**Comment on Proposed Regulation**:

DPH-17-004

Medical Cannabis Manufacturing License

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**Incorporating public health best practices from tobacco and alcohol regulation is necessary to protect public health by providing more information to consumers, restricting harmful formulations, and preventing abusive industry marketing tactics**

**General Comments**

      Legalization of cannabis for medical and, more recently, recreational use in California and other states represents a massive shift in the regulatory approach to the substance, even despite its continued illegality under federal law. Positive impacts of this change may include an end to enforcement practices that have disproportionately impacted many communities, particularly communities of color, as a result of criminalization. However, ***the creation and government endorsement of a legal cannabis industry that will span both medical and recreational 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]**](https://mail.phi.org/owa/#_ftn1)***or that such other industries may seek to enter and dominate the new cannabis markets.***[**[2]**](https://mail.phi.org/owa/#_ftn2)

      Research into potential harms and benefits of medical cannabis is still developing, but existing evidence of harms is sufficient to support a precautionary approach. Among other risks, marijuana and tobacco smoke share similar toxicity profiles,[[3]](https://mail.phi.org/owa/#_ftn3) and the State of California  includes marijuana smoke as carcinogenic on the State’s Proposition 65 list.[[4]](https://mail.phi.org/owa/#_ftn4),[[5]](https://mail.phi.org/owa/#_ftn5) The recent National Academies Report *The Health Effects of Cannabis and Cannabinoid*s[[6]](https://mail.phi.org/owa/#_ftn6) concluded that there was substantial evidence of an association between marijuana smoking and worse respiratory symptoms and more frequent chronic bronchitis episodes, as well as moderate evidence of other respiratory effects. Even secondhand exposure to marijuana smoke appears to have negative cardiovascular effects, as a recent study in rats found that one minute of exposure impaired normal functioning of arteries (endothelial function) for at least ninety minutes.[[7]](https://mail.phi.org/owa/#_ftn7) Changes in endothelial function are associated with long-term development of heart disease and triggering heart attacks.[[8]](https://mail.phi.org/owa/#_ftn8),[[9]](https://mail.phi.org/owa/#_ftn9)Vaporized forms of cannabis may reduce some respiratory risks associated specifically with combustion, but likely still present risks like those of e-cigarettes and similar products, including inhalation of ultrafine particles and various chemical additives (e.g., diacetyl, propylene glycol, flavoring compounds).[[10]](https://mail.phi.org/owa/#_ftn10),[[11]](https://mail.phi.org/owa/#_ftn11),[[12]](https://mail.phi.org/owa/#_ftn12) Inhalation of ultrafine particles causes cardiovascular and pulmonary disease, including triggering heart attacks and asthma attacks.[[13]](https://mail.phi.org/owa/#_ftn13),[[14]](https://mail.phi.org/owa/#_ftn14)Additionally, use of high-potency cannabis concentrates such as butane hash oil may increase risks for dependence, tolerance, and withdrawal among users.[[15]](https://mail.phi.org/owa/#_ftn15)

      The Department of Public Health should model its cannabis regulations on best practices from established public health frameworks for regulating tobacco and alcohol.[[16]](https://mail.phi.org/owa/#_ftn16),[[17]](https://mail.phi.org/owa/#_ftn17) ***Public health objectives require that both medical and recreational cannabis markets be well controlled and designed to prevent diversion to illicit markets, abuse, increased prevalence, youth use, and the creation of a powerful industry that may encourage such outcomes using methods commonly employed by the tobacco and alcohol industries.***

      ***Problems specifically relevant in regulating medical cannabis include preventing disingenuous overstatement of potential health benefits and discouraging perceptions of harmlessness, especially among youth.*** In contrast to the state’s forthcoming recreational cannabis framework, which establishes a minimum age of 21 for purchase, medical cannabis has no such age restriction, making it particularly important to create effective barriers to deter misuse and abuse of the medical cannabis system for nonmedical use, especially by youth.

      ***Many elements of the proposed regulations are already consistent with public health best practices, including several elements which are likely to raise objections from the nascent cannabis industry but which are strongly grounded in evidence from tobacco and alcohol control models.***These include:

Implementing a sliding scale for licensure fees (§ 40150) to discourage dominance by larger and more powerful industry elements

Restricting simultaneous holding of certain types of licenses (§ 40175) to limit vertical integration

Requiring the use of a track and trace system (§ 40272) to reduce diversion to illicit markets

Prohibiting additives that increase potency or addictive potential (§ 40300) to moderate abuse risk

Limiting THC content in manufactured products (§§ 40305, 40306) to reduce risks associated with accidental consumption and overconsumption

Mandating labels and warnings with specific content (§§ 40410, 40412) that will counter the influence of abusive marketing practices.

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

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 medical cannabis in California that will minimize adverse effects on the health of Californians.

**Specific Recommendations**

**1.      Increase Visibility of Primary Panel Labeling, Ideally Utilizing a Plain Packaging Standard (§ 40405)**

**Lessons from tobacco control indicate that the ideal label for harmful and addictive products is a fully standardized or “plain packaging” label, which is free of all logos, colors, and branding.**[**[18]**](https://mail.phi.org/owa/#_ftn18) Tobacco companies have long used their packaging as an advertising tool,[[19]](https://mail.phi.org/owa/#_ftn19) including to establish brand identification among youth and young adults and other target populations.[[20]](https://mail.phi.org/owa/#_ftn20) The potential use of similar tactics by the cannabis industry justifies strong safeguards to prevent the repetition of such harmful practices. The youth marketing effect of package branding is powerful at in-store displays,[[21]](https://mail.phi.org/owa/#_ftn21) a key reason for keeping non-patients and unaccompanied young patients out of licensed dispensaries.  However, simply restricting access to the point of sale does not negate the ability of branding to reach youth. The powerful effects of branding also arise when children encounter branded products used by others. For example, when a licensed medical cannabis user purchases a product in a branded package and takes it home, it may be seen not just by the user, but also by any children in the home. The tobacco industry has long recognized this type of secondary promotion, best exemplified by a tobacco trade magazine coaching manufacturers that even if advertising bans disallowed the use of billboards or glossy magazine ads, the brands could still use packaging to “at least court smokers from the retailer’s shelf, or from wherever it is placed by those already wed to it.”[[22]](https://mail.phi.org/owa/#_ftn22)

**Plain packaging reduces the appeal of cigarettes to adolescents and young adults.**[**[23]**](https://mail.phi.org/owa/#_ftn23)**,**[**[24]**](https://mail.phi.org/owa/#_ftn24)**,**[**[25]**](https://mail.phi.org/owa/#_ftn25)**,**[**[26]**](https://mail.phi.org/owa/#_ftn26)**Applying a similar approach to cannabis in both medical and non-medical contexts will effectively reduce the appeal of cannabis products to these groups.** The proposed medical cannabis regulations apply to products marketed as medical in nature and available only with a recommendation from a medical professional. Similar products typically are not permitted to use their product packaging as a marketing and advertising opportunity. Prescription medications, for example, are commonly provided in plain plastic containers or similar standardized packages lacking any trade dress whatsoever. As such, plain packaging for medical cannabis would follow a well-established approach for other medical products.

**If plain packaging is not adopted, more strictly standardized labels may limit opportunities for manufacturers to utilize packaging for advertising purposes.** For example, Nevada requires all medical cannabis-infused products to carry front and rear labels substantially in the form reproduced below and in a minimum 12-point font size:[[27]](https://mail.phi.org/owa/#_ftn27)

**Nevada Label (FRONT)**

|  |
| --- |
| We Care Dispensary, 123 Main Street, Carson City, NV 89701 **Date Dispensed:** 3/27/2014  **To:** John J. Smith #1234987 Cookie**Net Weight:**6oz (168 Grams)**Serving Size:**10mg of THC**Contains 10 servings and a total of 100 MG of THC****Use by:**6/3/2014Myrcene 5.6 mg/g   Limonene 5.1 mg/g   Valencene 3.5 mg/g  **CAUTION:**When eaten or swallowed the intoxicating effects of this product can be delayed 2 or more hours. **This product may be unlawful outside the State of Nevada.** |

**Nevada Label (REAR)**

|  |
| --- |
| **Manufactured at:**Joe’s Kitchen        Cert.#: 321654987101 0401123 Main Street, Las Vegas, NV on 2/1/14Lot#: 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 effectsand may be habit forming. |

**At a minimum, the Department should increase the size of the labels required under the proposed regulations to 50% of the principal display and increase the minimum text size to 12 point font.** Best policies from tobacco control, adopted in the WHO Framework Convention on Tobacco Control, provide that health warnings should cover 50% or more of the principal display area of a package, with a minimum coverage threshold of 30%.[[28]](https://mail.phi.org/owa/#_ftn28)

The proposed regulations at § 40405(b) require a primary panel label with minimum 6-point font size “in relation to the size of the primary panel and container.” This font size is smaller than that required in some other states, including Nevada as noted above. **In sharp contrast to the clear text of the above example, the same content in 6-pt font is essentially unreadable:**

**Modified Nevada Label (FRONT) – 6pt Font**

|  |
| --- |
| We Care Dispensary, 123 Main Street, Carson City, NV 89701 **Date Dispensed:** 3/27/2014  **To:** John J. Smith #1234987 Cookie**Net Weight:**6oz (168 Grams)**Serving Size:**10mg of THC**Contains 10 servings and a total of 100 MG of THC****Use by:**6/3/2014Myrcene 5.6 mg/g   Limonene 5.1 mg/g   Valencene 3.5 mg/g  **CAUTION:**When eaten or swallowed the intoxicating effects of this product can be delayed 2 or more hours. **This product may be unlawful outside the State of Nevada.** |

**Modified Nevada Label (REAR) – 6pt Font**

|  |
| --- |
| **Manufactured at:**Joe’s Kitchen        Cert.#: 321654987101 0401123 Main Street, Las Vegas, NV on 2/1/14Lot#: 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 effectsand may be habit forming. |

The size relative to the package is also vague in the proposed regulation and so will be subject to manipulation by industry. Requiring labels to cover a minimum of 50% or more of the primary panel would be more consistent with existing public health best practices identified from tobacco control.[[29]](https://mail.phi.org/owa/#_ftn29),[[30]](https://mail.phi.org/owa/#_ftn30),[[31]](https://mail.phi.org/owa/#_ftn31) Using this standard, **§ 40405(b) should be modified to read: “text must be in type size no less than ~~6~~ *12* point font and be in relation to the size of the primary panel and container*, covering no less than 50% of the primary panel*.”**

**2.      The Messages Should be Rotating Health Warning Language that Incorporate Pictorial Warnings (§ 40408)**

Warning labels are more effective when messages are periodically changed to avoid “burn out.”[[32]](https://mail.phi.org/owa/#_ftn32),[[33]](https://mail.phi.org/owa/#_ftn33),[[34]](https://mail.phi.org/owa/#_ftn34) In addition to the statements required by statute and those added under the Department’s proposed § 40408(a), we recommend the addition of a rotating set of additional warnings consistent with existing information on marijuana use and secondhand exposure.[[35]](https://mail.phi.org/owa/#_ftn35) **Rotating messages should address risks of dependence,**[**[36]**](https://mail.phi.org/owa/#_ftn36)**,**[**[37]**](https://mail.phi.org/owa/#_ftn37)**cardiovascular,**[**[38]**](https://mail.phi.org/owa/#_ftn38)**,**[**[39]**](https://mail.phi.org/owa/#_ftn39)**,**[**[40]**](https://mail.phi.org/owa/#_ftn40)**respiratory,**[**[41]**](https://mail.phi.org/owa/#_ftn41)**and neurological disease,**[**[42]**](https://mail.phi.org/owa/#_ftn42)**and cancer**[**[43]**](https://mail.phi.org/owa/#_ftn43)**associated with cannabis and cannabis product use, including risks linked to chemical additives,**[**[44]**](https://mail.phi.org/owa/#_ftn44)**,**[**[45]**](https://mail.phi.org/owa/#_ftn45)**as appropriate based on product type.**

The impact of health warning labels is higher and more informative with the use of pictorial warnings. Based on tobacco control research, pictorial warnings are more effective in communicating health risks[[46]](https://mail.phi.org/owa/#_ftn46),[[47]](https://mail.phi.org/owa/#_ftn47),[[48]](https://mail.phi.org/owa/#_ftn48) and decreasing the attractiveness of the product to youth.[[49]](https://mail.phi.org/owa/#_ftn49)  While the FDA has not yet implemented them, color graphic warnings for tobacco products are mandated by the Family Smoking Prevention and Tobacco Control Act,[[50]](https://mail.phi.org/owa/#_ftn50) and the legality of this requirement has been upheld by the U.S. Court of Appeals for the Sixth Circuit.[[51]](https://mail.phi.org/owa/#_ftn51) Based on their effectiveness in other jurisdictions around the world, pictorial warnings are likely to effectively convey health warning information for other substances, as well, including cannabis. **The label requirements (§ 40408 ) should mandate pictorial warnings into the label requirements to improve the impact and salience of these labels, including for low-literacy and non-English speaking populations and youth.**

**3.      The Packaging Restrictions should be Broadened to Eliminate Appeals to Children and Imitation of Other Non-Cannabis Products (§§ 40410, 40415)**

Under proposed § 40410(c)(2)-(c)(3), prohibited packaging content includes “Any likeness to images, characters, or phrases that are popularly used to advertise to children; or Any imitation of candy packaging or labeling.”  Nevertheless, this language may still permit packaging that appeals to children and adolescents.

Many products that are attractive to children and adolescents include elements that are not “popularly used to advertise to children” but remain appealing to children and teens, such as themes of glamour, beauty, sex, or adventure. Preventing inappropriate appeal to youth requires a broader prohibition on such elements. For example, proposed Canadian recreational cannabis statutory language prohibits packaging and labeling that associates the product with “a way of life such as one that includes glamour, recreation, excitement, vitality, risk or daring.”[[52]](https://mail.phi.org/owa/#_ftn52)  Similarly, the proposed Canadian law prohibits packaging and labeling “if there are reasonable grounds to believe that the package or label could be appealing to young persons.”[[53]](https://mail.phi.org/owa/#_ftn53)

Even broader language such as the proposed Canadian standard still invites subjectivity. For example, regulators must assess what constitutes “reasonable grounds” or determine what qualifies as “glamour.” **Adoption of a plain packaging standard avoids such interpretive problems and undermines the opportunity to use packaging to mislead consumers and unlawfully market to youth.**

Plain packaging uses standardized packages that remove all branding, images, logos, and trademarks, allowing only plain text of brand and variant information in specified size, font, and position.[[54]](https://mail.phi.org/owa/#_ftn54) Using this standard makes health warnings more noticeable[[55]](https://mail.phi.org/owa/#_ftn55),[[56]](https://mail.phi.org/owa/#_ftn56)and effective,[[57]](https://mail.phi.org/owa/#_ftn57) and it reduces the impact of misleading branding on beliefs about harmfulness.[[58]](https://mail.phi.org/owa/#_ftn58),[[59]](https://mail.phi.org/owa/#_ftn59) Plain packaging also extends the impact and reach of accompanying public health media campaigns, especially when the packaging also incorporates larger graphic health warning labels.[[60]](https://mail.phi.org/owa/#_ftn60)

**Without plain packaging, cannabis product manufacturers may use various tactics to inappropriately market to youth.**Among other issues, product imitation presents a concern already recognized by the Department. The current proposed prohibition on the imitation of “candy” packaging in § 40410(c)(2) partially addresses this issue but does 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. A complete prohibition on the imitation of all non-cannabis products would more effectively reduce the risk of accidental consumption. To that end, **§ 40410(c)(3) should be revised to prohibit: “Any imitation of ~~candy~~ *the* packaging or labeling *of an unrelated, non-cannabis product, including but not limited to candy*.”**

Neither plain packaging requirements nor prohibiting product imitation would meaningfully restrict any legitimate marketing interests of medical cannabis manufacturers. Imitation packaging merely trades on the intellectual property of others, as well as likely violating trademark rights. For example, Hershey® recently settled trademark infringement suits against cannabis businesses that sold edible cannabis products with names that parodied the candy maker’s branded products (e.g., “Hasheath” for Heath®, “Mr. Dankbar” for Mr. Goodbar®).[[61]](https://mail.phi.org/owa/#_ftn61) Cannabis manufacturers, especially in the medical cannabis market, have no legitimate business interest in using packaging that mimics non-cannabis products, whether those other products are candy, snack food, prescription or nonprescription medication, or any other category of product.

Similarly, restrictions on packaging in § 40415 prohibit packaging that imitates “any package used for products typically marketed to children.” However, many products not “typically marketed to children” are nevertheless attractive to them. For example, an expensive brand of chocolate may appeal to children but market exclusively to adult consumers. Additionally, tobacco and alcohol products are specifically barred from marketing to children, but there can be little doubt that the products remain appealing to them, given high rates of youth use. As discussed above, medical cannabis manufacturers have no legitimate interest in imitating other products, regardless of their nature. **The prohibition in** **§ 40415(d) should be revised as: “The package shall not imitate any package used for *other, unrelated* products*, including but not limited to those* typically marketed to children.”**

**4.      Clarify the Prohibition on Additives to Exclude All Forms of Nicotine and Caffeine and Explicitly Prohibit Use of Menthol and Other Characterizing Flavors (§ 40300)**

As written, § 40300(b) prohibits the use of certain additives in cannabis products, but the extent of the prohibition is unclear as it relates to some potential sources of the substances. This clause prohibits additives in cannabis products “that would increase potency, toxicity or addictive potential.”[[62]](https://mail.phi.org/owa/#_ftn62) More specifically, “Prohibited additives include but are not limited to nicotine and caffeine.”

**The Department should clarify the term “additive” to include both the pure substance and any product containing the substance.** For example, with respect to caffeine, it is currently unclear whether the prohibition extends only to use of pure powdered caffeine or would also include substances with naturally occurring caffeine, such as guarana. Similarly, it is unclear whether it would apply to infusions of products such as coffee, tea, or cola and whether it would also extend to products that contain smaller amounts of naturally occurring caffeine, such as chocolate. These questions are also relevant to the prohibition on nicotine, which in the interest of public health should extend to any and all tobacco products and other nicotine sources, whether naturally or artificially derived, such as e-cigarette liquid and similar products. In the Initial Statement of Reasons, the Department appropriately recognizes the risks of tobacco and cannabis co-use and the potential risks of mixing stimulants such as caffeine with cannabis. **To most effectively protect against these risks, § 40300(b) should be revised to read: “Prohibited additives include but are not limited to nicotine and caffeine*, in any form.*”**

**The Department should also add menthol to the list of explicitly prohibited additives alongside caffeine and nicotine.** With respect to tobacco, research indicates that those who smoke menthol cigarettes experience more difficulty quitting, with particular challenges for racial/ethnic minority populations and younger smokers.[[63]](https://mail.phi.org/owa/#_ftn63) Use of menthol cigarettes is also substantially more common among these groups and others frequently targeted by the tobacco industry, such as youth of color, women, and LGBTQ populations.[[64]](https://mail.phi.org/owa/#_ftn64),[[65]](https://mail.phi.org/owa/#_ftn65)Potential relationships or interactions between menthol and cannabis are not completely understood,[[66]](https://mail.phi.org/owa/#_ftn66),[[67]](https://mail.phi.org/owa/#_ftn67) but the links between menthol and nicotine addiction support a cautious approach to the use of menthol in cannabis products to avoid increases in addictive potential and appeal to youth.

      **The addition of a broad prohibition on characterizing flavors is needed to discourage inappropriate use of medical cannabis products for nonmedical purposes and deter youth use based on lessons from tobacco control.** Most adolescent tobacco users report that they began with flavored products, and most current adolescent tobacco users use flavored products.[[68]](https://mail.phi.org/owa/#_ftn68) The FDA’s 2009 ban on cigarettes with characterizing flavors (authorized by the Family Smoking Prevention and Tobacco Control Act) was associated with an overall reduction in adolescent tobacco use and a substantial reduction in the probability of being a cigarette smoker and in cigarettes smoked among adolescents.[[69]](https://mail.phi.org/owa/#_ftn69) However, because the 2009 ban did not include menthol cigarettes or other forms of flavored tobacco, there was an increase in use of menthol cigarettes, cigars, and pipes that implies substitution of these products for flavored cigarettes and limited the impact on adolescent tobacco use.[[70]](https://mail.phi.org/owa/#_ftn70) These patterns are likely to present in the use of legalized cannabis products, as well, in the absence of strong constraints on the use of flavorings and additives. **The Department needs to anticipate and prevent such an effect in its regulations.**We recognize that such a prohibition may substantially constrain preparations of edible medical cannabis products. However, while some patients may prefer such products, any medicinal effect is unrelated to flavorings or other ingredients that increase the potential for misuse.

**5.      Increase the Salience and Visibility of Cannabis Product Symbol (§ 40412)**

Under the proposed regulations, § 40412(a) provides a required form and color for the warning symbol intended to denote that a medical cannabis product contains THC. **While this symbol is similar to others currently in use in other states, a slight modification (depicted below) to either remove the exclamation point or place it before rather than after “THC” may better convey the message of warning rather than approval.** In its current form, the symbol may be read as a positive marketing claim that the product is superior because it contains THC.

Research originally conducted by tobacco companies to understand the effect of packaging colors on consumer perceptions also indicates that the most visually prominent color is black, particularly black text set against a lighter background color, as used for roadside warning signs. Yellow is the most effective at gaining and keeping consumers’ attention and signals a warning. In contrast, white (such as that on the proposed THC symbol) signals health and safety.[71] **The most effective form of symbol for informing consumers about THC content and keeping their attention is therefore black text on a yellow background (depicted below). In addition to the required symbol, this color scheme could also improve the visibility and effectiveness of other labels and warnings required by the Department, including labeling elements under § 40405 (*See* discussion above).**

Examples of revised symbol:

Additionally, § 40412(b) requires that the symbol be “no smaller in size than half (.5) inch by half (.5) inch and shall be printed legibly and conspicuously.” **The potential variation in the size of medical cannabis product packaging supports a requirement that the symbol cover a minimum percentage of the product’s primary panel, avoiding instances where a product’s other colors, symbols, or markings may be so large and prominent as to dominate the required warning symbol and render it ineffective.** For example, a revised § 40412(b) could provide that the symbol be “no smaller in size than half (.5) inch by half (.5) inch and shall be printed legibly and conspicuously*, covering no less than 10% of the primary panel of a medical cannabis product*.”

In conjunction with the required warning labels under § 40405, total coverage of 50% or more of a package’s principal surfaces would best utilize public health best practices that incorporate lessons from tobacco control, including the World Health Organization’s Framework Convention on Tobacco Control (FCTC), which promotes health warnings that cover 50% or more of principal display areas of tobacco products and requires coverage of 30% of the principal display area.[[72]](https://mail.phi.org/owa/#_ftn72)

**6.      The Regulations Should Limit Topical THC Concentration by Volume, as well as by Unit (§ 40306)**

The proposed regulations limit all types of nonedible manufactured cannabis products to 1000 mg THC per unit, but topical products may have risks that distinguish them from other products. Similar to edible products, topical cannabis products can resemble household products that children may commonly encounter, such as lotions or balms, resulting in accidental use. **The Department should separately limit the maximum THC content of topical cannabis products on the basis of percentage THC by volume to mitigate potential effects from accidental use or consumption.** For example, Oregon allows a maximum 6% THC by volume for topical products.[[73]](https://mail.phi.org/owa/#_ftn73) This limit should be in addition to restrictions on total THC per unit for these products. The specific limit to be set by the Department should be based on the best available evidence and should be released for public comment prior to implementation.

**7.      The Regulations Should Set a Lower THC Limit for Smoked or Vaporized Concentrates Relative to Other Nonedible Cannabis Products (§ 40306)**

The proposed regulations collapse all types of nonedible manufactured cannabis products under a single limit on maximum THC content per unit. The Department notes that “capsules, tinctures, and topicals” are “more traditional medical delivery mechanisms,”[[74]](https://mail.phi.org/owa/#_ftn74) but the broad category of nonedible products also includes many with unique characteristics, such as potent concentrates designed to be heated and inhaled, often called “dabs.”  These products may be produced by a variety of methods, including butane extraction (clearly contemplated under § 40118 of the proposed regulations). Butane-extracted concentrates under various names (e.g., “wax,” “shatter,” “budder”) can contain over 75% THC[[75]](https://mail.phi.org/owa/#_ftn75) and are often consumed very rapidly, providing the equivalent of several joints in a single breath.[[76]](https://mail.phi.org/owa/#_ftn76) This combination of high THC concentration and rapid administration presents substantial risks of dependence that may be more acute compared to other forms of consumption, and overall scientific literature on dabs and other concentrated products is severely limited.[[77]](https://mail.phi.org/owa/#_ftn77),[[78]](https://mail.phi.org/owa/#_ftn78)Even slower consumption of concentrates (e.g., via vaporizer) likely presents significant cardiovascular and respiratory risks similar to those of e-cigarettes[[79]](https://mail.phi.org/owa/#_ftn79),[[80]](https://mail.phi.org/owa/#_ftn80),[[81]](https://mail.phi.org/owa/#_ftn81),[[82]](https://mail.phi.org/owa/#_ftn82),[[83]](https://mail.phi.org/owa/#_ftn83) due to the similar inhalation of ultrafine particles.

**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.**For example, Washington State limits most medical cannabis products to 100 mg per unit, but authorizes up to 500 mg of THC per package for “High THC compliant products,” a category restricted to capsules, tablets, tinctures, transdermal patches, and suppositories.[[84]](https://mail.phi.org/owa/#_ftn84) The specific limits to be set by the Department should be based on the best available evidence and should be released for public comment prior to implementation.

**8.      Reduce the Per Unit Limit on THC Content of All Nonedible Products (§ 40306)**

The National Academies Report *The Health Effects of Cannabis and Cannabinoids*[[85]](https://mail.phi.org/owa/#_ftn85)found that despite some evidence of cannabis as an effective treatment for certain conditions (e.g., chronic pain in adults), “very little is known about the efficacy, dose, routes of administration, or side effects” of various preparations and forms of cannabis products. Existing evidence from U.S. studies suggesting an effect on pain, for example, is limited to studies of smoked or vaporized cannabis flower, as this is the form provided for research by the National Institute on Drug Abuse (NIDA).[[86]](https://mail.phi.org/owa/#_ftn86),[[87]](https://mail.phi.org/owa/#_ftn87)

Evidence cited by the National Academies Report supporting the effectiveness of cannabinoids as an antiemetic to treat chemotherapy-induced nausea and vomiting is limited to pharmaceutical oral THC preparations nabilone and dronabinol, synthetic products that have been available for many years.[[88]](https://mail.phi.org/owa/#_ftn88) Despite some anecdotal support, the effectiveness of plant-based forms of cannabis for this condition has not been adequately tested using quality methods (e.g., high-quality randomized trials).

Three cannabinoid-based medications have been approved by the Food and Drug Administration (FDA): Marinol®, Syndros®, and Cesamet®. These medications are based on synthetic compounds, and multiple additional products derived from natural cannabis plant varieties are also in development, including Epidiolex® and Sativex®, which have been granted FDA Fast Track status, allowing expedited review. The current and future availability of cannabis-based medications via existing prescription drug frameworks diminishes the rationale for authorizing largely unsupervised and unmonitored experimentation with highly concentrated THC products in the form of both edible and nonedible products under the state’s medical cannabis program.

**The Department has appropriately proposed a 100 mg limit on per unit THC content for edible medical cannabis products and should take a similarly cautious approach to nonedible products.**As noted in the Department’s Initial Statement of Reasons, states vary in their approach to limiting the concentration of THC in nonedible products. Such products have reduced potential for accidental consumption compared to edible products, but do still present some risk of accidental consumption by children and pets and overconsumption by users. The Department’s survey of other states’ (Washington, Oregon, Alaska, Hawaii, Nevada, and Colorado) medical cannabis statutes and regulations as a reference point[[89]](https://mail.phi.org/owa/#_ftn89) is relevant and appropriate. **However, until more research is available validating the effects and appropriate dosages of nonedible manufactured cannabis products, a lower threshold is less likely to result in negative outcomes.**

A lower threshold reduces the risk of negative effects from accidental consumption or unintentional overconsumption, similar to the rationale for proposed limits on edible products. Existing evidence for the medical use of non-flower, non-synthetic cannabis does not support the wide discrepancy between allowable THC in edible (100mg) and nonedible (1000mg) products under the proposed regulations. Occasional users may experience a euphoric “high” at doses of only 2-3 mg of THC,[[90]](https://mail.phi.org/owa/#_ftn90),[[91]](https://mail.phi.org/owa/#_ftn91) though frequent users may develop tolerance. Applying even the higher 10 mg per serving edibles standard to nonedible products under the proposed regulations would authorize sales of nonedible products containing up to 100 doses per unit.

Until additional research information is available on such products, the Department should take a precautionary approach to their availability and concentration. As additional research develops, it may be appropriate to modify these rules. **Until an appropriate evidence base is available to support higher-concentration products, setting a lower threshold is more likely to avoid public health harms from medical cannabis products.** For example, Washington State limits total THC to 500 mg per package for nonedible products, and this amount is allowed only for capsules, tablets, tinctures, transdermal patches, and suppositories.[[92]](https://mail.phi.org/owa/#_ftn92) The specific limit to be set by the Department should be based on the best available evidence and should be released for public comment prior to implementation. The Department should also actively monitor new findings and revisit these limits on a specified and publicly announced schedule to ensure the regulations remain consistent with scientific evidence.

**CONCLUSION**

      The science surrounding the potential harms and benefits of medical cannabis is evolving, but known risks of 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 and alcohol control to improve the size and clarity of labels, restrict on-package marketing, limit total THC content, and prevent the addition of additives that increase risks of addiction and youth use will ensure a functional and well-regulated medical cannabis system that prioritizes protection of public health over business interests in the State of California.

This comment is also on my blog at [https://tobacco.ucsf.edu/public-comment-we-submitted-california-dept-health-proposed-marijuana-regulation-too-lax-protect-public-health](https://mail.phi.org/owa/redir.aspx?C=b7rWRNKhXlLQF_1odfgioIp2pWg6YoOCZuN6RdY6pT5WCimufbLUCA..&URL=https%3a%2f%2ftobacco.ucsf.edu%2fpublic-comment-we-submitted-california-dept-health-proposed-marijuana-regulation-too-lax-protect-public-health) and @ProfGlantz.

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