

Comment on Proposed Regulation:

DPH-17-010

Cannabis Manufacturing Licensing

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Incorporating best practices from tobacco control into California’s cannabis regulations is necessary to protect public health by restricting harmful product formulations, ensuring industry compliance and enforcement transparency, providing more complete and accurate information to consumers, and preventing abusive industry marketing tactics

GENERAL COMMENTS

Legalization of recreational (adult-use) cannabis in California and other states is a significant regulatory shift despite continued illegality under federal law. While there may be positive impacts of such change from a social justice perspective, there are also considerable public health risks, many of which echo those of tobacco. *The creation and government endorsement of a legal cannabis industry spanning medical and recreational use presents the risk that this newly legitimized 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 or that such industries may seek to enter the new cannabis markets.²*

While research into potential harms and benefits of cannabis use are still developing, existing evidence of negative health effects is sufficient to support a precautionary approach. Marijuana and tobacco smoke share similar toxicity profiles,³ and the State of California includes marijuana smoke as carcinogenic on the State's Proposition 65 list.^{4,5} The 2017 National Academies of Sciences, Engineering and Medicine (NASEM) report, *The Health Effects of Cannabis and Cannabinoids*⁶ concluded that there was substantial evidence of association between marijuana smoking and several negative health effects, including:

- worse respiratory symptoms and more frequent chronic bronchitis episodes (long-term cannabis smoking)
- problem use and dependence, particularly with increased frequency and initiation at an earlier age
- increased risk of motor vehicle accidents
- lower birth weight (maternal cannabis smoking)
- development of schizophrenia and other psychoses, with highest risk among most frequent users.

Additional evidence from more recent studies, animal studies, and studies of related tobacco and nicotine products also supports possible risks related to:

- secondhand smoke exposure^{3,7}
- chemical additives^{8,9}
- cardiovascular disease^{7,10,11}
- respiratory disease¹²
- neurological disease.¹³

Public health best practices drawn from successful tobacco control strategies can inform regulatory approaches to cannabis, and the Department of Public Health should model its cannabis regulations on these best practices. ***Protecting public health in an era of legal recreational cannabis markets requires that these markets be well-controlled and designed to prevent abuse, increased prevalence, youth use, diversion to illicit markets, and the creation of a powerful industry that encourages these negative outcomes.***

With a strong regulatory framework, the cannabis industry can be brought out of the shadows and allowed to operate legally without enabling the repetition of practices from other industries, such as tobacco or alcohol, that have been detrimental to public health.

Many elements of the proposed regulations are consistent with public health best practices and represent improvements on prior draft and emergency regulations. These include:

- Clarifying that prohibitions on harmful additives apply to *all* cannabis products, rather than only edible products (§ 40300) to restrict unsafe formulations

- Clarifying the Department’s authority and basis for determining that an edible cannabis product is attractive to children or easily confused with commercially available non-cannabis foods (§ 40300(k)-(l)) to limit appeal to youth
- Prohibiting government officials with duties related to cannabis enforcement from holding cannabis licenses or ownership interests (§ 40116) to prevent conflicts of interest
- 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 cannabis manufacturing activities at retail food establishments, processed food registrants, and locations licensed by the Department of Alcoholic Beverage Control and prohibiting manufacturing of non-cannabis products at cannabis manufacturer premises (§ 40175) to maintain separation of the cannabis industry from other regulated industries and prevent co-mingling of products
- Specifying compliance requirements for licensees operating under new shared use license types, including the potential for holding both Type S licensees and primary licensees responsible for violations when appropriate (§ 40196) to support enforcement
- Prohibiting pictures of edible products on the product label (§ 40410(e)) to limit appeal to youth and consumer confusion
- Prohibiting labeling cannabis products as organic absent authorization from the National Organic Program (§ 40410(f)) to prevent health-oriented marketing without appropriate basis
- Including statutorily-mandated restrictions on advertising and marketing (§ 40525) to improve compliance with these provisions.

The Department should maintain or strengthen these regulations even if industry and its allies object to them or seek to weaken them.

Building on the strong foundation established by the proposed regulations, the following specific changes will ensure that California’s cannabis legal framework is consistent with evidence-based best practices from tobacco control in order to create a well-regulated market that minimizes adverse effects on the health of Californians.

SPECIFIC RECOMMENDATIONS

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

The Department’s recognition and acceptance of the new product category “infused pre-roll” (§ 40100(w)) is concerning from a public health perspective. **Infusion of plant material intended to be smoked, including pre-rolls and packaged flower, presents significant public**

health risks for potency and harmful additives, and the Department should prohibit such products. Authorizing manufacturers to increase the potency (and thus addictive potential) of pre-rolled, smokeable 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, sugar) to increase the addictive potential by manipulating delivered dose and bioavailability of nicotine.¹⁴ 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 on these high-potency products (§ 40409(d)).

Infused pre-rolls arguably do not fall under any of the categories of THC concentration limits (§ 403015). By definition, infused pre-rolls are not edibles, orally-dissolving products, concentrates, or topicals. Though the total THC in the added concentrate would be limited (§ 40315(c)), this would potentially only restrict such a product to 1,000 mg THC *plus* the content in the plant material itself, allowing a dangerously high-potency product that is out of step with the Department’s overall approach to allowable THC concentration. **High-potency concentrates potentially present increased dependence risks¹⁵ and have been linked to psychosis in case reports.¹⁶ Such risks would only be magnified by allowing concentrates to be added to easy-to-use products like pre-rolls.**

The Department also proposes to allow manufacturers of infused pre-rolls to determine for themselves how to report THC concentration on labels (whether in milligrams or in both percentage in the flower and in milligrams added in concentrate (§ 40409(d)). This presents the opportunity for a bad actor to intentionally mislead consumers, despite the Department’s intention that manufacturers choose the method that is “most meaningful for consumers based on the specifics of the product.”^{17, p.153} *To ensure consistency, the Department should mandate the appropriate method of reporting THC content in infused pre-rolls if it allows such products to be sold.*

While experienced users may choose to mix concentrates and plant material themselves, there is no need to authorize such products to be sold in ready-to-use forms. The Department already recognizes that certain types of products should not be available at retail in combination with cannabis, such alcohol, nicotine, and caffeine (§§ 40300(a)-(b)), and the ability of consumers to make such combinations themselves at home does not alter the public health rationale of prohibiting the sale of unsafe combination products. The Department should require a clear separation of products containing solely plant material from those containing concentrates and any other additives.

Additionally, **allowing additives or infusions of any kind in pre-rolls open the door for flavored smokeable 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. Like cigarettes and cigars, pre-rolls are simple to use because they do not require the user

to understand dosage, use an unfamiliar product or process, or even know how to roll a joint. Packaging for pre-rolls is also frequently similar to tobacco products (i.e., single tubes or flip-top packs). The Food and Drug Administration (FDA) banned flavored cigarettes under the Family Smoking Prevention and Tobacco Control Act of 2009¹⁸ because of their detrimental public health effects, particularly their appeal to youth. Flavored products attract young smokers to tobacco.^{14,19-21} Most adolescent tobacco users report that they began with flavored products, and most current adolescent tobacco users use flavored products.²²

The Department has recognized this problem with regard to tobacco products with its high-profile Flavors Hook Kids campaign.²³ In addition, over 68% of San Francisco voters supported a ban on the sale of all flavored tobacco products in the June 2018 election²⁴ despite a \$12 million campaign against the measure funded almost exclusively by R.J. Reynolds Tobacco Company.²⁵ Other cities in California and around the country are pursuing similar laws.

The Department should not allow flavored smoked cannabis products to replicate the public health damage of flavored cigarettes. The underlying public health rationale for banning such products is sound and should be extended to cannabis products, consistent with the Department's statutory mandate to prioritize public health and safety.^{17, p.132,26} *The Department should explicitly prohibit the infusion of pre-rolls, including with concentrates and flavors, and should clearly distinguish products containing solely plant material from those containing concentrates.*

The Department should also develop and seek funds to implement a corresponding public education campaign for cannabis products that parallels its Flavors Hook Kids campaign on tobacco products.

2. Expand the Prohibition on Caffeine to Include Naturally-Derived Sources (§ 40300)

The Department appropriately prohibits the inclusion of non-cannabinoid additives that increase potency, toxicity, or addictive potential, and has properly added a further restriction on additives that “would create an unsafe combination with other psychoactive substances” (§ 40300(a)). As part of this restriction, the Department has stated that it “has made a determination to prohibit caffeine in cannabis products.”^{17, p.133} However, the proposed regulations plainly do not do so, as they permit combinations of cannabis and naturally caffeinated products (e.g., coffee)(§ 40300(b)). The Department's stated rationale is based on analogy to the Food and Drug Administration's determination that caffeine is an unsafe food additive in certain alcoholic beverages.^{17, p.133} **If the combination of (stimulant) caffeine and (depressant) cannabis is unsafe, and we agree with the Department's determination that it is, then it is unsafe irrespective of the source of the caffeine.** Caffeine levels can also vary dramatically in natural products. For example, drip coffee typically contains 10-20 mg of caffeine per fluid ounce, while espresso and cold-brew concentrates can contain more than 70 mg per fluid ounce.²⁷ *At*

minimum, the Department should specify a maximum allowable level of caffeine in manufactured cannabis products, or, better yet, prohibit caffeine in cannabis products.

3. Prohibit the Addition of Menthol and Other Characterizing Flavors (§ 40300)

The proposed regulations (§ 40300(b)) prohibit additives that "increase potency, toxicity or addictive potential." **The Department should broaden its interpretation of this critical restriction 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 reinforcement²⁸ and encouragement of breath holding, which increases nicotine exposure.²⁹ Stimulated by industry marketing, younger and newer smokers disproportionately use menthol cigarettes, drawn to the reduced harshness menthol contributes as a local anesthetic.^{14,30} 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.^{14,31} Menthol use is more common among groups targeted by the tobacco industry, including youth of color, women, and LGBTQ populations.³² Menthol smokers, especially persons of color and younger smokers, also experience more difficulty quitting.³³ *The Department should ensure that its regulations act to prevent 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.³⁴ Dual use of menthol cigarettes and cannabis also increased from 2005-2014.³⁵ Manufactured cannabis products incorporating menthol are already available.³⁶ 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 and non-edible cannabis products to prevent repetition of harms attributable to mentholated tobacco products.*

Menthol may, however, be appropriate in some topical cannabis products, as it is a common topical analgesic (among other medical uses) and does not present the same addiction-related concerns in such formulations.

Beyond menthol, a broad prohibition on characterizing flavors in non-edible products is necessary to deter youth use. Flavored products are a key tool for attracting young smokers to tobacco^{14,19,20} and e-cigarettes.^{37,38} Most adolescent tobacco and e-cigarette users currently use and initiated with flavored products.²² 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 Act¹⁸) 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.³⁹ 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.

Cannabis regulations should prevent similar effects by prohibiting characterizing flavors in all non-edible products. While some qualified patients prefer flavored products, any therapeutic effect is likely unrelated to flavorings (with the possible exception of menthol in topical products), and alternative formulations (e.g., tinctures) are readily available. Flavored edible products present related concerns that require further research on how they may impact use and initiation.

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

Requiring cannabis manufacturers to maintain an up-to-date list of products is an important means of facilitating the Department’s enforcement activity.^{17, pp.176-177} ***To ensure compliance, the Department should clarify what types of changes necessitate updating the product list.***

For example, the Department’s ISOR specifies that licensees must update the Department of “substantial or material alterations” to the physical premises and provides several examples (e.g., relocation of a doorway).^{17, p.176} The Department should similarly provide guidance on changes to a product that are significant enough to necessitate a change to the product list. For example, the addition of some chemicals to inhaled products may present health risks.^{8,9,40} and a change to 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 2009¹⁸ 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).**”¹⁸ ***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.

5. Extend Existing Conflict of Interest Protections to Include Industry Employment Immediately Following an Enforcement Position (§ 40116)

The proposed regulations appropriately 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). *To fully effectuate the Department’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,” the Department 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.⁴¹

6. Further Improve the Universal Symbol by Adopting a More Salient Background Color (§ 40412)

The Department’s proposed universal symbol (§ 40412), originally adopted in the emergency regulations, improves on the symbol from the April 2017 proposed medical cannabis regulations, but research from tobacco control suggests further modification. *The Department should alter the universal symbol to use yellow or orange as a background color.* The Department’s current proposed symbol uses dark text contrasted on light background, which research and tobacco control best practices from the WHO Framework Convention on Tobacco Control (FCTC) do suggest should enhance noticeability and legibility.^{42,43} **However, research on tobacco products has also found that the color white signals health, safety, and cleanliness, while yellow or orange combined with black text signals warning or danger.**⁴² Yellow is also the color with greatest visibility and fastest processing, and a black-on-yellow (or black-on-orange) shape will remain in memory longer than black-on-white.^{42,44} We have previously recommended a black-on-yellow diamond shape as a universal cannabis product symbol, based on road sign warnings (*see* Figure 1).⁴⁵⁻⁴⁷

Figure 1: Recommended Universal Cannabis Symbol



7. Move Warnings to the Primary Panel and Set a Large Enough Minimum Size to Ensure Visibility (§§ 40404; 40405; 40406; 40408)

Health warning labels influence perceptions of risk, but their effectiveness is affected by their appearance, including location, size, and design.^{14,43} The proposed regulations relegate critical warning information to the product’s “informational panel,” which can be anywhere on the package and will be less visible than the primary panel. **Warnings on the front/primary panel of tobacco packages are more effective and have greater impact,¹⁴ and these effects are likely to be similar for cannabis labeling.**

The implementing guidelines to the WHO FCTC, the widely adopted global tobacco control treaty, explicitly recognize that a product’s principal display area (equivalent to the “primary panel” in the Department’s regulations) is the most visible location for warnings.⁴³ Similar effects are likely for cannabis products, and the Department should incorporate these lessons from tobacco control into the cannabis packaging and labeling regulatory framework.

The Department should require warning labels to be part of primary panel labeling requirements to ensure visibility. This would be consistent with the Department’s rationale noted in the ISOR that “labels should not be hidden by other materials and should be prominent enough to be easily identified and read by consumers.”^{17, p.144} Allowing warning information to be placed on the side or back of the product as part of the informational panel (§§ 40404(b); 40408(b)) does not adequately ensure that those who encounter cannabis products are informed of health risks and may subject warning placement to industry manipulation.

The WHO FCTC requires health warnings on tobacco products cover at least 30% (ideally 50% or more) of the principal display area,⁴⁸ and this standard is associated with higher health knowledge and motivation to quit.^{14,43} Increasing label size also improves effectiveness among youth and adults.⁴⁹ It is reasonable to expect similar results for cannabis labels. **To improve visibility and effectiveness, the Department should require warning labels that cover at least 30% (ideally 50%) of the product’s primary panel.**

This standard is likely to meet with resistance. Tobacco companies have intensely opposed larger and more effective warning labels,⁵⁰ and there are indications that the cannabis industry will similarly oppose comprehensive warnings.⁵¹ However, the recommended standard is based on the best available evidence from tobacco control and is consistent with internationally recognized public health best practices.

8. Increase Font Size for Required Warning Labels (§§ 40404-40408)

The Department’s labeling requirements continue to impose a minimum 6 point font size for primary and informational panel labels (§§ 40404-40408). The Department notes that food manufacturing regulations set an even smaller requirement equivalent to 4.5 point font,^{17, p.146} but **the appropriate comparison for cannabis product warning labels should not be food**

manufacturing, but rather tobacco products. Even in the U.S., which lags behind almost every other country in the world in modernizing tobacco labeling consistent with best practices, FDA requires most tobacco products to carry text warnings with minimum 12 point font.⁵² *The Department should require minimum 12 point font for warnings, consistent with FDA’s requirements for tobacco, to ensure cannabis warnings are readable and noticeable.*

Other label information (e.g., packaging date, net product weight) may not require larger font, and food manufacturing may be an appropriate standard for these elements. However, **warnings serve a distinct function in ensuring consumers are informed of the risks of using a product, and most food products do not contain an equivalent statement.** As the Department notes, “[p]roduct information will not be effective if it is too small to read.”^{17, p.146} The same logic applies in tobacco control, and the WHO FCTC requires tobacco health warnings to be “large, clear, visible and legible.”⁴⁸ Larger warnings are more effective⁴⁹ and will better serve the Department’s stated goals and protect public health.

9. Add Additional Warning Information to Labels and Incorporate Rotating Warning Language and Pictorial Warnings (§§ 40404, 40408)

The proposed regulations only require a single, static, text-only warning statement that notes cannabis’s Schedule I status, advises to keep out of reach of children and animals, states that underage possession or use is not permitted (except for qualified patients), warns of impairment, and mentions possible harm from use while pregnant or breastfeeding (§§ 40404(b); 40408(a)). The only differences in warning language are the inclusion of “FOR MEDICAL USE ONLY” for products available only in the medical market and the inclusion of a statement that intoxicating effects may be delayed on products other than pre-rolls and packaged flower.

The single warning statement is too complicated and fails to address many significant health risks associated with cannabis use, including most of those noted by the 2017 National Academies of Sciences, Engineering and Medicine Report, *The Health Effects of Cannabis and Cannabinoids*,⁶ which found substantial evidence for associations of cannabis use with:

- worse respiratory symptoms and more frequent chronic bronchitis episodes (long-term cannabis smoking)
- problem use and dependence, particularly with increased frequency and initiation at an earlier age
- increased risk of motor vehicle accidents
- lower birth weight (maternal cannabis smoking)
- development of schizophrenia and other psychoses, with highest risk among most frequent users.

Of these, only general references to impaired driving and use while pregnant or breastfeeding are included in the proposed regulations. Moreover, the Department should consider evidence of risks in more recent studies, animal studies, and studies of related tobacco products that support

warnings on various cannabis product categories, especially combusted and other inhaled products, for:

- secondhand smoke exposure^{3,7}
- chemical additives^{8,9}
- cardiovascular disease^{7,10,11}
- respiratory disease¹²
- neurological disease¹³
- cancer.^{4,5}

Not every warning need be included on every package. Rather, based on evidence from tobacco control (and health communication more broadly), **rotating health warning messages should be simplified to improve communication by having each warning only address one topic so that users see a variety of warnings at any given time. Warnings should be updated and refreshed at least every two years to prevent them from becoming stale and to improve their impact and effectiveness.**¹⁴

In addition to rotating health warnings (i.e., several different warnings used at any given time), *the Department should maximize warning noticeability and effectiveness by utilizing pictorial warnings (also known as graphic warning labels)*. Text-only labels, as currently used for tobacco in the US, are poorly recalled and have low impact on use.⁵³ **Pictorial health warnings are more impactful and informative^{48,54,55} and decrease product attractiveness to youth.^{49,56} 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.⁴³** Based on their effectiveness for tobacco products, pictorial warnings are likely to improve the impact and effectiveness of cannabis warning labels.

Recent research on public perceptions of the harms of cannabis use further illustrates the importance of clear warnings that, taken together, provide comprehensive warnings for cannabis products. A 2017 survey of U.S. adults 18 and older found that among past-year marijuana users, 23.9% believed marijuana has no risks.⁵⁷ Analysis of surveys of adolescents in 2014-2015 similarly found that 21.4% of 12th-graders believed regular/weekly marijuana use posed no risks of harm, more than double the proportion that expressed this belief 10 years ago.⁵⁸

10. Adopt Tailored Warnings for Inhaled Cannabis Products (§§ 40404-40408)

The Department already acknowledges a class of cannabis products that are “inhaled products” (§§ 40100(i); 40403(c)(2)), and the Department should extend this logic to other sections of the regulations, particularly health warning labels, as such products carry specific risks. *The Department should require warnings for inhaled cannabis products that acknowledge the robust literature on the direct and secondhand harms of tobacco products and their similarity to cannabis products.* Other than nicotine and cannabinoid content, cannabis smoke and tobacco smoke are very similar.³ Tobacco smoking is causally related to diseases of

nearly every organ, diminished health status, fetal harm, cancer, inflammation, and impaired immune function.⁵⁹ Secondhand tobacco smoke exposure has negative effects on children and adults, including premature death and disease, immediate adverse cardiovascular effects, heart disease, and lung cancer.⁶⁰

While not yet as developed as the evidence for the harms of smoked tobacco, evidence for the health harms of non-combusted tobacco products (e.g., e-cigarettes) is significant and growing, including (among other concerns): links to asthma;⁶¹ impaired cardiovascular function;⁶² negative immediate effects on lung function;⁶³ lung immune response;⁶⁴ and reports of other negative effects including chest pain, blood when brushing teeth, and sores/ulcers in the mouth.⁶⁵ **While it is premature to extend such findings to related cannabis products, the absence of negative health findings is likely a function of limited research to date on such products and should not be assumed to indicate absence of adverse health effects.**

Based on the similarities between cannabis and tobacco smoke and the known dangers of the latter, it is reasonable to warn consumers of potentially similar risks from inhaled cannabis products unless and until research demonstrates otherwise. This rationale is in addition to the existing evidence of direct and secondhand harms from cannabis smoke.^{3,5-7,11-13} **Recent evidence indicates that consumers are frequently unaware of potential health risks from cannabis use.** A 2017 survey of U.S. adults⁵⁷ found that nearly *30% believed that smoking or vaping marijuana prevents health problems*, and that among past-year users:

- 22.9% believed marijuana had *no risks*
- 50% believed it was somewhat/completely *safe to expose adults to secondhand marijuana smoke*
- 20.6% believed it was somewhat/completely *safe to expose children to secondhand marijuana smoke*
- 23.9% believed it was somewhat/completely *safe for pregnant women to use marijuana*
- 53% believed marijuana was *not at all addictive*.

11. Require Plain Packaging for All Cannabis Products (§§ 40400-40415)

The proposed regulations (§ 40415) require cannabis product packaging to be tamper-evident, child-resistant, opaque (for edibles), and re-sealable (for multi-serving products), but do not restrict colors, logos, or branding. Tobacco companies use packaging as a marketing tool to bypass other marketing restrictions,⁶⁶ establishing brand identification among youth, young adults, and other target populations.⁶⁷ The youth marketing effect of package branding is powerful at in-store displays,⁶⁸ but extends beyond retail shelves. **For example, when an adult purchases a product, children at home will likely see the branded package.** For tobacco, WHO recommends⁴⁸ fully standardized “plain packaging” devoid of logos, colors, and branding, allowing only plain text brand and variant information in specified size, font, and position.^{66,69,70}

Plain cigarette packaging is associated with reduced brand awareness and identification⁷¹ and reduced appeal of cigarettes to adolescents and young adults.⁷²⁻⁷⁵ Plain packaging also makes health warnings more noticeable and effective^{14,76,77} and reduces the impact of misleading branding on beliefs about harmfulness.^{75,77} Combining plain packaging and large graphic labels extends the reach and impact of public health media campaigns⁷⁸ and diminishes tobacco's appeal to adolescents by increasing attention and perceptions of harm and reducing social appeal.⁵⁶

Cannabis plain packaging examples are currently limited. Oregon permits cannabis companies using generic packaging and labels to bypass the state's label preapproval process and fee.^{79,80} Uruguay prohibits the two private companies supplying cannabis to the recreational market from including company labels on packaging.⁸¹ *The Department should mandate plain packaging to eliminate a promotional avenue used routinely by the tobacco industry, with likely positive impacts on cannabis use and perceptions of harmfulness.*

12. Broaden Packaging Restrictions to Eliminate Appeals to Children and Imitation of Other Non-cannabis Products (§§ 40410, 40415)

The proposed regulations (§ 40410(b)) prohibit labeling content that is or is designed to be attractive to persons under 21, including 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 glamour, beauty, sex, or adventure. A broader prohibition on such elements is necessary to prevent industry targeting of youth, but still invites subjectivity, such as what constitutes glamour. The current proposed prohibition on the imitation of “candy” packaging or labeling (§ 40410(b)(3)) and “products typically marketed to children” (§ 40415(d)) do not account for the wide variety of products that may be attractive to children. For example, the proposed language would not prohibit imitation of common snack foods that children would frequently encounter that are marketed to adults (e.g., granola bars). **A complete prohibition on the imitation of all non-cannabis products would more effectively reduce the risk of accidental consumption and use of packaging to appeal to youth.** Adopting a plain packaging standard would even more effectively address these concerns and would also avoid interpretive problems. *The Department should expand packaging restrictions to prohibit imitation of any non-cannabis product.*

CONCLUSION

The science surrounding the potential harms and benefits of medical cannabis is evolving, but known risks, including dependence, cardiovascular and pulmonary disease, and other concerns, justify a precautionary approach. The Department's proposed regulations reflect many

public health best practices, but fall short in other areas. Incorporating additional best practices from tobacco control to restrict harmful product formulations and additives that increase risks of addiction and youth use, ensure industry compliance and transparency in enforcement, improve the effectiveness and comprehensiveness of warning labels, and prevent packaging that is misleading or attractive to youth will ensure a functional and well-regulated cannabis system that prioritizes protection of public health over business interests in the State of California.

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