**Model comments on the CDPH 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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***Acknowledgement:*** *Significant sections of these comments, for example on pre-rolls, flavored products, plain packaging, warning symbols and pictorial warnings and on caffeine are taken from or adapted from UCSF’s Center for Tobacco Control Research and Education comments with appreciation for their valuable contributions.*

**Notes on submission:**

Comments can be submitted three ways:

1. Through **email** to regulations@cdph.ca.gov

with subject line “Proposed regulations (DPH-17-010)”

2) Through **physical mail** to

CDPH Office of Regulations

1415 L Street, Suite 500

Sacramento, CA 95814

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

Hearing schedule can be found on the CDPH website:

<https://www.cdph.ca.gov/Programs/CEH/DFDCS/MCSB/Pages/Rulemaking.aspx>

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 sender.

This Instructions Page Should be Deleted prior to Submission.

[INSERT DATE]

CDPH Office of Regulations

1415 L Street, Suite 500

Sacramento, CA 95814

**regulations@cdph.ca.gov**

Re: (DPH-17-010)

**Comment on California Department of Public Health, Manufactured Cannabis Safety Branch, Proposed Text of Regulations**

**CALIFORNIA CODE OF REGULATIONS TITLE 17, DIVISION 1, CHAPTER 13
MANUFACTURED CANNABIS SAFETY**

**Comment Summary:**

**proposed regulations incorporate some positive steps which we strongly support. However, incorporating lessons learned from tobacco, alcohol AND PHARMACEUTICAL regulation is urgently necessary to protect public health. These MEASURES include prohibiting manufactured cannabis products that are of particularly high risk or used to attract children and youth, including high potency flower and conceNtrates, flavored products, cannabis beverages, and infused pre-rolls and commissioning a full evaluation of potential public helth impact of these products free of conflicts of interest; reinstating the essential protection of children from accidental ingestion through child RESISTANT packaging; asSuring legible prominent warnings, COMPLIANT WITH LEGAL REQUIREMENTS, that inform consumers on products and marketing; preventing abusive industry marketing tactics particularly those that attract children and youth; and more actively preventing conflicts of interest. adoption of these measures will help to assure a better balance between the benefits of legalization anD the reduction of harms from an expanded market.**

**About the Submitting Organization:**

[INSERT ORGANIZATION NAME AND DESCRIPTION OF WORK]

**GENERAL COMMENTS:**

Legalization of cannabis for adult use in California and other states represents a massive shift in the regulatory approach to the substance, despite its continued illegality under federal law. Positive impacts of this change may include an end to enforcement practices that have disproportionately resulted in mass incarceration, particularly in communities of color, as well as safer products. However, the creation and government endorsement of a legal cannabis industry that will span both medical and adult use also 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**,[[1]](#footnote-1) or that such other industries may seek to enter and dominate the new cannabis markets.[[2]](#footnote-2)

The multiplication of marketed products clearly aimed at attracting youth and expanding use, as well as vast increases in potency, are dangerous trends that have already been clearly established in the previously little regulated medical cannabis market.

Ample evidence exists which supports a measured precautionary approach. Cannabis use during pregnancy is associated with low birthweight.[[3]](#footnote-3) Cannabis use, like alcohol, is associated with motor vehicle accidents.[[4]](#footnote-4) Cannabis use is clearly associated with development of substance use disorders[[5]](#footnote-5),[[6]](#footnote-6) and schizophrenia and other psychoses.[[7]](#footnote-7) Cannabis smoking is associated with respiratory health harms,[[8]](#footnote-8) stroke,[[9]](#footnote-9) and cardiovascular disease,[[10]](#footnote-10),[[11]](#footnote-11),[[12]](#footnote-12) as well as secondhand smoke risks.[[13]](#footnote-13) Cannabis and tobacco smoke share similar toxicity profiles,[[14]](#footnote-14) and California has identified cannabis smoke as a known human carcinogen since 2009.[[15]](#footnote-15),[[16]](#footnote-16) Daily cannabis use by youth is associated with more than halving high school graduation rates.[[17]](#footnote-17) While some clear evidence exists, the full portrait of cannabis’s negative health effects and/or medical efficacy is still emerging, and will continue to do so in the coming years, owing largely to longstanding barriers to research stemming from illegality, as well as constant change in the products in use.[[18]](#footnote-18),[[19]](#footnote-19)

Users may opt for manufactured cannabis products to avoid negative health effects associated with combustion,[[20]](#footnote-20),[[21]](#footnote-21) but manufactured products also present very significant risks. Some vaporized products (e.g., extracts and oils) are similar to e-cigarettes and sometimes use the same hardware,[[22]](#footnote-22) likely presenting similar risks, which for e-cigarettes include inhalation of ultrafine particles and chemical additives that can cause cardiovascular and pulmonary effects.[[23]](#footnote-23),[[24]](#footnote-24),[[25]](#footnote-25),[[26]](#footnote-26) High-potency cannabis concentrates may increase risks for dependence, tolerance, and withdrawal,[[27]](#footnote-27) and heating these concentrates for inhalation (“dabbing,” which can produce combustion at higher temperatures[[28]](#footnote-28)) can release toxic chemicals including methacrolein and benzene.[[29]](#footnote-29) Edibles can be unintentionally overconsumed by adults[[30]](#footnote-30) and accidentally consumed by children.[[31]](#footnote-31) Most importantly, through aggressive diversification of the cannabis supply, in particular imitation of processed foods, the industry will (whether intended or not) attract youth and adults, create new consumers, and increase consumption by existing consumers.

California is the largest US medical cannabis market and will be the largest legal adult-use market in the world, with the potential to influence national and global policy. It is critically important that the Department of Public Health recognize the current and likely future health impacts and model its cannabis regulations on best practices from established public health frameworks for regulating tobacco and alcohol.[[32]](#footnote-32),[[33]](#footnote-33) **Public health objectives require that both cannabis markets be well controlled and designed to prevent diversion to illicit markets, abuse, negative health effects, increased prevalence, youth use, and the creation of a powerful industry that may encourage addiction and harmful use using methods commonly employed by the tobacco and alcohol industries. Our state has a moral responsibility to its residents to “Get it Right from the Start.”**

**Specific Recommendations:**

**Positive Provisions**

Many elements of the proposed regulations keep and maintain elements from the emergency regulations that are consistent with public health best practices. The proposed text of regulations contains some important and valuable provisions for structuring the process of legalization. These include:

* Adding to the definition of “edible cannabis product” to clarify that it includes products that “resemble conventional food or beverages and cannabis products that dissolve or disintegrate in the mouth” (§ 40100)
* Requiring manufacturers to provide up-to-date lists of products (§§ 40131(d); 40177(f)) to aid enforcement and potentially enable better tracking of product types and assessment of their public health impacts
* Prohibiting the manufacture, preparation, packaging and labeling of cannabis products in a location that is operating as a retail food establishment or a location licensed by the Department of Alcoholic Beverage Control (§4 0175)
* Prohibiting products that the Department deems to be attractive to children as well as products in the shape of humans, animals, insects, or fruit or imprinted with such shapes (§ 40300)
* Prohibiting products easily confused with commercially available foods without cannabis and limiting labeling of products that contain commercially available candy or foods (§ 40300)
* Prohibiting additives (such as nicotine or caffeine) that increase potency, mask intoxication, or augment addictive potential (§ 40300) to moderate abuse risk
* Clarifying that prohibitions on harmful additives apply to *all* cannabis products rather than only edible products to restrict unsafe formulations (§ 40300)
* Limiting THC content in manufactured products (§ 40315) to reduce risks associated with accidental consumption and overconsumption and requiring products in excess of that amount to be for medicinal use only
* Additional prohibitions on certain potentially hazardous foods (§ 40300)
* Requiring that the labeling requirements (including the universal symbol) be applied not only to the outside container such as a box, but also any inside container that is separable from the outside box (§ 40403)
* Clarifying the label requirements for THC and CBD content for all packages of cannabis product (§ 40409)
* Prohibiting labeling attractive to children and youth including cartoons, images, characters and phrases used to advertise to children, imitations of candy packaging or labeling, the term candy or variations thereof such as “kandy” or “kandeez” (§ 40410)
* Prohibiting images of any edible products on the label of those products (§ 40410)
* Prohibiting the use of “organic” or alternatives such as “organix” until such time as the federal Organic Food Production Act of 1990 authorizes organic designation/certification for cannabis (§ 40410)
* Requiring the use of a track and trace system (§ 40510 et seq.) to reduce diversion to illicit markets
* Mandating labels and warnings with specific content (§§ 40408, 40410, 40412) that will counter the influence of abusive marketing practices
* Increasing license fees for the largest operators to discourage dominance by larger and more powerful industry elements (§ 40150(b))
* Strengthening the prohibition on labels containing health-related statements that are not supported by evidence (§ 40410)
* Prohibiting persons tasked with cannabis enforcement from holding licenses (§ 40116)

We strongly support these provisions and recommend that the Department should maintain or strengthen these regulations even if industry and its allies object to them or seek to weaken them. These are essential for public health protection and should not be omitted under any circumstances.

Building on these positive elements of the proposed regulations, the following specific changes are needed to ensure that the proposed regulations are fully consistent with evidence-based best practices from tobacco and alcohol control in order to create a well-regulated legal market for cannabis in California that will minimize adverse effects on the health of Californians.

Once a product is legally manufactured in the state and allowed on the market it will become much more difficult to withdraw permission for its manufacture and marketing – therefore this is the time to exercise caution.

SPECIFIC RECOMMENDATIONS

**1.** **Not allow manufacture of certain products with strong evidence for increased public health risk or attraction to youth**

There is a significant group of products that are not traditional cannabis products, and which represent the recent effort by the industry to diversify its supply and expand its market in ways which will inevitably attract youth as well as adults, increase risk of dependency, and/or increase risk of adverse effects. Legalization of cannabis does not require legalization of every conceivable formulation of cannabis. **We recommend that manufacturing of specific product groups be disallowed under the proposed regulations. At a minimum they should not be allowed until such time as a full and formal product specific regulatory risk assessment and public process occurs. These products include, but are not limited to: high potency flower, high potency concentrates, infused pre-rolls, flavored non-edible cannabis products, and cannabis beverages.**

Specifically:

 **1.a.) High potency cannabis and cannabis products**

In 2007, Judge Gladys Kessler, in a landmark decision in *US v Philip Morris*, 449 F.Supp.2d 1 (D.D.C. 2006)[[34]](#footnote-34), held the tobacco companies liable for violating the Racketeer Influenced and Corrupt Organizations Act (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.[[35]](#footnote-35)*

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 systematically 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. As California’s medical market emerged, it included not only high potency flower, but a large number of ultra-high potency concentrates whose safety is of deep concern. Some varieties of high potency cannabis concentrate include “oil,” “wax,” and “dabs” typically created by butane extraction.[[36]](#footnote-36)

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.”[[37]](#footnote-37)*

This transition to higher potency has been particularly dramatic **post-legalization of adult-use 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:

*“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)[[38]](#footnote-38)*

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,[[39]](#footnote-39) while still other studies have shown that individuals do not adjust their use when using higher potency products.[[40]](#footnote-40) Increased exposure to THC has also been associated with increased symptoms of cannabis use disorders,[[41]](#footnote-41),[[42]](#footnote-42), increased risk for of psychosis, [[43]](#footnote-43),[[44]](#footnote-44) and, as observed in acute administration studies, impaired cognition.[[45]](#footnote-45),[[46]](#footnote-46),[[47]](#footnote-47) 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.”[[48]](#footnote-48)*



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 the “best high” or “preferred.”[[49]](#footnote-49) Published case reports have shown “**significant psychosis, neurotoxicity, and cardiotoxicity associated with dabs.**”[[50]](#footnote-50) Concentrates are also known to cause psychotic reactions in some and severe unpleasant highs in others.[[51]](#footnote-51) 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 seeking care (See Figure).[[52]](#footnote-52) 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.[[53]](#footnote-53) Recent recommendations for legalization in the United Kingdom endorse restricting legalization to products below 15% THC.[[54]](#footnote-54) Canada’s Task Force on Cannabis Legalization and Regulation recognized increasing potency as a fundamental public health challenge that needs to be addressed.[[55]](#footnote-55) New Mexico limited potency of manufactured products to 70%.[[56]](#footnote-56) 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 manufacturing in the State of California, it is essential that CDPH act now to slow this rapid and dangerous trend. While there is still much debate about the best approach to be used, for example optimal potency maxima *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 for use as flower or pre-rolls to below 20% THC content, and of concentrates to 50% THC or below.

 **1.b.) Non-edible products employing characterizing flavors known to be attractive to youth**

We recommend prohibiting the addition of menthol and other characterizing flavors in non-topical and non-edible products. The proposed regulations (§ 40300(b)) prohibit additives that "increase potency, toxicity or addictive potential.” **CDPH should add “attraction to children and youth” to these criteria, and broaden its interpretation to include all flavor additives, including, but not limited to, menthol, in non-edible and non-topical products.**

In tobacco products, menthol is more than a flavoring agent. Menthol affects nicotine dependence through behavioral reinforcement[[57]](#footnote-57) and encouragement of breath holding, which increases nicotine exposure.[[58]](#footnote-58) Stimulated by industry marketing, younger and newer smokers disproportionately use menthol cigarettes, drawn to the reduced harshness menthol contributes as a local anesthetic.[[59]](#footnote-59),[[60]](#footnote-60) Menthol contributes to the inequitable tobacco burden on the health of African-American smokers, who disproportionately smoke menthol cigarettes and have higher rates of tobacco-related diseases despite smoking fewer cigarettes per day and initiating smoking later.[[61]](#footnote-61),[[62]](#footnote-62) Menthol use is more common among groups targeted by the tobacco industry, including youth of color, women, and LGBTQ populations.[[63]](#footnote-63) Menthol smokers, especially persons of color and younger smokers, also experience more difficulty quitting.[[64]](#footnote-64) **CDPH should act to prevent the repetition of these harms and inequities in the cannabis market.**

Menthol cigarette smokers are more likely than non-menthol smokers to report past 30-day cannabis use.[[65]](#footnote-65) Dual use of menthol cigarettes and cannabis also increased from 2005-2014.[[66]](#footnote-66) Manufactured cannabis products incorporating menthol are already available.[[67]](#footnote-67) Menthol’s sensory effects potentially contribute similar behavioral reinforcement for cannabis use as for tobacco use, and menthol likely produces similar anesthetizing and cooling effects for inhaled cannabis products as for tobacco. **Menthol’s links to nicotine addiction and health inequities and its existing associations with cannabis use support a cautious policy prohibiting menthol in non-topical cannabis products to prevent repetition of harms attributable to mentholated tobacco products.**

**Beyond menthol, a broad prohibition on characterizing flavors in nonedible products is necessary to deter youth use.** Flavored products with a wide variety of flavors are a key tool for attracting young smokers to tobacco,[[68]](#footnote-68),[[69]](#footnote-69),[[70]](#footnote-70) and e-cigarettes.[[71]](#footnote-71),[[72]](#footnote-72) Most adolescent tobacco and e-cigarette users currently use and initiated with flavored products.[[73]](#footnote-73) Disguising unpleasant tastes with flavors to attract young users is a tobacco industry strategy that could easily repeat for manufactured cannabis products absent strong regulations. The FDA’s 2009 ban on cigarettes with characterizing flavors (authorized by the Family Smoking Prevention and Tobacco Control Act) was followed by a decrease in adolescent tobacco use and substantial reductions in the probability of being a cigarette smoker and in cigarettes smoked among adolescents.[[74]](#footnote-74) Because the final 2009 ban controversially failed to include menthol cigarettes or flavored non-cigarette tobacco, increased use of cigars, pipes, and menthol cigarettes limited the impact on adolescent tobacco use.

The existing medical cannabis market in our state has clearly adopted this key strategy of the tobacco industry to attract youth. While flavored flower is not widely present, a wide range of other flavored products including flavored pre-rolls, as well as flavor named strains or extracts (even when they do not actually contain the flavor) are available. **Cannabis regulations should prevent similar effects by prohibiting characterizing flavors in nonedible products whether for the medical or adult-use market.**

**An additional issue which should also be addressed is the prohibition of misleading branding names that imply, but do not even offer, typical fruit flavors attractive to youth** (for example Leafly’s “Cherry Pie” or “Strawberry” cannabis; or Greenwolf and Moxie’s Strawberry Banana Lemonade).

Flavored edible products present similar concerns that require further research on how they may impact use and initiation. While some patients prefer flavored products, any therapeutic effect is likely unrelated to flavorings, and alternative formulations (e.g., tinctures) are available.

**It took decades for Congress to pass a law and the FDA to get most flavored tobacco off the market, and they are still struggling to get menthol off the market despite massive evidence of harm. CDPH has been actively engaged in the effort to end flavored tobacco. It makes no sense for CDPH to permit the launch of the state’s newly legal cannabis market repeating grave past regulatory mistakes leading to youth use and dependency.**

**1.c.) Cannabis infused beverages** **(§ 40300)**

**There is absolutely no need for medical or adult-use beverages and they represent a clear marketing strategy to increase and trivialize consumption, by mimicking common beverages, and to attract youth.** **Their manufacture should not be allowed**. Today there is orange soda cannabis and ice tea cannabis for sale in dispensaries. Recently, the well-known Lagunitas Brewing Company has teamed up with CannaCraft to allow for Lagunitas-branded cannabis infused sparkling water called “HiFi Hops”.[[75]](#footnote-75) As CDPH and the entire nation works to reduce consumption of sugar sweetened beverages, and even artificially sweetened ones, and communities increasingly ban “alco-pops,” it is completely unjustifiable to permit the launch of a new portfolio of harmful beverages combined with cannabis, a public health double whammy. Sugar sweetened beverage consumption has been clearly linked in a massive body of research to obesity, diabetes, heart disease and other health problems, and even artificially sweetened beverage consumption has growing evidence of associated harm.[[76]](#footnote-76) Alco-pops, the model for many of these infused beverages, have been associated with adolescent drinking.[[77]](#footnote-77) After a tax was instituted to reduce their consumption in Australia, injuries in 15-29 year olds declined.[[78]](#footnote-78) Why would we wish to duplicate this harmful model with cannabis?

Cannabis infused dried meats or other typical food products pose a similar issue, albeit less likely to be scaled up. The standards for juice may also be contradictory, in that on the one hand the standards disallow products that resemble typical foods, but then speak to whether they are required to be shelf-stable or require refrigeration (§ 40300), rather than simply disallowing.

At least two California jurisdictions (Mono County and Pasadena) have already taken the positive steps of banning cannabis-infused beverages and more may follow, however this leadership should ideally come from the state.

**1.d.)** **Prohibit Infused Pre-Roll Cannabis Products (§40100(w); §40120; §40300; 40315)**

CDPH’s decision to allow a new type of product called an “infused pre-roll” is deeply concerning from a public health perspective. Infusion of plant material that is intended to be smoked poses a public health risk both due to harmful additives and potency concerns. Authorizing manufacturers to increase the potency (and thus addictive potential) of pre-rolled, smoke-able cannabis may allow or encourage them to follow the practices of the tobacco industry, which has continually manipulated levels of specific chemicals (including nicotine, ammonia, and sugar) to increase the addictive potential by manipulating delivered dose and bioavailability of nicotine.[[79]](#footnote-79) **The Department’s proposed approach here is particularly risky because there are no apparent THC concentration limits on infused pre-rolls and manufacturers may choose for themselves how to report THC concentration in these high-potency products (§40409(d)).**

Infused pre-rolls are defined in the proposed regulations as “a pre-roll into which cannabis concentrate (other than kief) or other ingredients have been incorporated.” § 40100(w). Pre-rolls are defined as any combination of flower, shake, leaf or kief rolled in paper (§ 40100(ll)). Infused pre-rolls are not edibles, orally-disintegrating products, concentrates, or topicals and as such do not appear to fall under any of the categories of THC concentration limits set forth in section 40315. Furthermore, while the **added** concentrate in the infused pre-roll cannot exceed 1,000mg THC (§ 40315(c)), this 1,000mg of additive is in **addition to the content in the plant itself** allowing for a dangerously high-potency product that is out of step with CDPH’s overall approach to allowable THC concentration. High-potency concentrates present unique and serious health risks including increased dependence risks,[[80]](#footnote-80) and have been linked to psychosis in case reports.[[81]](#footnote-81) These risks would be magnified by allowing concentrates to be added to easy-to-use products like infused pre-rolls. See also comments under section 1(a) on potency.

Additionally, CDPH proposes in section 40409(d) to allow manufacturers to determine for themselves how to best label THC content in their products (whether in milligrams or in both percentage in the flower and in milligrams added in the concentrate 40409(d)). Although the stated reason for such a rule is to allow manufacturers to choose the method that is “most meaningful for consumers based on the specifics of the product,”[[82]](#footnote-82) this has the potential to result in a bad actor intentionally misleading consumers. As a result, if the department decides to allow infused pre-rolls to be sold, **CDPH must mandate the appropriate method of reporting THC content in these products.**

**We recommend that the labelling require both % THC by weight and total mg of THC in a pre-roll product.**

The fact that experienced users might choose to mix concentrates and plant materials on their own does not mean that CDPH should authorize such products to be sold in ready-to-use form. CDPH already prohibits the retail sale of certain types of products combined with cannabis (for instance, alcohol, tobacco, and caffeine) (§ 40300(a)-(b)) because there is a public health rationale for prohibiting unsafe combination products. **We recommend not allowing manufacture of these products**. If CDPH continues to allow them, it should require a clear separation of products containing solely plant material from those containing concentrates and other additives.

**2.** **Clarify Types of Changes that Necessitate Updating a Manufacturer’s Product List (§ 40131(d); 40177(f))**

Section 40177(f) mandates that a licensee notify CDPH of any changes to its product list within 10 days of making any changes. This is an important regulation that will help facilitate CDPH’s enforcement activities. **However, in order to ensure compliance, CDPH should clarify what types of changes necessitate updating the product list.**

The regulations require that licensees update CDPH whenever “substantial or material alterations” are made to the physical premises. The ISOR provides several examples of the types of alterations that would require an update, including moving a doorway, entryway or interior partition. Likewise, CDPH should clarify what product changes are significant enough to require updating the product list. For example, the addition of some chemicals to inhaled products may present health risks[[83]](#footnote-83),[[84]](#footnote-84),[[85]](#footnote-85) and a change to the ingredients of an edible product could affect THC absorption. Such modifications should be considered to have created a new product and should trigger mandatory updates to the product list.

Section 910 of the Family Smoking and Tobacco Prevention Control Act of 2009 requires tobacco companies to apply for premarket review for “new tobacco products” including those that have undergone “any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or any other additive or ingredient).”[[86]](#footnote-86) The Department should apply a similar standard to define changes to cannabis products that must be reported. As no similar type of premarket review is currently required for cannabis products, the burden on licensed cannabis manufacturers to update their product list within 10 business days via the Manufactured Cannabis Licensing System is minimal, particularly in light of related requirements to maintain a Master Manufacturing Protocol (§ 40262) that includes comprehensive details on ingredients and processes “for each unique formulation of cannabis product manufactured, and for each batch size.” **The Department should seek authorization and funding for a system of premarket approval for new cannabis products based on FDA’s tobacco product model.**

**3. Expand the Prohibition on Caffeine to Include “naturally derived sources” (§ 40300)**

CDPH appropriately prohibits the inclusion of non-cannabinoid additives that increase potency, toxicity, or addictive potential and has added a further restriction on additives that would “create an unsafe combination with other psychoactive substances.” (§ 40300(a)). In CDPH’s Initial Statement of Reasons, it states that CDPH would prohibit the addition of caffeine as an additive because “cannabis can similarly behave as a depressant, causing the same unsafe combination with caffeine as does alcohol. In order to protect public health, the Department has made a determination to prohibit caffeine in cannabis products.”[[87]](#footnote-87) However, despite its recognition that caffeine can be a dangerous additive to cannabis products, CDPH does not in fact prohibit this combination because the regulations clearly allow for cannabis to be combined with “naturally caffeinated products (coffee, tea) (§ 40300(b)). If the combination of a stimulant (caffeine) and a depressant (cannabis) is unsafe (and we agree with CDPH’s assessment), then it is unsafe regardless of the source of the caffeine. Caffeine levels also vary dramatically in natural products. For example, drip coffee typically contains 10-20mg of caffeine per fluid ounce, whereas espresso and cold-brew concentrates can have more than 70mg per fluid ounce.[[88]](#footnote-88)

**To be consistent with its own analysis, CDPH should prohibit all caffeine, regarded of origin, in cannabis products, or at minimum, specify a maximum allowable level of caffeine in manufactured products.**

**4. Establish a More Detailed and Inclusive Definition of “Attractive to Children or Youth”** (§ 40410(b))

While CDPH’s proposed regulation makes important progress, this definition should include products, packaging or labeling or advertising that encourages persons under age 21 to initiate cannabis consumption or to consume cannabis or cannabis products. For example:

**4.a.)** We applaud CDPH’s decision to prohibit products “in the shape of, or imprinted with the shape of a human being, either realistic or caricature, animal, insect, or fruit.” (§ 40300(m)). We would further recommend prohibiting products that (1) resemble a non-cannabis consumer product of a type that is typically consumed by, or marketed to, children or youth such as a specific candy or baked treats; (2) that are edible in the form of baked or other grain-based goods typically marketed to youth or sent to school, such as Rice Krispies treats, cupcakes, granola bars, and animal crackers, that may be mistaken for non-cannabis products.

**4.b.)** In packaging and labeling, this should include packaging or labeling that (1) resembles packaging or labeling of a non-cannabis consumer product of a type that is typically consumed by, or marketed to, youth; (2) includes images depicting a cartoon, animal or other animate creature, toy, candy, baked good, vehicle, or robot; (3) includes text describing a cartoon, animal or other animate creature, toy, vehicle, or robot; (4) any likeness to images, characters, or phrases that are popularly used to advertise to children; or (5) describes any characterizing flavor except that for edible products only terms such as “lemon-flavored” describing a characterizing flavor may be used, and only in font sizes that do not exceed that of the largest word in the “Warning” on the packages.

**4.c.)** In advertising, this should include (1) appeals that mimic advertising of a non-cannabis consumer product of a type that is typically consumed by, or marketed to children or youth; (2) the depiction of cartoons, animals or other animate creatures, toys, candy, baked goods, vehicles or robots typically marketed to youth; (2) the use of actors or characters who appear to be under age 21 or are under age 25; (3) the use of celebrities who specifically appeal to youth; or (4) the use of images, sound or language that associate cannabis, directly or indirectly, with outcomes such as social acceptance, wealth, romance, or success in physical activities/sports.

**4.d.)** Cartoon can be defined as: any animation, drawing or other depiction of an object, person, animal, creature or similar caricature that satisfies any of the following criteria:

 i. The use of comically exaggerated features;

 ii. The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or

 iii. The attribution of super, unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.

These recommendations are based on a systematic review of the literature on youth perceptions of advertising for alcohol, tobacco and food, which identified specific content features to which minors are particularly susceptible due to their unique developmental stage, propensity for high risk behaviors, and relative inexperience with consumption of alcohol and tobacco.[[89]](#footnote-89),[[90]](#footnote-90),[[91]](#footnote-91),[[92]](#footnote-92),[[93]](#footnote-93),[[94]](#footnote-94),[[95]](#footnote-95) A subsequent analysis found a positive association between the use of such features in alcohol brand advertisements and youth consumption of those brands, and no association with adult alcohol consumption of those brands, suggesting that they have particular appeal to youth.[[96]](#footnote-96) Discussions with Oregon officials, who carry out product by product assessments, have noted the importance of clearly and strongly defining what it means to be attractive to youth in order for marketers to have clear instruction and to be able to assess compliance objectively.

The proposed regulations (§ 40410(c)) prohibit packaging with cartoons, “images, characters, or phrases that are popularly used to advertise to children,” or “imitation of candy packaging or labeling.” However, elements not “popularly used to advertise to children” often remain appealing to children and teens, including themes of social acceptance, wealth, romance, or success in physical activities/sports. A broader prohibition on such elements is necessary to prevent industry targeting of youth. While we are pleased to see that the current proposed regulation has added prohibitions against alternative spellings of “candy” (including “kandy” and “kandeez”, the proposed prohibitions still do not go far enough to account for the wide variety of products that may be attractive to youth. A complete prohibition on the imitation of all non-cannabis products, both for the product and packaging, would more effectively reduce the risk of accidental consumption. **Adoption of a plain packaging standard (see below) avoids interpretive problems and undermines the opportunity to use packaging to mislead consumers and unlawfully market to youth.** The city of Santa Ana has already adopted regulations that prohibit any packaging that can be considered “attractive” to minors (Sec. 40-8(3)(j)).

**5. Increase Visibility of Warning Labels (§§ 40405, 40408)**

The proposed regulations (§ 40404), (§ 40405) require a primary panel label and a separate informational panel label that includes mandatory warnings (§ 40408), both with a miniscule minimum 6-point font. The size, prominence, position, and design of health warning labels influence their impact on risk perceptions.[[97]](#footnote-97),[[98]](#footnote-98) Tobacco health warnings that cover at least 30% and ideally 50% or more of the package’s principal display area, as required under the WHO Framework Convention on Tobacco Control (FCTC)[[99]](#footnote-99) are associated with higher health knowledge and motivation to quit.[[100]](#footnote-100),[[101]](#footnote-101) Increasing label size also improves effectiveness among youth.[[102]](#footnote-102) Some countries’ tobacco warnings occupy up to 90% of the package,[[103]](#footnote-103) and the tobacco industry has intensely opposed larger and more effective warnings.[[104]](#footnote-104) The proposed regulations’ standard is vulnerable to industry manipulation. **Requiring warnings on the primary panel and covering a minimum 30% (ideally 50%) of the principal display area would eliminate ambiguity and likely produce gains in health knowledge and warning effectiveness.**

The proposed minimum 6-point font is consistent with Oregon,[[105]](#footnote-105) but considerably smaller than Nevada,[[106]](#footnote-106) which requires front and rear labels with minimum 12-point font. A 6-point font standard is also smaller than the approximately 10-point font a 2017 cannabis industry white paper suggests.[[107]](#footnote-107) **Requiring minimum 12-point font would be consistent with FDA’s requirements for most tobacco warnings[[108]](#footnote-108) and ensure cannabis warnings are readable and salient,** paralleling the FCTC’s requirement that tobacco health warnings to be “large, clear, visible and legible.”[[109]](#footnote-109) A larger warning label would also permit a larger, more prominent font size.

A 6-point font is challenging to read, as illustrated in the following comparison:

**Manufactured at:** Joe’s Kitchen Cert.#:

 321654987101 0401

 123 Main Street, Las Vegas, NV on 2/1/14

Lot#: 1234 Batch #5463

 **INGREDIENTS:** Flour, Butter, Canola Oil, Sugar, Chocolate, Marijuana, Strawberries

 **CONTAINS ALLERGENS:** Milk, Wheat

**Contains marijuana extract processed with butane.**

**WARNING:** This product may have intoxicating effects and may be habit forming.

**Manufactured at:** Joe’s Kitchen Cert.#:

 321654987101 0401

 123 Main Street, Las Vegas, NV on 2/1/14

 Lot#: 1234 Batch #5463

 **INGREDIENTS:** Flour, Butter, Canola Oil,

 Sugar, Chocolate, Marijuana, Strawberries

 **CONTAINS ALLERGENS:** Milk, Wheat

 **Contains marijuana extract processed with butane.**

 **WARNING:** This product may have intoxicating effects and may be

 habit forming.

Even more problematic is that the **proposed regulations appear to ignore the plain language of state law** and suggest allowing relegation of all product warnings for manufactured products from the prime real estate of the informational panel, to “package insert, fold-out or booklet label, or a hanging tag” § 40408(c), instead. The proposed regulations do not define “package insert,” “fold-out or booklet label,” or “hanging tag.” These alternatives make a bad regulation even worse, by allowing movement of essential information to pieces that we know consumer routinely discard or disregard, and which be essentially hidden from the consumer. State law establishes that *“All cannabis and cannabis****product labels and inserts****shall include the following information prominently displayed in a clear and legible fashion in accordance with the requirements, including font size, prescribed by the State Department of Public Health..."* 26120(c). State law **does not** say product labels **OR** inserts, as the proposed regulation appears to imply.

**We recommend that the regulations respect the legal requirement for warnings on the package label rather than by package insert or booklet**. Package labels are more likely to be seen by the consumer or any other person who comes across the product after the initial purchase because it is too easy for package inserts to be discarded with the exit packaging without ever being seen.

There is substantial evidence from tobacco and alcohol studies that package labels work. Warning labels on packages have been shown to increase knowledge of the risks of smoking, make smokers think about quitting, and prevent non-smokers from starting.[[110]](#footnote-110) The effectiveness of warning labels is highest when the warnings are large, prominent, full color and contain graphic images.[[111]](#footnote-111)

On the other hand, there is very little evidence on the effectiveness of package inserts. However, what evidence does exist indicates that package inserts are effective when coupled with package warning labels.[[112]](#footnote-112) There is an abundance of evidence from alcohol and tobacco that warning label features such as font size, inclusion of images and graphics, and clear information improves consumer recall, perception of risks, and intentions to cut down or quit as appropriate.[[113]](#footnote-113),[[114]](#footnote-114),[[115]](#footnote-115)

**6. Include Rotating Health Warnings and Pictorial Warnings (§ 40408)**

The proposed regulations (§ 40408) mandate textual warnings of hazards for children and animals, use while pregnant or breastfeeding, delayed intoxication, and impaired driving. Tobacco warning labels are more effective when changed periodically. To better educate consumers and reduce perceptions of harmlessness, cannabis labels should include comprehensive and rotating health warnings consistent with current risk information, including secondhand exposure,[[116]](#footnote-116) chemical additives[[117]](#footnote-117),[[118]](#footnote-118)dependence[[119]](#footnote-119),[[120]](#footnote-120) cardiovascular disease,[[121]](#footnote-121),[[122]](#footnote-122),[[123]](#footnote-123),[[124]](#footnote-124) respiratory disease,[[125]](#footnote-125) neurological disease,[[126]](#footnote-126) and cancer[[127]](#footnote-127),[[128]](#footnote-128) based on product type.

Text-only labels, as currently used for tobacco in the US, and proposed by CDPH, are poorly recalled and have less impact on use.[[129]](#footnote-129) **Pictorial health warnings are more impactful and informative [[130]](#footnote-130),[[131]](#footnote-131),[[132]](#footnote-132) and decrease product attractiveness to youth.[[133]](#footnote-133),[[134]](#footnote-134) Pictorial warnings are also more likely to be seen by low-literacy adults and children and to reach those who cannot read the language used for text.**[[135]](#footnote-135) Based on their effectiveness for tobacco, pictorial warnings are likely to improve the impact and effectiveness of cannabis warning labels.

**7.** **Adopt a Highly Visible and Salient Cannabis Product Symbol (§ 40412)**

The proposed regulations (§ 40412(a)) require a warning symbol denoting the presence of cannabis. Tobacco companies’ research on packaging color and consumer perceptions indicates that black is most visually prominent, particularly black text on a lighter background.[[136]](#footnote-136) The color required under the proposed regulations appears to be black text on white background based on the document available on the Department’s website. Yellow is more effective for quickly gaining and keeping attention, is perceived as less attractive, and signals a warning, especially paired with black text as in road sign warnings.[[137]](#footnote-137) A warning symbol using black text and yellow background that emulates road warning style and shape,[[138]](#footnote-138) as the option illustrates below, would more effectively attract and maintain consumer attention. We do concur that a cannabis leaf may be more informative and widely recognized than the highly technical term “THC.”



The proposed regulations (§ 40412(b)) require the symbol be at least ½ inch by ½ inch and “printed legibly and conspicuously.” Likely packaging variation among cannabis products supports also mandating coverage of a minimum percentage of the product’s primary panel to prevent companies from using large package size, colors, or other markings to render the symbol ineffective. The symbol should be incorporated into warnings covering at least 30% and ideally more than 50% of the principal display area. We recommend that the Department implement this requirement immediately but also carry out the appropriate research to assess what shapes, colors and messages best transmit the information for the future.

**8. Require Resealable Child Resistant Packaging (not delegated to exit packaging) and Plain Packaging (§ 40415)**

Most worrisome, the proposed regulations completely remove the previous requirement *“((c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for “special packaging” as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.15(b)(1)) (Rev. December 1983July 1995), which is hereby incorporated by reference. ….(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.”* Instead, child-resistant packaging is only required for exit-packaging when leaving the retailer. Exit packaging is likely to be thrown out by the consumer, leaving a product packaged in a manner that is not child-resistant, and exit packaging will clearly not be reused once the package is opened. This has the potential to lead to significant health harms to young children who will be easily able to access cannabis products.

Several recent studies highlight the dangers of this measure. A recent review of pediatric poisoning confirms increasing incidence of unintentional ingestion in states having decriminalized medical and recreational cannabis. Reports range from children 8 months to 12 years of age. The most common ingestion was cannabis resin, followed by cookies and joints. Other exposures included passive smoke, medical cannabis, candies, beverages, and hemp oil. Lethargy was the most common presenting sign, followed by ataxia. Tachycardia, mydriasis, and hypotonia were also commonly observed. Eighteen percent required admission to the pediatric intensive care unit, and 6% were intubated, demonstrating the potential severity, especially if a child ingests a high potency product.[[139]](#footnote-139) Regional poison control (RPC) pediatric marijuana cases quintupled in Colorado between 2009 and 2015. Colorado had an average increase in RPC cases of 34% (P < .001) **per year** while the remainder of the United States had an increase of 19% (P < .001). Product not in a child-resistant container was a contributing factor; with poor child supervision or product storage as frequent factors as well. Edible products were responsible for 52% of exposures. [[140]](#footnote-140) In 2014 the MMWR reported one death from excessive marijuana ingestion by 19 year old, due to altered mental status and hostile behavior leading to a jump from a 4th floor.[[141]](#footnote-141) While this death was of a youth, it illustrates how excessive cannabis ingestion can act not just through direct toxicity but also through cannabis induced mental status changes leading to injuries. Levi *et al* reported sudden onset encephalopathy in infants due to cannabis intoxication.[[142]](#footnote-142) Boadu reports on pediatric ingestion presenting as seizures and reviews National Poison Data System reports of cannabis intoxication in children younger than 6, which have increased dramatically over the past decade (Figure below), reaching over 400 in 2015 alone.



Other cases which they review presented with symptoms as serious as coma and respiratory insufficiency.[[143]](#footnote-143) Clearly, allegations by the cannabis industry, heard extensively at hearings, that the need for childproof packaging is exaggerated and a waste of material, ignore the growing body of evidence from the pediatric and emergency medicine literature of more frequent and significant pediatric ingestions. While no pediatric deaths from direct toxicity have yet been reported, if children already need to be intubated, it is clear that this will eventually occur.

###### **Given the growing body of epidemiologic evidence of increasing numbers of pediatric poisonings, including those exhibiting clinically dangerous presentations of seizures, respiratory insufficiency and coma, we cannot too strongly recommend returning this requirement to the regulations to offer the minimum required protection to children who may come into contact accidentally with cannabis products.**

The proposed regulations (§ 40415) also require cannabis product packaging to be tamper-evident, and opaque (for edibles), but do not restrict colors, logos, or branding. Regarding these other aspects of packaging, it is well known that tobacco companies use packaging as a marketing tool to bypass other marketing restrictions,[[144]](#footnote-144) establishing brand identification among youth, young adults, and other target populations.[[145]](#footnote-145) The youth marketing effect of package branding is powerful at in-store displays, [[146]](#footnote-146) but extends beyond retailers. **For example, when an adult purchases a product, children at home will likely see the branded package.** For tobacco, WHO recommends[[147]](#footnote-147) fully standardized “plain packaging” free of logos, colors, and branding, allowing only plain text brand and variant information in specified size, font, and position.[[148]](#footnote-148),[[149]](#footnote-149),[[150]](#footnote-150)

Plain cigarette packaging is associated with reduced brand awareness and identification[[151]](#footnote-151) and reduced appeal of cigarettes to adolescents and young adults.[[152]](#footnote-152),[[153]](#footnote-153),[[154]](#footnote-154),[[155]](#footnote-155) Plain packaging also makes health warnings more noticeable and effective[[156]](#footnote-156),[[157]](#footnote-157),[[158]](#footnote-158) and reduces the impact of misleading branding on beliefs about harmlessness.[[159]](#footnote-159),[[160]](#footnote-160) Combining plain packaging and large graphic labels extends the reach and impact of public health media campaigns[[161]](#footnote-161) and diminishes tobacco’s appeal to adolescents by increasing attention and perceptions of harm and reducing social appeal.[[162]](#footnote-162)

Cannabis plain packaging examples are limited. Oregon permits cannabis companies using generic packaging and labels to bypass the state’s label preapproval process and fee.[[163]](#footnote-163),[[164]](#footnote-164) Uruguay prohibits the two private companies supplying cannabis to the adult-use market from including company labels on packaging.[[165]](#footnote-165) **Mandatory plain packaging would eliminate a promotional avenue used routinely by the tobacco industry, with likely positive impacts on cannabis use and perceptions of harmfulness.**

**9. Set lower THC limits for concentrates and other products likely to be accidentally consumed (§ 40306)**

The proposed regulations (§ 40306) limit nonedible manufactured medical cannabis products to 2000 mg THC per package and adult use products to 1000 mg per package, both far higher than the 100 mg permitted for edibles (§ 40305). Nonedible products also present accidental consumption risks. In the Initial Statement of Reasons for earlier draft medical cannabis regulations, the Department noted that “capsules, tinctures, and topicals” are “more traditional medical delivery mechanisms”[[166]](#footnote-166) however, nonedible products is a broad category that includes highly potent concentrates that can be heated and quickly inhaled[[167]](#footnote-167) providing the THC equivalent of several joints in one breath.[[168]](#footnote-168) Such products potentially present increased dependence risks[[169]](#footnote-169) and have been linked to psychosis in case reports.[[170]](#footnote-170)

Vaporizing liquid extracts causes inhalation of ultrafine particles, which present cardiovascular and respiratory risks in e-cigarettes[[171]](#footnote-171),[[172]](#footnote-172),[[173]](#footnote-173) and likely have similar risks for vaporized cannabis products. Many concentrates and extracts also resemble food (e.g., honey[[174]](#footnote-174)) or trade on foodlike flavors or aromas (e.g., “Pineapple Dream Concentrate”[[175]](#footnote-175)). Harmful pediatric exposures to e-cigarette and nicotine liquids are increasingly frequent,[[176]](#footnote-176) and similar preparations of cannabis extracts could present related risks. **Inhaled cannabis products present specific risks distinct from other forms of consumption, and the Department should reduce allowable THC content of these products relative to forms such as capsules and tinctures.** A 600 mg THC per unit limit on all inhaled manufactured cannabis products would better protect public health and denormalization of smoking behavior. This would be roughly proportional to the 1:5.71 pharmacokinetic equivalency estimated in the Colorado marijuana equivalency study to a maximum of 100 mg in an edible package.[[177]](#footnote-177)

Non-cannabis topical products account for 5.3% of pediatric exposure calls to poison centers nationally[[178]](#footnote-178) and capsules and concentrates/extracts intended for sublingual administration add additional risks, especially those resembling products children commonly encounter, such as lotions.[[179]](#footnote-179) While most cannabis topicals are not psychoactive when used as directed (because few cannabinoids reach the brain via this pathway), accidental ingestion remains concerning. Therefore, **we recommend also using a 600 mg THC per package limit for all manufactured cannabis products that are not inhaled nor regulated as an edible, all of which can pose a significant accidental consumption risk, including concentrates, extracts, and topicals.[[180]](#footnote-180)**

**10. Marketing by manufacturers (§ 40525): Do not allow therapeutic claims and require a warning label on advertising**

The proposed regulation of marketing and advertising, long understood to be an essential part of controlling harm from tobacco and alcohol, is extraordinarily weak. Proposed regulations fall far short of those adopted in other states which have reduced outdoor advertising, billboards, radio and television use.

**10.a.) No health related statements in marketing**

**We recommend that no health-related statements be allowed in the marketing of cannabis products, or at a minimum, of adult-use cannabis products.** 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 not be marketed 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. To this end, we applaud CDPH’s decision to prohibit the use of “organic” or “organix” on product labels and suggest this be continued even if there is ever a federally recognized designation of organic cannabis. Inclusion of the words “organic” or variants thereof, can mislead consumers into believing that the product is a healthier option than regular cannabis. Tobacco studies have consistently shown that the inclusion of words such as “organic” or “natural” on cigarettes is perceived to be less harmful.[[181]](#footnote-181) In a national 2017 study, “organic” and “natural” elicited lower perceived harm than “light” on cigarettes, which is concerning given that “light” is already banned on cigarettes as misleading.

**This recommendation includes both product labeling itself and marketing and advertising materials.** Just as such statements are not present on alcohol products or cigarettes, they should not be permitted on cannabis products.

Some local jurisdictions are already taking the steps to prohibit health-related claims of any kind. For instance, Mono County code §5.60.180(C) states:

*“Permittees shall not include on the label of any cannabis or cannabis product or publish or disseminate advertising or marketing containing any health-related statement.”*

We have also received support for prohibiting health-related claims in cannabis advertising from the State Advisory Committee on Cannabis. The proposal to prohibit the use of health or therapeutic claims in advertising for adult-use products was endorsed by the State advisory commission on cannabis. 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.*” Furthermore, the recommendation would meet and further the mandate of the Medical and Adult-Use Safety Act (MAUCRSA) which:

 1. Requires all advertising to “be truthful and appropriately substantiated.” (§ 26151)

 2. Prohibits a licensee from advertising or marketing in a manner that is “false or untrue in any material particular, or that, irrespective of falsity, directly, or by ambiguity, omission, or inference, or by the addition of irrelevant, scientific, or technical matter, tends to create a misleading impression.” (§26152)

 3. Prohibits a licensee from publishing or disseminating “advertising or marketing containing any health-related statement[s] that [are] untrue in any particular manner or tends to create a misleading impression as to the effects on health of cannabis consumption.” (§26154)

If such health-related claims are allowed, we have significant concerns about the adequacy of the infrastructure in place to regulate and monitor those claims. CDPH does not have the FDA-like structures, staff and resources to ascertain the validity of these claims and there is no funding currently in place to allow CDPH to take on this type of role. Furthermore, there are no clear guidelines in place for ascertaining the validity of such health-related claims. We know from longstanding experience at FDA and other similar regulatory bodies that it requires a high level of investment and scientific staff capability to reliably verify these claims. Since the state does not appear to be investing in that capability, such claims should not be allowed at this time.

**10.b.) Warnings Labels on Advertising**

We strongly recommend the requirement for a prominent 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:

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 warning 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.

**10.c.) Limitations on Displays in Advertising and Marketing Materials**

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

**10.d.) No Branded Merchandise Attractive to Children or Youth**

We recommend that no cannabis business or cannabis or cannabis product brand identification, including logos, trademarks or names, may 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. Mono County is an example of a local jurisdiction that has enacted youth-protective regulations relating to branding. (§ 5.60.180(E))

**10.e.) Any Branded Merchandise Should Display Mandatory Warning as Above**

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.

**11. Warnings to Immigrant Workers**

Because cannabis is still Schedule 1 under federal law, possession, acknowledgement of consumption, or of working in the industry can subject immigrants, even legal permanent residents, to being penalized or even deported, according to the Immigrant Legal Resources Center. Manufacturers should be required to inform and prominently post a warning to workers about potential legal risks of working in the cannabis industry for immigrants. Such a sign could include the following information:

*“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 work or are considering working in the marijuana industry, see an immigration attorney for advice. The State of California provides this information as a service to immigrant residents.”*

**12. Equity of Access (§ 40102-40165)**

Also of note is the paucity of considerations given to promoting access to participation in this industry by individuals from communities that have been strongly harmed by mass incarceration as a result of cannabis’ illegality. We strongly encourage the Department to include provisions to prioritize and facilitate businesses created by individuals from communities with high rates of drug-related incarceration or committed to generating employment for those communities.

There are already examples of local jurisdictions enacting regulations that make equity a priority and these can serve as an example for CDPH. For example, L.A. City requires that permittees make a good faith effort to ensure that at least 30% of their workforce is performed by individuals living within 3 miles of the retail store. Furthermore, at least 10% of the weekly hours of the permittee’s workforce is to be given to “transitional workers” which are defined as “a person who, at the time of starting employment at the Business Premises, resides in an Economically Disadvantaged Area or Extremely Economically Disadvantaged Area” and meets one of several other criteria such as being homeless, receiving public assistance, having a criminal record, lacking a GED, or being chronically unemployed. (Sec. 104.10(l)).

The city of Oakland also has equity-related regulations. For example, at least half of the 8 new retail permits allowed annually must go to “equity applicants,” (Sec. 5.80.020(C)) defined as an Oakland resident, with annual income at or less than 80% of Oakland Average Medium Income and has either lived in specified “police beats” or possesses a cannabis-related conviction committed in Oakland. Equity applicants are also eligible to participate in the “equity assistance” program which includes industry-specific technical assistance, business ownership technical assistance, no-interest business start-up loans, and waivers of city permitting fees. (Sec. 5.80.045(C)).

In the March 15, 2018 minutes for the meeting of the State Cannabis Advisory Committee, the committee adopted all eight (8) of the subcommittee on equity’s recommendations on equity. This includes the recommendation that state licensing authorities adopt a “state-level equity licensing program that supports the local equity licensing programs that have been developed and supports equity applicants from jurisdictions where programs have not been developed.” The Committee also recommends considering fee waivers or reductions for equity applicants and having the licensing authorities “explore access for equity applicants to property and premises. This could include working with local licensing programs to allow annual licensees to sublease a portion of their licensed premises to an equity applicant; allowing co-location or shared premises by equity applicants; developing pre-licensing programs for equity applicants; and, to the extent possible, creating incentives and protections for property owners to lease to equity applicants.” The Committee further recommended examining the current equity programs in certain California cities “to support the development of a state-adopted policy statement that embraces a statewide equity program.”

**We recommend that CDPH adopt equity-promoting provisions into their regulations on manufacturing licensing.**

**13. Persons Prohibited from Holding Licenses (§ 40116)**

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). 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.[[182]](#footnote-182)

We further recommend that the regulations also explicitly prohibit manufacturers 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. 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.

**CONCLUSION**

In summary, while the science surrounding the potential harms and benefits of cannabis is evolving, clearly identified risks of dependence, cardiovascular and pulmonary disease, and irreversible effects on mental health, low birth weight and accidents, amongst other concerns, justify a cautious approach to rolling out legalization. Legalizing cannabis should not mean legalizing every conceivable cannabis product. Permitting unfettered marketing that will rapidly consolidate the presence of a wide variety of products we already know to be particularly risky, is deeply unwise. It is also not required by MAUCRSA and the legalization process. While the Department’s proposed regulations reflect many public health best practices, they fall short in other areas. Incorporating additional best practices from tobacco and alcohol control to limit the presence of products which are particularly harmful or attractive to youth, limiting potency of cannabis and concentrates and prohibiting flavors attractive to youth, protecting children from accidental ingestion, improving the size and clarity of warnings, restricting marketing, limiting total THC content, and preventing the addition of additives that increase risks of addiction and youth use will 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.

Sincerely,

[INSERT SIGNATURE(S)]

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