensed. Legalizing cannabis without creating an excess density of cannabis outlets, or an excess of sites concentrated on vulnerable communities as has traditionally occurred with tobacco and alcohol outlets, is a critically important part of getting cannabis legalization right. A recent study found that higher dispensary density in states with legal cannabis laws was associated with higher likelihood of youth ages 14-18 experimenting with cannabis vaping and edibles (OR_{vaping}: 2.68, 95% CI: 2.12, 3.38; $OR_{edibles}$: 3.31, 95% CI: 2.56, 4.26). Even density of legal cannabis dispensaries as low as 1/100,000 residents were associated with increases.[20] Similarly, a review of studies of tobacco retailer density and adolescent smoking found that tobacco retailer density and proximity were correlated with adolescent lifetime smoking, past 12-month smoking, past 30-day smoking, and susceptibility to smoking.[21] Studies have consistently found a relationship between greater alcohol outlet density with increased alcohol consumption and related harms, including medical harms, injury, crime, and violence.[22] Alcohol outlet density has been found to be highly relevant to the amount of alcohol teens consume and therefore to teens' impaired driving. Policies such as those regulating the age of bartenders, sellers, or servers, and social host civil liability laws, do not appear to have the same impact on teens' alcohol-related crash incidence as other types of policies such as restricting alcohol outlet density.

Once licenses are issued, as we know from years of tobacco and alcohol experience, it is extraordinarily difficult to revoke them, as businesses have invested in their creation. Permitting excessive outlet density to occur from the start represents clear negligence in public health protection in light of decades of experience that provide extensive evidence of probable harm.

For that reason we believe the proposed regulations should under no circumstances allow an unlimited number of licenses. The longer-term decision on optimal density to reduce or eliminate the illegal market while minimizing harm from a legal market should be taken only after careful study and increased gradually if

[20] Borodovsky JT, Lee DC, Crosier BS, Gabrielli JL, Sargent JD, Budney AJ. (2017). U.S. cannabis legalization and use of vaping and edible products among youth. *Drug Alcohol Depend*. *0*(0). doi:10.1016/j.drugalcdep.2017.02.017.
[21] Gwon SH, DeGuzman PB, Kulbok PA, Jeong S (2017). Density and Proximity of Licensed Tobacco Retailers and Adolescent Smoking. *J Sch Nurs. 33*(1):18-29. doi: 10.1177/1059840516679710.
[22] Grubesic TH[1], Pridemore WA, Williams DA, Philip-Tabb L. (2013). Alcohol outlet density and violence: the role of risky retailers and alcohol-related expenditures. *Alcohol & Alcoholism, 48*(5):613-9. doi: 10.1093/alcalc/agt055. Epub 2013 Jun 23.

appropriate. Using the same proportion as Washington did initially, of 1:22,000 inhabitants, would be roughly 1,784 licenses. **We recommend that BCC propose an initial cap at no more than 1,500 retailer licenses issued statewide, and no more than 1:22,000 inhabitants in any county. We also recommend that there be a distance of at least 1,000 feet between licensed retailers**. Excessive licensing in this first period could lead to irreversible harms in some communities. The proposed conditions for denying licenses for excessive concentration (§5019) have no absolute standard in relation to population, only in relation to other census tracts in the same county or county rules, if these exist. Local government needs time to consider these rules and put appropriate systems in place. There should be no risk of outlet flooding or "fait accompli" through excessively lax initial regulation.

Several local jurisdictions are already taking the step of limiting the number of retailers in their jurisdiction. For instance, San Diego City permits a maximum of 4 retailers in each of their 9 council districts for a total of 36 retailers (max) or 1:37,000. Pasadena has likewise limited the number of retailers in its jurisdiction to approximately 1:24,000.

- *§ 5025. Premises*

Mandatory warning signs should be required in stores to advise consumers of hazards of cannabis use and legal risk to immigrants.

Public perception of the risk of cannabis consumption have fallen dramatically in recent years from 58.3% to 31.1% of youth nationally between 2000 and 2016.[23] Consumption during pregnancy, for example, has increased,[24] and recent research found nearly 70% of dispensaries in Colorado responded to an inquiry from a pregnant woman recommending use of cannabis to treat morning sickness.[25]

Legal risk to consumers in certain categories persists despite state legalization. It is therefore extremely important that retailers be obligated to inform the public of the health and legal risks they may face. The best and lowest cost way to do this is through prominent point-of sale information to consumers. The tobacco and alcohol industry have long invested heavily in point of sale advertising, and that effectiveness is the same reason we must use it to inform consumers. In this way we can provide a basic public health message to every consumer who enters a retail outlet with little or no ongoing cost, and no cost to government.

a. **A Cannabis Retailer should be required to display a health warning sign prominently behind the main dispensing counter**. The sign should be at least 3 feet by 3 feet and be displayed at eye height (i.e., with mid-point 5 feet above the floor). Black letters on a yellow background with a black border should be required.

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[23] Johnston LD, O'Malley PM, Miech RA, Bachman JG, Schulenberg JE. (2017). ***Monitoring the Future National Survey Results on Drug Use, 1975-2016: Overview, Key Findings on Adolescent Drug Use***. Ann Arbor: Institute for Social Research, The University of Michigan.
[24] Brown QL, Sarvet AL, Shmulewitz D, Martins SS, Wall MM, Hasin DS. (2017). Trends in Marijuana Use Among Pregnant and Nonpregnant Reproductive-Aged Women, 2002-2014. *JAMA. 317*(2):207-209. doi: 10.1001/jama.2016.17383.
[25] Dickson, B., Mansfield, C., Ghiahi, M., Allshouse, A., Borgelt, L., Sheeder, J., Silver, R., & Metz, T. (2018). Recommendations from cannabis dispensaries about first-trimester cannabis use. *Obstetrics & Gynecology, 131*(6): 1031-1038. DOI: 10.1097/AOG.0000000000002619

“**HEALTH WARNINGS**

i) **Are you pregnant or breastfeeding?** Marijuana use during pregnancy can be harmful to your baby’s health, including causing low birth weight and developmental problems, according to the U.S. Centers for Disease Control and Prevention (CDC).

ii) **Driving while high is a DUI.** Marijuana use increases your risk of motor vehicle crashes.

iii) **Not for Kids or Teens!** Starting marijuana use young or using frequently may lead to problem use and may harm the developing teen brain.

iv) Marijuana use may be associated with **greater risk of developing schizophrenia** or other psychoses. Risk is highest for frequent users.

v) Smoking marijuana long-term may **make breathing problems worse**.

THESE WARNINGS ARE PROVIDED BY STATE OF CALIFORNIA AS A PUBLIC SERVICE”

b. **A Cannabis Retailer should be required to display three other warning signs**, which are i) at least 2 feet wide by 1 foot tall; ii) posted at eye height (i.e., with mid-point 5 feet above the floor); and posted behind the main dispensing counter, stating in English and Spanish at a minimum.

“ATTENTION IMMIGRANTS: Even in California, **using or possessing marijuana or working in the marijuana industry is legally dangerous for any noncitizen**. This includes lawful permanent residents, undocumented persons, students, and others. Marijuana is illegal under federal law, and federal law controls immigration. If you need to take medical marijuana, see an immigration attorney for advice. The State of California provides this information as a service to immigrant members of our community.”

“INDIVIDUALS ON PROBATION OR PAROLE: If you are prohibited from using drugs as a condition of your probation or parole, then possession or use of marijuana could violate your probation or parole. Warning from the State of California”

“ARE YOU BETWEEN 18-20 YEARS OF AGE?: If you are caught possessing marijuana without medical authorization, you could face legal consequences. Warning from the State of California”

The text of the required health warnings should be reviewed and updated by CDPH as needed, and at least every three years based on current scientific evidence, including communication effectiveness, and legal information.

- *§ 5026. Premises Location (a) A premises licensed under this division shall not be located within a 600-foot radius of a school providing instruction in kindergarten or any grades 1 through 12, day care center, or youth center that is in existence at the time the license is issued.*

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 and extended to include community colleges and universities, given that a large part or even the majority of students may be under age 21.

- *§ 5026. Premises Location (b) Notwithstanding subsection (a) of this section, if a local jurisdiction has issued a license or permit to conduct commercial cannabis activity at a premises that is located within a 600-foot radius of a school providing instruction in kindergarten or any grades 1 through 12, day care center, or youth center, the Bureau may approve the premises for licensure if the following conditions are met: (1) The applicant submits a copy of a valid license or permit from the local jurisdiction with the application for licensure;…*

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.

- *§ 5040. Advertising Placement (a)(1) Shall only be displayed after a licensee has obtained reliable up-to-date audience composition data demonstrating that at least 71.6 percent of the audience viewing the advertising or marketing is reasonably expected to be 21 years of age or older*

This rule as written will allow rampant advertising exposure of children and youth in broadcast, cable, print and digital media. We recommend using a more stringent youth exposure threshold. The 71.6% adult target market threshold is adopted from alcohol industry self-regulatory guidelines[26,27] which have been found in research to be wholly inadequate to protect youth from advertising exposure. A report from the National Research Council and Institute of Medicine recommended a minimum 85% adult market threshold. The remaining 15% reflects the proportion of U.S. youth between the ages of 12 and 20, who comprise the young people most at risk of initiating substance use. The NRC/IOM reported that this as standard would preclude alcohol advertising on only 34.0 percent of television programming if the base included children ages 2 and above, and 19.2 percent of programming if the base were limited to person age 12 and above.[28]

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[26] Distilled Spirits Council of the United States. (2011). *Code of Responsible Practices for Beverage Alcohol Advertising and Marketing*. Washington, DC.
[27] Beer Institute. (2011). *Advertising and Marketing Code*. Washington, DC. http://www.beerinstitute.org/assets/uploads/BI-AdCode-5-2011.pdf.
[28] National Research Council and Institute of Medicine. (2004). *Reducing Underage Drinking: A Collective Responsibility.* Washington, D.C.: National Academies Press.

The State Advisory Commission already approved recommending the increase in the audience threshold to match the IOM recommendation of 85%, and were informing the state legislature of their recommendation.

- *§ 5040. Advertising Placement (a)(2)-(3)*

Though we applaud the addition of a definition of **advertising content with appeal to minors** and the prohibition against the use of images or depictions of those under age 18, the age cut-off should be at least 21+, and not cater to the small subset of minors who are eligible to purchase medical cannabis at 18. Much of the content that is appealing to youth ages 18-20 is appealing to youth under age 18, so in allowing marketers to target those age 18-20 through the use of images or depictions of and content appealing to that demographic, they will likely also be inadvertently targeting minors under age 18, encouraging them to initiate cannabis consumption or to consume cannabis or cannabis products. Even the code of responsible practices of the Beer Institute and the Distilled Spirits Council of the United States require that models and actors employed to appear in advertising appear to be over 21 years of age and in fact be a minimum of 25 years of age.[29,30]

We also recommend that no **health-related statements** be allowed in the advertising of cannabis products of any type. The proposal to prohibit the use of health or therapeutic claims in advertising for recreational products was endorsed by the State Cannabis Advisory Committee. The following is an excerpt from their minutes:

"RECOMMENDATION #4: Health Claim Advertising

Adopted by the Subcommittee on: 3-1-18 Vote: 3-0-2

Recommendation: Adult-use cannabis should not be allowed to make health claims in advertising.

Given the absence of any legal and verifiable framework for identifying the veracity of claims, medicinal cannabis uses should be guided by the medical knowledge of the prescribing physician or professional based on science. Adult use cannabis should especially not be marketed or advertised as therapeutic. Claims in relation to being "natural" or to potency other than factual statements of THC or CBD content should also not be allowed in either marketing materials or advertising.

We strongly recommend the **requirement for a prominent rotating warning label statement on any and all cannabis advertising**, similar to that on tobacco advertising, including on branded merchandise. Any advertiser who posts or who causes to be posted a Cannabis Retail business, Cannabis or Cannabis Product advertisement including, without limitation, any logo, that identifies, promotes, or markets a retailer name, Cannabis or a Cannabis Product, or brand name that is for sale in the State should be required to place on the advertisement one of the following warning statements:

[29] Distilled Spirits Council of the United States. (2011). *Code of Responsible Practices for Beverage Alcohol Advertising and Marketing*. Washington, DC. http://www.discus.org/assets/1/7/May_26_2011_DISCUS_Code_Word_Version1.pdf
[30] Beer Institute. (2011). *Advertising and Marketing Code*. Washington, DC. http://www.beerinstitute.org/assets/uploads/BI-AdCode-5-2011.pdf.

i) **Are you pregnant or breastfeeding?** Marijuana use during pregnancy can be harmful to your baby's health, including causing low birth weight and developmental problems according to the Centers for Disease Control and Prevention.

ii) **Driving while high is a DUI.** Marijuana use increases your risk of motor vehicle crashes.

iii) **Not for Kids or Teens!** Starting marijuana use young or using frequently may lead to problem use and, according to the Centers for Disease Control and Prevention, may harm the developing teen brain.

iv) Marijuana use may be associated with **greater risk of developing schizophrenia** or other psychoses. Risk is highest for frequent users.

v) Smoking marijuana long term may **make breathing problems worse**.

Followed by: "**Warning from the State of California.**

Advertisements and marketing materials should be required to include messages "(i)" through "(v)" above in equal and rotating proportions and approximate audience exposure for any advertisement. These warnings should be enclosed in a box occupying at least 20% of the surface of any advertisement or 20% of the spoken word time, and be present on each page. The warning box should be required to use black type on a yellow background, and the text to be printed in a size and manner so as to be clearly legible to the intended viewers of the advertisements and marketing materials. The text of the Warning should be required to be positioned in the upper right hand corner such that the Warning and other information on the Advertisement or Marketing materials have the same orientation (for example, left to right, or bottom to top). The Warning should be indelibly printed on or permanently affixed to each print Advertisement or Marketing material.

Advertising and Marketing materials should not be permitted to:

(1) Display consumption of cannabis or cannabis products;

(2) Contain material that encourages the use of cannabis because of its intoxicating effect;

(3) Depict activities or conditions that could be considered risky when under the influence of cannabis, such as operating a motorized vehicle or boat, being pregnant, or breastfeeding.

(4) Be on public property or transportation including school buses, buses, trains, transportation stops or shelters.

Finally, an adult-use cannabis retailer should not be permitted to **use in its name** any **words or phrases implying health or therapeutic benefits**, including but not limited to "health," "wellness" or "clinic."

- *§ 5040. Advertising Placement (c) For the purposes of this section, "reliable up-to-date audience composition data" means data regarding the age and location*

demographics of the audience viewing a particular advertising or marketing medium.

The definition should specify "reliable, up-to-date, ***local*** audience composition data." It is the local market data which needs to be assessed, not national, as research in alcohol advertising has shown there is considerable variation in audience composition across locales, and relying on national data has resulted in overexposure of youth to harmful advertising.[31]

- *§ 5041. Age Confirmation in Advertising*

To ensure avoiding exposure of minors, no initial direct communication through any form, including in-person, telephone, physical mail, or electronic should be unsolicited, after which, age affirmation to verify the recipient is 21 years of age or older should occur.

- *§ 5403. Hours of Operation. A licensed retailer shall sell and deliver cannabis goods only between the hours of 6:00 a.m. Pacific Time and 10:00 p.m. Pacific Time.*

Reducing hours of operation for alcohol outlets has been found to be effective for reducing negative effects of alcohol consumption. Parts of Colorado used 7pm. Oregon uses 8 am to 10 pm. A dispensary owner we interviewed felt that hours should not cater excessively and recommended 8 pm. In California, Berkeley, Blythe, Mammoth Lakes, Mono County, Pasadena, Sacramento, and San Diego, for example, have all adopted more limited hours. In general, late night purchases are more likely to be combined with consumption and associated with accidents. Late night hours may also increase risk of robberies. **We recommend maximum hours of 8 am to 8 pm and closed on Sunday**.

- *§ 5404. Retail Customers (a) A licensed retailer shall only sell adult-use cannabis goods to individuals who are at least 21 years of age after confirming the customer's age and identity by inspecting a valid form of identification provided by the customer as required by subsection (c) of this section.*

Retailers should be required to use **ID scanning technology** to immediately identify fake IDs and verify age, in addition to a traditional visual inspection to verify the ID match to the potential customer and ID expiration. This kind of technology is increasingly less costly and less burdensome, for example, New York state is currently piloting the use of a smartphone app for identifying invalid IDs in bars. The app, called "Law ID", has tested at 99.9% accuracy has a commercial version currently available.[32]

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[31] Jernigan, D., Ostroff, J., & Ross, C.J. (2005). Alcohol Advertising and Youth: A Measured Approach, *Journal of Public Health Policy, 26;* 312-325
[32] https://cbs6albany.com/news/local/new-york-first-state-to-test-new-app-busting-underage-drinkers-using-fake-ids

- *§ 5407. Sale of Non-Cannabis Goods on Premises. In addition to cannabis goods, a licensed retailer may sell only cannabis accessories and any licensee's branded merchandise or promotional materials.*

a) We recommend that non-cannabis **branded merchandise not be allowed for sale** in a cannabis licensee, nor can its provision be conditioned on sale of any cannabis item. Cannabis brands should be clearly limited to cannabis products and not contribute to social normalization by branding clothing, foods or other products for sale on the premises of a licensee.

b) We recommend that no cannabis business or cannabis or cannabis product brand identification, including logos, trademarks or names, be used or licensed for use on clothing, toys, games, or game equipment, or other items typically marketed to or used by persons under the age of 21 or attractive to children or youth.

c) Any branded merchandise (hats, T-shirts, pens, etc.) using the name of a cannabis business or brand, cannabis, or a cannabis product should be required to carry a mandatory warning box described above in at least the size of the business, brand or product name whichever is largest.

- *§ 5408. Sale of Live Plants and Seeds [Considerations on Potency of Products]*

In 2007, Judge Gladys Kessler, in a landmark decision in *US v Philip Morris*, 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."*[33]

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 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, and commercial sales, whether legal or illegal,

[33] 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)

have 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 Δ⁹-tetrahydrocannabinol to cannabidiol from 14 times in 1995 to ~80 times in 2014."* [34]

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:

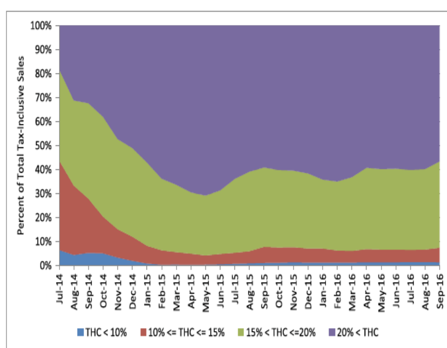

Figure 3 Market shares for cannabis flower products sold, by delta-9-tetrahydrocannabinol (THC) % category. Market share is calculated as a percent of total cannabis flower expenditures (excise-tax-inclusive). [Colour figure can be viewed at wileyonlinelibrary.com]

> *"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)*[35]

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

> *"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*[36]*, while still other studies have shown that*

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[34] ElSohly, 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

[35] Smart R, Caulkins JP, Kilmer B, Davenport S, Midgette G. (2017). Variation in cannabis potency and prices in a newly legal market: evidence from 30 million cannabis sales in Wshington state. *Addiction. 112*(12):2167-2177. doi: 10.1111/add.13886.

[36] van der Pol, P., Liebregts, 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

individuals do not adjust their use when using higher potency products[37]. Increased exposure to THC has also been associated with increased symptoms of cannabis use disorders[38,39] increased risk for psychosis,[40,41] and, as observed in acute administration studies, impaired cognition.[42,43,44] 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.[45]

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." [46] Consumption of higher potency products also corresponds over time to major upsurges on care seeking behavior for cannabis dependency in Europe, now the leading substance of abuse for seeking care (See Figure).[47]

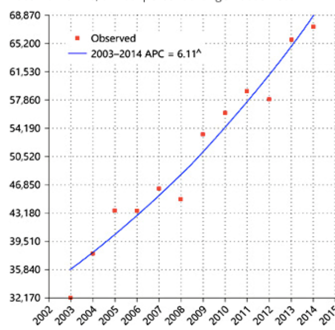

Fig. 1
Trends in the number of first-time cannabis treatment admission in Eu-22 - joinpoint regression outcome, 2003-2014. APC, annual percent change - observed.

At a time when the US is in the throes of a major opioid epidemic, 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.[48] Recent recommendations for legalization in the United

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[37] 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/2543018[10]

[38] 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

[39] van der Pol, ibid

[40] Di Forti, M., Marconi, A., Carra, E., Fraietta, 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

[41] 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

[42] 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

[43] Kowal, M. A., Hazekamp, A., Colzato, L. S., van Steenbergen, 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

[44] 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

[45] Rigucci et al., 2016Rigucci, 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

[46] Freeman TP, Winstock AR. (2015). Examining the profile of high-potency cannabis and its association with severity of cannabis dependence. *Psychol Med. 45*(15):3181-9. doi: 10.1017/S003329171500117 8.

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

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

Kingdom endorse restricting legalization to products below 15% THC.[49] Canada's Task Force on Cannabis Legalization and Regulation recognized increasing potency as a fundamental public health challenge that needs to be addressed.[50] 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.

There is also much debate on which cannabis concentrates should be allowed for sale.[51,52,53] In particular, ultra high potency products such as waxes and shatter have been associated with more severe problems including psychosis. While there are thoughtful arguments to be made both for legalizing manufacturing of high potency concentrates (reducing accidents from illegal butane extraction and impurities, reducing illegal sale), and for prohibiting them (higher rates of psychosis, dependency, and growing normalization of use of dabbing and higher potency with greater harm), a precautionary approach should be used until this issue is more carefully examined.

As the lead agency responsible for regulating cannabis retailing in the State of California, it is essential that BCC act now to prohibit the sale of high potency flower and concentrates. While there is still much debate about the best approach to be used, 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, free of conflicts of interest such as relationships with the cannabis industry, to produce a study of the public health risks of increasing cannabis potency, decreasing THC:CBD, as well as of flavored cannabis products that are potentially attractive to youth, 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 for sale at 20% THC, a limit on plants and seeds for sale to 20% THC when mature, and cannabis concentrates for sale by licensed retailers at 50% THC, with aligned limits on cultivation and manufacturing.

A further, related issue concerns the allowance of infused pre-rolls in the CDPH proposed text of regulations. Allowing additives and infusions of any kind in pre-rolls opens the door for both high potency and flavored smokable products that may replicate the public health harms of flavored tobacco products. Pre-rolls are the cannabis product most similar to tobacco cigarettes and cigars. Flavored products attract young smokers to

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

[50] McLellan, A. A., Ware, M. A., Boyd, S., Chow, G., Jesso, M., Kendall, P., … Zahn, C. (2016). A Framework for the Legalization and Regulation of Cannabis in Canada (policies). Health Canada. Retrieved from https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/task-force-cannabis-legalization-regulation/framework-legalization-regulation-cannabis-in-canada.html

[51] Alzghari SK, Fung V, Rickner SS, Chacko L, Fleming SW. (2017). To Dab or Not to Dab: Rising Concerns Regarding the Toxicity of Cannabis Concentrates. *Cureus. 9*(9):e1676. doi: 10.7759/cureus.1676.

[52] Sagar KA, Lambros AM, Dahlgren MK, Smith RT, Gruber SA. (2018). Made from concentrate? A national web survey assessing dab use in the United States. *Drug Alcohol Depend. 190*:133-142. doi: 10.1016/j.drugalcdep.2018.05.022.

[53] Pierre JM, Gandal M, Son M, (2016). Cannabis-induced psychosis associated with high potency "wax dabs". *Schizophr Res. 172*(1-3):211-2. doi: 10.1016/j.schres.2016.01.056.

tobacco.[54,55,56,57] Most adolescent tobacco users report that they began with flavored products and most current adolescent tobacco users use flavored products.[58] We have provided further rationale in our comments to CDPH in support of **prohibiting the infusion of pre-rolls, including with concentrates and flavors, and if allowed for sale against this recommendation, clearly distinguishing between products that contain only plant material from those containing concentrates.**

- *§ 5409. Daily Limits*

We agree with the Bureau in the need to impose a limit on the amount of cannabis that may be dispensed or sold to a patient to deter over-use, dependency, and dispensation leading to diversion of the product. However, these limits are for daily sales from a dispensary and do not need to be identical to the possession limits in state law. Other states have adopted significantly lower limits.

The eight (8) ounce or half a pound daily limit for medicinal cannabis proposed in § 5409 is greatly excessive, may contribute to diversion of the product to illegal markets, and may attract crime to patients possessing that amount of product.

In addition, the limit on "medicinal cannabis" appears to apply to a product containing cannabis, including, but not limited to, dry flower concentrates and extractions, intended to be sold for use by medical- and recreational-cannabis consumers in California. In contrast, the 8-ounce possession limit in MAUCRSA **applies only to medical use dry cannabis** and does not require that the daily sales limit should be the same.

The Bureau's draft regulation § 5409 mandates a daily sale limit of eight (8) ounces to a qualifying patient. In relevant part, "(b) A licensed retailer shall not sell more than the following amounts to a single medicinal cannabis patient, or to a patient's primary caregiver purchasing medicinal cannabis on behalf of the patient, in a single day: (1) eight ounces of medical cannabis in the form of dried mature flowers or the plant conversion as provided in Health and Safety Code section 11362.77." Imposition of a sale limit is justified in imposing a sale limit to: (1) prevent patients and caregivers from running afoul of the possession limit in Cal. Health & Safety Code § 11362.77(a); (2) stem the urge for a patient to purchase more than she can use and divert the excess to the grey or black markets; and (3) reduce the risk that a patient becomes a target of crime after they exit the dispensary.

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[54] Surgeon General. (2012). *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Department of Health and Human Services.

[55] Carpenter CM, Wayne GF, Pauly JL, Koh HK, Connolly GN. (2005). New cigarette brands with flavors that appeal to youth: tobacco marketing strategies. *Health Aff (Millwood)*. *24*(6):1601-1610.

[56] Villanti AC, Johnson AL, Ambrose BK, et al. (2017). Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014).*Am J. Prev Med*. *53*(2): 139-151.

[57] Villanti AC, Richardson A, Vallone DM, Rath JM. Flavored tobacco product use among U.S. young adults. (2013). *Am J Prev Med. 44*(4)388-391.

[58] Ambrose BK, Day HR, Rostron B., et al. (2015). Flavored Tobacco Product Use Among US Aged 12-17 Years, 2013-2014. *JAMA*. *314*(17): 1871-1873.

Even for dry cannabis, at 2 grams per joint, eight ounces of dried flower is equivalent to about 113 joints.[59] Given the negative health effects of consuming that much cannabis smoke, a patient requiring higher dosages of medical cannabis for treatment would be better off consuming a concentrated form of cannabis, such as a tincture.

Even assuming that a patient is withdrawing enough for a monthly supply, **eight (8) ounces of dry flower per day is an excessive limit that encourages over-use, driving dependency and diversion to the illicit market or to youth.** UCSF's survey of 21 states and Washington, D.C. that have legalized medical cannabis indicates that **California's eight (8) ounce daily sale limit of medical cannabis would be the highest in the nation**:

- Two states impose daily sale limits of 1-2 ounces of medical cannabis
- Sale Limit Outliers
  - One state imposes a two-ounce sale limit for a ten-day period
  - New Mexico imposes an eight-ounce sale limit for a three-month period
  - Massachusetts imposes a ten-ounce sale limit for a two-month period
- Eight states impose a biweekly sale limit between 2.5-4 ounces of medical cannabis
- Three states and Washington, D.C. imposed a monthly sale limit of 2.5 ounces of medical cannabis
- The regulatory election to tie the sale limit to the discretion of a physician is sound practice and bears resemblance to accepted practice in the medical and pharmacological fields
- Two states impose comparable eight ounce limits with dispensing terms of one month and three months

Finally, a patient possessing an excessive amount of medical cannabis may attract robberies. The proposal of an eight-ounce sale limit is inconsistent with the objective of secure operations, as a criminal has greater incentive to rob a patient carrying a half pound of cannabis.

To harmonize the eight-ounce dry medicinal cannabis possession limit and the potential needs of patients while inhibiting diversion, **the Bureau should create a transitional standard to reduce the daily limit for purchase to two ounces for medicinal cannabis and restrict that to dry cannabis as per MAUCRSA.** It should create similar limits for edibles and concentrates based on THC content, roughly no more than 9600 mg of THC in concentrates or 168 10 mg THC doses of edibles, approximately.

Daily limits for adult-use should be lower and be defined for edibles. § 5409 provides a daily limit of 8 grams for concentrates, identical to the state possession limit in MAUCRSA. Colorado's cannabis equivalency study suggested that one ounce of cannabis is roughly equivalent to 83 ten mg doses of edibles or 7.7 grams of concentrate at an average of 62% potency. They estimate base pharmacokinetic equivalency ratio is 1 to 5.71 for edibles to flower or average concentrate. If accurate, this means that one milligram of THC in edible form, is equivalent to 5.71 milligrams of THC in smokable

[59] *Assumption*: Average large joint contains 2 grams of dry flower; 8 ounce daily limit X 28.3 grams/ounce = 227 grams; 227 grams/ average 2 gram joint = 113 average large joints

form.[60] Therefore if one ounce of cannabis at 17% contains 4845 mg of THC, that would be roughly equivalent to 848 mg of THC in edibles or 84 of the 10 mg doses.

Nevertheless these amounts are quite high. Reducing the daily limit may help reduce diversion, exceeding possession limits, and illegal resales to youth. We therefore recommend that the daily sale limit for adult-use be lowered by half for flower and concentrate and created for edibles, based on THC equivalency to:

- one half-ounce flower
- 2400 mg of THC in concentrate
- 40 doses of 10 mg of edibles.

Table ES-2. Pharmacokinetic Dosage Equivalency

	Average THC Potency	Effective Uptake Ratio	1 Gram Equivalent	1 Ounce Equivalent
Buds/Flower	17.1%	1.00	1 Gram	1 Ounce
Edibles	N/A	5.71	3 Servings	83 Servings
Concentrates	62.1%	1.00	0.28 Grams	7.72 Grams

Source: Author calculations based on metrc™ data.

Ref: Marijuana Equivalency in Portion and Dosage, 2015[16]

- *§ 5411. Free Cannabis Goods*

We agree with this provision that prohibits providing free cannabis goods to any person, which was also present in the emergency regulations. However, there are a number of other sales measures that encourage consumers to purchase more products than they might otherwise choose, such as discounting practices, and honoring or redeeming coupons to allow the purchase of a cannabis product for less than full retail price. **Prohibiting retailers from offering or redeeming such instruments still allows cannabis retailers to set prices as they see fit and to modify them, including setting them low enough to help capture the illegal market**. Such steps have already been taken by local governments, including Sonoma County. Policies prohibiting discounting have been adopted in tobacco control to positive effect, including by California jurisdictions.

- *§ 5413 Exit Packaging*

This section states that: Cannabis goods purchased by a customer shall not leave the licensed retailer's premises unless the goods are placed in a resealable child-resistant opaque exit package. While we applaud the idea of child resistant packaking, moving that requirement from the primary package of the product to store exit packaging undermines the purpose of child resistant packaging, as it is likely to be discarded once the primary package is opened or taken out of the exit packaging. Given the growing evidence in the

[60] Orens A, Light M, Rowberry J, Matsen J, Lewandowski B. (2015). Marijuana Equivalency in Portion and Dosage An assessment of physical and pharmacokinetic relationships in marijuana production and consumption in Colorado. Marijuana Policy Group. University of Colorado, Leeds School of Business, Business Research Division, Marijuana Policy Group, and BBC Research & Consulting for the Colorado Department of Revenue.

pediatric and emergency medicine of more frequent and serious ingestions by children, this proposal makes little sense and will result in a greater number of pediatric ingestions. Child resistant primary packaging should remain the requirement. See comments on CDPH regulations for full documentation.

- *§ 5416. Delivery to a Physical Address*
  - *(a) A delivery employee may only deliver cannabis goods to a physical address in California.*

Delivery should not be allowed for recreational cannabis. While there are arguments to be made for delivery of medicinal cannabis, delivery of adult-use cannabis simply facilitates consumption. Home delivery of alcohol has been found to increase youth consumption. It should simply not be permitted.[61,62] If it is allowed, it should only be allowed to residential addresses. Delivery to workplaces should not be allowed in general. If delivery to non-residential addresses is permitted despite this recommendation, delivery to youth serving institutions including schools, day care centers, libraries, community colleges, universities or within 50 feet of their entryways should not be allowed. Within residential addresses, delivery to college dormitories or other student residential facilities where youth under age 21 typically reside should not be allowed. The BCC proposed regulations as written would facilitate, for example, the delivery of half a pound of flower per day to a 19 year old in a college dormitory with a medicinal card, who could then easily turn around and sell the excessive quantity illegally.

- *§ 5416. Delivery to a Physical Address (d): A delivery employee may deliver to any jurisdiction within the State of California.*

Proposed Regulation §5416(d) is highly problematic and appears to be in violation of state law and of the clear intent of the voters to preserve local decision-making authority that was a central tenet of Proposition 64. The language suggests that a local jurisdiction is no longer able to prohibit the delivery of cannabis in violation of the clear wording of state law.

Cal. & Prof. Bus. Code §26200(a)(1) states:

> This division shall not be interpreted to supersede or limit the authority of a local jurisdiction to adopt and enforce local ordinances to regulate businesses licensed under this division, including, but not limited to, local zoning and land use requirements, business license requirements, and requirements related to reducing exposure to secondhand smoke, or **to completely prohibit the establishment or operation of one or more types of businesses licensed under this division within the local jurisdiction.** (emphasis added).

Clearly, state law leaves it up to local jurisdictions to regulate cannabis businesses and assures the authority to not only completely prohibit "establishment" of a licensed business, but also the authority to prohibit its "operation," which would address the

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[61] Fletcher LA, Toomey TL, Wagenaar AC, Short B, Willenbring ML. (2000). Alcohol home delivery services: a source of alcohol for underage drinkers. *J Stud Alcohol. 61*(1):81-84.
[62] Williams RS, Ribisl KM. (2012). Internet Alcohol Sales to Minors. *Arch Pediatr Adolesc Med. 166*(9):808-813. doi:10.1001/archpediatrics.2012.265.

operation even of a business licensed in another jurisdiction. Delivery of cannabis is a type of cannabis business operation authorized under state law and which can be completely prohibited at the local level. Proposed section 5416(d) strips local jurisdictions of the authority to block the commercial sale of cannabis to locations within their jurisdictions, in clear violation of the expressed will of California voters. In brief, Proposition 64 provides that "[i]t is the intent of the People in enacting this Act to…[a]llow local governments to ban nonmedical businesses…"[63]

Our concerns about this interpretation are well-founded. News media is reporting that the new regulations mean local jurisdictions can no longer prohibit delivery. In an article in The Mercury News (July 14, 2018)[64] it stated: "Cannabis retailers soon may be able to deliver cannabis anywhere in California, **no matter what city or county rules say.** Industry representatives are also interpreting this regulation as a major expansion in cannabis access, stating: "Given that most California cities still don't allow retail cannabis sales, any expansion of delivery services figures to make cannabis more accessible to more people."

California law is clear that though entitled to deference when constructing regulations, an agency cannot alter or amend a statute or issue regulations that plainly conflict with the statute. Government Code §11342 provides:

> Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute

The plain language of the state law gives local jurisdictions the authority to prohibit any type of cannabis business.

In City of San Jose v. Department of Health Services, 66 Cal. App. 4th 35 (6th Dist. 1998), the court was asked to determine whether a local jurisdiction could put tighter restrictions on smoking in public places than appeared in state law. In determining that the local jurisdiction's authority was not preempted by state law, the court looked at the language in the state statute which expressly authorized "local agencies to 'ban completely the smoking of tobacco' in any manner not inconsistent with the law." City of San Jose, 66 Cal.App. 4th at 42. This language, the court reasoned, showed the legislature's intent to "leave to the local authorities the matter of regulating the smoking of tobacco in their respective jurisdictions, provided the regulations so adopted do not conflict with statutory law." Id.

The court further noted that the police powers of a local jurisdiction are "as broad as the police power exercised by the legislature itself." It fell within the police powers of the local jurisdiction to protect the public's health by regulating the smoking of tobacco. Likewise, in the instant matter, local jurisdictions should be able to regulate whether or not cannabis businesses are allowed to deliver within their jurisdiction.

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[63] Initiative Measure (Prop. 64), §3(d), approved Nov. 8, 2016, eff. Nov. 9, 2016

[64] https://www.mercurynews.com/2018/07/14/cannabis-delivery-edibles-and-ads-could-change-under-new-permanent-state-regs/

Further, an influx of unapproved local cannabis deliveries will decrease transparency of cannabis operations and increase public safety obligations and costs for local law enforcement agencies.

That section 5416(d) contradicts existing law is illustrated further by the failure of Sen. Ricardo Lara's SB 1302, which would have similarly preempted a local government from adopting or enforcing an ordinance that would ban cannabis deliveries within its jurisdiction. Legislative counsel required a 2/3rds vote for passage, recognizing that this bill fundamentally altered the intent of the ballot initiative. Not only did SB 1302 fail to attain the required two-thirds vote required by Proposition 64 for the enactment of amendments that substantively modify the intent, it failed to pass out of its house of origin.

Because section 5416(d) goes beyond the statutory provisions of Proposition 64 and MAUCRSA, adoption of 5416(d) would exceed the Bureau of Cannabis Control's (BCC) regulatory authority. California Business and Professions Code section 26013 limits the regulatory authority of the BCC to enacting rules and regulations that are "consistent with the purposes and intent of [Proposition 64]." By allowing deliveries in every jurisdiction in California, the BCC is fundamentally changing Proposition 64, not simply clarifying existing law, and undermining the expressed will of California voters. For these reasons, section 5416(d) must be removed from the regulations.

- *§ 5601. Temporary Cannabis Event License*

Temporary cannabis event licenses should be restricted to trade only events which can only be attended by those over 21. The presence of cannabis promotion at community events or county fairs serves only to promote and normalize consumption. We would not want a tobacco retailer at a county fair and we should not have cannabis retailers there. Event licenses should be used exclusively for trade fairs targeting the industry only with controlled entry to those over 21 years of age.

- *§ 5800. Right of Access & § 5805. Minor Decoys*

Robust enforcement of proper identification verification procedures is essential to reduce or eliminate efforts to bypass the age limit for adult-use cannabis, or to misuse or abuse the medical cannabis program by those under the lawful age for non-medical cannabis consumption and tobacco consumption who may seek to substitute cannabis for tobacco. Best practices from alcohol and tobacco control indicate that unannounced compliance checks ideally every 3 months but no less than twice a year are a critical component of ensuring that retailers conform to sales regulations that protect public health.

- *§ 5900. Eligibility, 5901. Request for Proposals & § 5902. Selection Process and Criteria*

The proposed mechanism for administering the research funding ignores decades of highly positive experience with the widely recognized excellence and competent administration of similar research funding in the State of California's premier public

university system. **The BCC should disburse the funds to the Office of the President of the University of California to be administered through a competitive grants similar to California Tobacco Related Disease Research Program (TRDRP), responsive to the priorities identified in MAUCRSA and to additional research needs identified annually by licensing agencies. Since MAUCRSA includes amongst its priorities for research the evaluation of the work of the licensing agencies, as well as its public health impact, this work should clearly be contracted for independently to assure its independence and integrity.**

The regulations as written appear to position BCC to become a research administration agency. Yet BCC is an agency that has absolutely no history or competency whatsoever in administration of research funding and should not seek to play the role of directly designing or administering research funding programs. It would take large investments in development of research expertise and new staff for BCC, unlike the University of California, which has well established and world-famous expertise and capacity for administering research funding.

In addition, the language goes beyond the language of MAUCRSA, which requires that funds be initially disbursed to public universities,and could be misconstrued in such a way as to impermissibly limit the award of research funds from public universities through competitive research awards, subgrants, or collaborations with other types of public or nonprofit research or provider organizations. This erroneous interpretation of state law, and potential discarding of decades of positive research funding administration experience in the state of California, would unduly restrict the breadth and quality of research that could be carried out with this funding. TRDRP, for example, has granted funds to a broader range of research organizations, with highly positive results. We propose that receipt of research funds awarded by the public university (ies) receiving funds be restricted to California based public or nonprofit universities or other organizations with qualified research capacity. For example, Kaiser Permanente's research arm is carrying out groundbreaking research on the impact of legalization on cannabis exposure during pregnancy and neonatal outcomes and has unique data due to its massive patient population in the state. The regulatory language as written could, for example, be misconstrued as prevent the University of California from granting an award to Kaiser or even engaging in collaborative research that benefits from this unique data. Similarly, a nonprofit compassionate use organization could be construed as ineleigible to receive funds to collaborate with a public university in research activities under the proposed language.

To assure the quality, independence and integrity of research findings to understand this major new legal industry and its regulation, this language should urgently revised.

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**.

The BCC'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 under-regulated industry. While some of the Bureau's provisions adopt best practices, they fall short in other areas. The proposed text of regulations risk permitting an excess of licensed facilities, fail to advance any proposals to assure greater equity in access to licenses, set daily sales limits which are excessive, allow the shift to high potency products to continue unabated, and fail to inform customers of risks, and establish a research administration plan that ignores successful California models and would greatly diminish the effectiveness of allocated research funding. Permitting relatively unfettered marketing and outlets is deeply unwise. Incorporating lessons learned from tobacco and alcohol control and from other states legalizing marijuana is essential to promote a functional and well-regulated cannabis system that prioritizes protection of public health over business interests in the State of California.

These issues should be corrected in the regulation, with most urgent attention to those which would very difficult to reverse in the future, such as issuance of excessive licenses.

Thank you for considering these recommendations.

Sincerely,

[INSERT SIGNATURE(S)]