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Re: Public Comment - Proposed Consolidated Cannabis Regulations Filed on March 4, 2022

To Whom It May Concern:

We write on behalf of the Los Angeles County Bar Association ("LACBA") Cannabis Section concerning the proposed Consolidated Cannabis Regulations (the "Proposed Non-Emergency Regulations")[1] filed by the Department of Cannabis Control ("DCC") on March 4, 2022.

LACBA was founded in 1878 and is one of the largest voluntary metropolitan bar associations in the country, with more than 20,000 members. LACBA serves attorneys, judges, and other legal professionals through 28 sections, committees, networking events, live and on-demand CLE programs, and pro bono opportunities, as well as public service and informational resources.

LACBA formed its Cannabis Section in 2019, which is one of the newest among LACBA's many sections. LACBA formed its Cannabis Section out of an interest among its members and the foresight of its leadership. LACBA's Cannabis Section provides top-tier continuing legal education concerning the legal cannabis industry and its many complex issues, including: state and local regulatory compliance, corporate and tax structuring, banking, real

[1] Unless otherwise stated, all section references herein are to the Proposed Non-Emergency Regulations.

estate, labor and employment, intellectual property, insurance, litigation, distribution, marketing, and ethics. The Cannabis Section serves as a source of expertise for other attorneys, government bodies, and the news media on issues regarding cannabis laws, regulations and developments, and serves as a forum for the consideration of public policies dealing with or regarding cannabis generally.

The attorney members of LACBA's Cannabis Section represent clients throughout the State of California in all aspects of the cannabis industry, including retailers, cultivators, manufacturers, distributors, investment funds, landlords, brands, and suppliers of ancillary products and services. Our clients seek legal solutions to the full range of rulemaking, regulatory, transactional, legislative, and litigation challenges they confront, and our members seek to provide clear advice about the varying contours and conflicts within the law that must be navigated and respected. Many of our members have also assisted with creating policy and ordinances in various local municipalities throughout the State.

On behalf of LACBA's Cannabis Section, we wish to express our appreciation to DCC for its continued efforts to refine, streamline and strengthen the existing regulatory framework for the State's cannabis industry. While we recognize that many of the Proposed Non-Emergency Regulations simply re-adopt the existing regulations that are currently in effect as emergency regulations, we have concerns that some of the proposed changes require further clarification and/or fail to address certain significant pain points for the industry's legal operators.

Branded Merchandise

Section 15041.1 provides that all "branded merchandise" must identify the "licensee responsible for its content" by displaying a "permanently affixed" license number for such licensee.

Comment: Aside from the fact that the "permanently affixed" requirement is extremely costly and overly burdensome to licensees, the language in Section 15041.1 lends itself to ambiguity and varying interpretations. For instance, if there are multiple license holders or affiliated licensees who are each involved with the production of branded merchandise, how does DCC determine which licensee is "responsible" for the content of the "branded merchandise"? Additionally, if a brand licenses its intellectual property to a licensee for commercial cannabis purposes while also licensing the same intellectual property to non-cannabis businesses for non-cannabis purposes (such as fashion or apparel), what "responsibility" (if any) does the licensee have for any merchandise being sold by the non-cannabis businesses? These types of questions illustrate our concern over the lack of clarity surrounding Section 15041.1. Given that a violation of Section 15041.1 is considered a serious Tier 1 violation[2], we recommend that DCC provide additional

[2] *See* DCC Disciplinary Guidelines, Amended July 2021 [violation of CCR § 10541 is considered a Tier 1 violation, with a minimum punishment of suspension and/or fine and a maximum punishment of revocation].

guidance regarding its interpretation of Section 10541.1 in order to prevent inadvertent violations by licensees.

Licensees Should be Able to Destroy Cannabis or Cannabis Products That Have Been Returned

Section 15052(a) creates additional requirements for returns between licensees. Among other requirements, Section 15052(a)(2) provides that after being returned, cannabis and cannabis products that have been returned shall be transported to a licensed distributor to undergo laboratory testing.

Comment: A licensee should be able to destroy cannabis or cannabis products that have been returned because the cannabis or cannabis products are non-compliant or defective. Section 15052(a)(2) should be revised to clarify that licensees may destroy returned cannabis or cannabis products and that such products do not have to undergo laboratory testing. There is no logic to requiring lab testing of cannabis or cannabis products that are designated for destruction, let alone imposing that cost upon a licensee. We recommend that Section 15052(a)(2) be revised as follows:

> "After being returned, cannabis and cannabis products that have been returned and that have not been destroyed shall be transported to a licensed distributor to undergo laboratory testing in accordance with chapters 2 and 6 and quality assurance review pursuant to sections 15307 and 15307.1 prior to being transported to a licensed retailer."

Corrective Action Plans for Returns

Section 15052 creates additional requirements for returns between licensees. Among other requirements, Section 15052(a)(1) provides that a corrective action plan must be submitted to DCC prior to the re-processing, re-branding, re-labeling, physical re-packaging, or other modification of cannabis and cannabis products.

Comment: Requiring a corrective action plan to be approved prior to reprocessing will help ensure cannabis and cannabis products are safe to re-enter the commercial market. However, requiring the same corrective action plan to be submitted and approved every time cannabis and cannabis products must be re-labeled, re-branded, and re-packaged will cause a significant slowdown in the supply chain. Articles 3 and 4 of DCC's regulations provide comprehensive guidelines for licensee compliance on labeling, packaging, and branding. Further, distributors are responsible for quality assurance review of all cannabis and cannabis products prior to distribution to retail. We recommend that DCC modify the language of Section 15052(a)(1) to instead require a licensee to submit notice to DCC when returned cannabis or cannabis products have been re-labeled, re-branded, or re-packaged but not wait for approval before they can re-enter the commercial market. If the notice provided to DCC fails to demonstrate how the returned cannabis and cannabis products are now compliant, DCC should have the authority to

suspend them from the commercial market and require the licensee to await approval of the corrective action plan before re-entry.

Trade Samples

Section 15041.7(a)(1)-(3) provides the following quantity limits for the designation of trade samples in a calendar month period: (a) for dried flower, a total of 2 pounds; (b) for manufactured and non-manufactured cannabis products, a total of 900 individual units; and (c) for seeds, immature plants, and other propagated materials, 18 seeds, 12 seedlings, 8 cuttings, or tissue cultures per strain. Section 15041.7(b)(1)-(3) provides the following quantity limits for the provision of trade samples to each recipient licensee in a calendar month period: (x) for dried flower, 5 grams per strain and no more than 6 strains; (y) for manufactured and non-manufactured cannabis products, 5 individual units per SKU and no more than 6 SKUs; and (z) for seeds, immature plants, and other propagated materials, no more than 6 strains.

Comment: While the addition of trade samples is certainly an improvement for the state's cannabis industry, the "one-size-fits-all" approach under Section 15041.7(a) is, in many cases, unworkable and overly strict. By imposing a monthly weight or quantity limit on trade sample: regardless of the size or scale of the licensee's business, both large-scale businesses and smaller businesses with numerous and rapidly developing product lines are unable to meaningfully avail themselves of the benefits conferred by trade samples. Accordingly, we recommend that the trade sample limits under Section 15041.7(a) be adjusted to allow for more flexibility and scale. Instead of imposing uniform weight or quantity limits on a licensee's trade samples during any given calendar month period, we recommend that DCC impose (a) trade sample limits on a licensee based upon a certain volume percentage or unit count (as applicable) per production batch, or, alternatively, (b) uniform weight or quantity limits upon the number and amount of trade samples that may be provided to any single recipient licensee during a given time period.

Raffles/Sweepstakes

Section 15040(a)(4)(C) prohibits the advertisement of any "contests, sweepstakes or raffles" for free cannabis goods or cannabis accessories (underlined text proposed for addition). Correspondingly, Section 15040.2(a) prohibits a licensee from giving away "any amount of cannabis or cannabis products, or any cannabis accessory, as part of a business promotion." Section 15040.2(b) would extend restrictions on licensee business activities much further by stating that "[a] licensee shall not hold a raffle or sweepstakes as part of a business promotion."

Comment: A blanket prohibition on holding a raffle or sweepstakes on business promotions not involving cannabis products or cannabis accessories is an overly broad restraint on commerce and overly burdensome to cannabis licensees. Licensees, who already bear high regulatory costs, special taxes and restrictive operating conditions, often have business ventures outside of the sale of cannabis products and accessories and use promotional opportunities to distinguish their brands and marks amongst both licensees and

non-licensees. In offering promotions of goods or services other than cannabis products or cannabis accessories, licensees should be permitted to operate in the same manner as non-licensees, who already bear a competitive advantage in branding and marketing. Further, it is impractical for the state to regulate non-cannabis activities of licensees. Finally, the state of California already imposes and enforces robust regulations on the conduct of raffles and sweepstakes that are applicable to all California business ventures and safeguard the interests of California residents. We recommend that subsection (b) of Section 15040.2 be deleted accordingly.

The Definition of Designated Responsible Party Should be Consistent Throughout The Regulations

Section 15000(t) defines the term "Designated Responsible Party" as "the individual identified by the commercial cannabis business who has legal authority to bind the commercial cannabis business and who is the primary contact for the application and license-related issues." Section 15002(b)(10) requires applicants to disclose the "contact information for the owner of the commercial cannabis business who will serve as the designated primary contact person *or* designated responsible party for the business."..

Comment: The language in Section 15002(b)(10) conflicts with the definition of Designated Responsible Party in Section 15000(t) in that it requires that the primary contact or designated responsible party for the business be an owner of the commercial cannabis business. Given that cannabis businesses frequently use consultants and/or attorneys to assist them with licensing, cannabis businesses should be allowed to designate a non-owner representative as a designated responsible party or a primary contact. We recommend that Section 15002(b)(10) be amended as follows:

> "Contact information for the ~~owner of the commercial cannabis business~~ individual who will serve as the designated primary contact person or designated responsible party for the business, including the name, title, phone number, and email address of the individual."

Certificates of Analysis

Section 15306(c) requires distributors to provide a copy of a batch's certificate of analysis to the licensee that produced the batch.

Comment: It is common practice in the cannabis industry for multiple licensees to be involved in the supply chain and the distributor arranging testing for regulatory compliance is not always the licensee who acquired the cannabis or cannabis products from the licensee that produced the batch. Some licensed distributors often act as brokers between other licensees and maintaining the identity of their licensed suppliers is essential to their business model. Requiring distributors to provide a copy of a batch's certificate of analysis to the licensee that produced the batch would interfere with these common practices and place an unnecessary administrative burden on distributors arranging testing for regulatory

compliance. As a result, we recommend that the following language be deleted in its entirety from Section 15306(c): "A copy of the certificate of analysis shall also be provided to the licensee that produced the batch."

Additional Requirements for Cannabis and Cannabis Products

Sections 17300, *et seq*. create additional requirements for cannabis and cannabis products. For example:

- Section 17300 adds prohibitions on, among other things, inhalable cannabis goods that are delivered into the lungs through a metered-dose inhaler or dry-powder inhaler; cannabis goods in the shape, or imprinted with the shape, of a human being, animal, insect or fruit; and any products that are manufactured by application of cannabinoid concentrate or extract to commercially available candy or snack food items without further processing of the product. *See* § 17300(a)-(p).
- Section 17302.1 adds additional requirements for tinctures including that they be no more than 2 fluid ounces and include a calibrated dropper or similar device. *See* § 17302.1(a).
- Section 17303.1(a) adds additional requirements for inhaled products including that they only contain cannabis, cannabis concentrate, botanically-derived terpenes, rolling paper or leaf, and ingredients permitted by the United States Food and Drug Administration (USFDA) as inactive ingredients. *See* § 17303.1(a).

Comment: While we fully support any and all changes that are geared towards ensuring consumer safety, we are concerned that the imposition of new requirements for cannabis products, without any enforcement grace period, will result in huge financial losses for licensees who currently have a large inventory of currently-compliant products, but who are otherwise unable to timely sell off such products that become non-compliant when the Proposed Non-Emergency Regulations go into effect (such products are referred to herein as "Legally Nonconforming Products"). Accordingly, we recommend that all Legally Nonconforming Products be expressly excluded from the new requirements contained in Sections 17300, *et seq*. It is worth noting that, to the extent DCC determines that a licensee's continued sale of any Legally Nonconforming Products endangers public health, safety or welfare, DCC would still have the authority under Section 17810 to petition for an interim order to impose additional licensing restrictions on such licensee, such as restricting the licensee's sale and/or ordering the destruction of any Legally Nonconforming Products which endanger public health, safety or welfare.

The Proposed Additional Requirements for Inhaled Products Need Further Clarification

As discussed above, Section 17303.1(a) provides an exhaustive list of ingredients for inhalable cannabis products.

Comment: Although the list contained in Section 17303.1(a) includes "botanically-derived terpenes" and ingredients permitted by the USFDA as an "inactive ingredient" for inhalation, as specified in the USFDA Inactive Ingredients Database, Section 17303.1(a) fails to define the term "botanically-derived" while also failing to include other naturally-derived ingredients typically used with inhalable manufactured products.

A common practice amongst manufacturers of inhalable cannabis products is to combine other safe, naturally-derived ingredients with naturally-derived terpenes to form "terpene blends" that create complex flavor profiles. Naturally-derived ingredients, which are also found naturally-occurring in cannabis, used in terpene blends include compounds such as ketones, aldehydes, esters, and alcohols. These ingredients, although naturally sourced and safe, do not fall under the limited definition of "botanical" or "terpenes" nor do they appear on the USFDA's list of safe "inactive ingredients" for drug products. As a result, the current proposed language would prohibit the use of many naturally-occurring ingredients that are often used in combination with terpenes to create terpene blends for use in inhalable cannabis products.

It is important to note that even though the proposed regulations would allow for the use of "botanically-derived" terpenes in inhalable products, many are not permitted by the USFDA as inactive ingredients for inhalation. If botanically-derived terpenes are permissible in inhalable cannabis products by DCC, other botanically-derived ingredients should also be permitted. This is especially so because the USFDA inactive ingredient list is merely an inventory of inactive ingredients found in approved drug products and is neither a list of approved ingredients nor an exhaustive list of inactive ingredients that could be found in future approved drug products.

Other states have expressly incorporated the use of naturally-derived ingredients, other than terpenes, into their regulations. For example, Colorado regulators have addressed the use of botanically-derived compounds in cannabis products in 1 CCR 212-3-335(I) by permitting a licensed cannabis manufacturer to use *marijuana-derived ingredients, botanically-derived compounds, and botanically-derived terpenoids* as ingredients. Oregon regulators have also addressed the use of "non-cannabis additives" in inhalable cannabis products in OAR 845-025-3265. OAR 845-025-1015(72) defines the term "non-cannabis additives" as ingredients derived from non-cannabis sources, such as botanically-derived ketones, aldehydes, essential oils, and alcohols. In other words, Oregon regulators allow for the use of non-cannabis additives in inhalable cannabis products so long as inhalable products comply with OAR 845-025-3265. Instead of providing an exhaustive list of *approved* ingredients for inhalable cannabis products, OAR 845-025-3265 provides an exhaustive list of *prohibited* ingredients for inhalable cannabis products known to have dangerous or harmful effects when inhaled.

In light of the above, we believe that the term "botanically-derived terpenes" would unduly limit other commonly used safe and natural ingredients, including compounds produced by the cannabis plant, and recommend that DCC: (x) replace "botanically-derived terpenes" with "naturally-derived ingredients"; or alternatively, (y) provide an

exhaustive list of prohibited ingredients for inhalable cannabis products known to have dangerous or harmful effects when inhaled.

Entity Substitutions

Section 15023(c)(1)(A) provides that "[a] change in ownership occurs when a new person meets the definition of owner in section 15003 of this division." (Emphasis added.) Section 15032(e) further provides that a licensee shall notify DCC of any changes in the name, DBA or contact information of a licensee.

Comment: When someone originally applies for and is approved for a license as an individual/sole proprietor or in the names of multiple individuals, many times, these individuals come to realize, either because of the potential legal and liability disclosure, or because they wish to seek investment, or simply because they want to separate their assets, that it would be prudent to hold their ownership of their cannabis licenses in a limited liability entity. We recommend that, just as applicants are allowed to change their name, DBA, and contact information, *if ownership remains exactly the same*, then licensees who are individuals/sole proprietors should also be allowed to change how they hold title to their license (i.e. from holding title as individuals/sole proprietors to holding title as a limited liability entity) if there is no difference in the beneficial ownership. As it stands now, when presented with this situation, applicants are being instructed by DCC that a new application must be submitted by the limited liability entity pursuant to Section 15002(c)(1) despite the fact that the beneficial ownership remains exactly the same. However, in these situation, there is no new owner per Section 15003(c)(1)(A) and thus there is no ownership change, so it does not stand to reason that individuals/sole proprietors must incur the extreme unnecessary cost and expense of submitting an entirely new application for a limited liability entity *with the exact same ownership*. Accordingly, we recommend that DCC add a provision to Section 15023(e) permitting individuals/sole proprietors to change the name under which their ownership is held from an individual to a limited liability entity, provided that all ownership remains the same and notice is timely given to DCC.

We thank DCC for its consideration of these comments and for its public service.

Sincerely,

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