Quinn Emanuel Cannabis Litigation Practice Alert

Navigating CBD Labeling Litigation Risk Under California and Federal Law

Earlier this month, California's new labeling requirements for CBD products went into effect under Assembly Bill 45 ("AB 45"), which legalized the addition of hemp-derived CBD to food, beverages, dietary supplements, and cosmetics in California. Although the sale of cannabis-derived CBD products has been permitted in licensed California dispensaries for some time now, AB 45 opened California to the $2 billion hemp-derived CBD market, which is expected to generate millions in annual tax revenue.[1]

However, AB 45's labeling requirements, which affect products manufactured after January 4, 2022,[2] will likely create unexpected issues. This is because the Food, Drug, and Cosmetic Act ("FDCA") preempts any non-identical state labeling laws, rendering them "without effect."[3] Because the FDCA and AB 45 differ in several respects, FDCA preemption may create roadblocks for the government and private plaintiffs seeking to enforce AB 45's labeling requirements in some instances and, in others, may make CBD companies more susceptible to labeling litigation.

Accordingly, in this client alert, we take a look at some of AB 45's and the FDCA's key provisions addressing food labeling, examine how FDCA preemption may stymie and amplify labeling litigation in different situations, and explain the potential impact on CBD companies.

I. AB 45 And The FDCA

Both AB 45 and the FDCA regulate how food containing CBD must be labeled. AB 45 creates a statutory regime for hemp-derived CBD products in California[4] and states how hemp-derived CBD products must be labeled and tested.[5] The FDCA, on the other hand, is the federal law that governs, among other things, food labeling in United States,[6] including labeling for gummies, beverages, chocolate, and other food to which CBD is frequently added and sold.[7]

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1 ROSIELYN PULMANO, ASSEMBLY FLOOR ANALYSIS, 2 (Sept. 2, 2021), https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=202120220AB45# (follow "09/09/21-Assembly Floor Analysis" hyperlink).

2 CAL. Health & SAFETY CODE § 111926.2(b) ("The requirements of this section shall apply to products manufactured 90 days or more after the enactment of this section").

3 *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013).

4 *E.g.* CAL. HEALTH & SAFETY CODE §§ 110065(a), 110469, 111921.

5 CAL. HEALTH & SAFETY CODE §§ 111925-26.3.

6 21 U.S.C. § 321(f).

7 Although the FDA has stated food containing CBD cannot be introduced into interstate commerce, the FDA acknowledges food containing CBD is still a "food" within the purview of the FDCA and subject to its requirements. Letter from Donald D. Ashley, Director, FDA Center for Drug Evaluation and Research Office of Compliance, to Audriana D. Castro, Owner, Bella Rose Labs (Nov. 22, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bella-rose-labs-594246-11222019 ("CBD added to a conventional food is a food additive under section 201(s) of the FD&C Act and is subject to the provisions of section 409 of the FD&C Act."); Letter from Donald D. Ashley, Director, FDA Center for Drug Evaluation and Research

As a federal law, however, the FDCA is the "supreme Law of the Land"[8] and expressly preempts (*i.e.* prohibits) states from establishing "any requirement for nutrition labeling of food that is not identical" to those set forth in the FDCA.[9] This means that "no state may 'directly or indirectly establish any requirement for the labeling of food that is not identical' to the federal requirements.'"[10] Thus, this gives litigants the ability to argue that AB 45's labeling requirements are preempted and "without effect" in any instance they are not identical to the FDCA.[11]

II. Differences In AB 45's And The FDCA's Labeling Requirements

Because AB 45's labeling requirements are arguably "without effect" to the extent they are "not identical" to the FDCA, it is important to note where the two laws differ. And they differ in several respects.

A. Different Items Required to Be Listed on Labels

For instance, AB 45 and the FDCA have different requirements for what must be listed on CBD product labels. AB 45 requires food, dietary supplements, or beverages containing hemp-derived CBD to be labeled with the following warnings:

- A statement indicating that children or those who are pregnant or breastfeeding should avoid using the product prior to consulting with a health care professional about its safety;
- A statement that products containing cannabinoids should be kept out of reach of children; and
- The following statement, "THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY."[12]

AB 45 also requires CBD product labeling include "[a] label, scannable barcode, internet website, or quick response (QR) code" that links to a certificate of analysis showing, among other things, (1) the concentration of cannabinoids (including THC and any marketed cannabinoids) and (2) approximately 100 specified contaminant levels in the product.[13]

The FDCA, on the other hand, does not require food labels to contain AB 45's warnings, a link to a certificate of analysis, cannabinoid concentration, or a list of contaminant levels.[14] Under the FDCA, the only relevant requirement is that food labels must not to be "false or misleading."[15] However, because the FDCA does not require food labeling to list cannabinoid content or the

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Office of Compliance, to Shiloh Thibodeaux, Founding Partner, Plant Organix (Nov. 22, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/organix-industries-inc-dba-plant-organix-593512-11222019 (same).

8 U.S. Const., Art. VI, cl. 2.

9 21 U.S.C. § 343–1(a)(4).

10 *Hawkins v. Kroger Co.*, 906 F.3d 763, 769 (9th Cir. 2018); *see Clark v. Perfect Bar, LLC*, 816 F. App'x 141, 143 (9th Cir. 2020).

11 *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013).

12 CAL. HEALTH & SAFETY CODE § 111926.2(a)(3) - (5).

13 CAL. HEALTH & SAFETY CODE §§ 111926.2(a)(1), 111925.4; CAL. CODE REGS. tit. 4, §§ 15718-25.

14 21 U.S.C. § 343(q); 21 C.F.R. 101.9(c).

15 21 U.S.C. § 343(a).

contaminant levels required by AB 45, the "false or misleading" standard only applies to the extent these items are voluntarily listed on product labels.[16]

B. Different Testing Standards for Labeled Items

Both AB 45 and the FDCA also outline different testing standards to determine whether contents stated on labels comply with the relevant regulations. For instance, AB 45 requires hemp-derived CBD products undergo contaminant testing for approximately 100 different contaminants listed on the certificate of analysis,[17] some of which cause the product to fail if they are detected in any concentration at all and others which are allowed within only specified ranges.[18] Although AB 45 is silent as to cannabinoid content testing requirements, the bill's legislative history indicates they would be the same as those used for cannabis products,[19] which must test within plus or minus 10% of the amount of CBD claimed on their labels.[20] The sampling procedure for these tests, however, is left up to the individual laboratories, which develop their own sampling procedures and submit them to the Department of Cannabis Control.[21]

The FDCA, on the other hand, has different testing standards.[22] Under the FDCA, nutrient quantities listed on a product label must be tested using "a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot."[23] But, for nutrients other than "vitamin[s], mineral[s], protein[s], total carbohydrate[s], dietary fiber[s], soluble fiber[s], insoluble fiber[s], [and] polyunsaturated or monounsaturated fat[s]," FDCA regulations are unclear on how much variability is allowed in test results before the labeled amount runs awry of the FDCA's "false or misleading" standard.[24]

III. The Practical Effects Of Preemption

Given that (1) the FDCA arguably preempts AB 45's labeling requirements that are "not identical' to" the FDCA's and (2) the FDCA and AB 45 have different labeling requirements, this creates an opportunity for litigants to argue that several of AB 45's labeling requirements are preempted. However, what practical effect will this have on labeling litigation against CBD companies? The answer, unsurprisingly, depends on the facts underlying each case.

Below we discuss how preemption affects labeling litigation in two hypothetical scenarios: (1) when CBD companies fail to include AB 45's required labeling and (2) when CBD companies misstate the amount of CBD or contaminants in their products. Lastly, we discuss how plaintiffs may argue

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16 21 C.F.R. 101.13(i).

17 CAL. CODE REGS. tit. 4, §§ 15714, 15718-23. These standards are the same as those for cannabis-derived CBD products and will remain in place until the Department of Public Health sets different standards specifically for hemp-derived CBD products.

18 CAL. CODE REGS. tit. 4, §§ 15719, 15720, 15723.

19 ROSIELYN PULMANO, ASSEMBLY FLOOR ANALYSIS, 3 (Sept. 2, 2021). 2021), https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=202120220AB45# (follow "09/09/21- Assembly Floor Analysis" hyperlink).

20 CAL. CODE REGS. tit. 4, §§ 15307-7.1.

21 CAL. CODE REGS. tit. 4, §§ 15704 (a), 15705(c).

22 21 U.S.C. § 101.9(g).

23 21 C.F.R. § 101.13(o); 21 C.F.R. 101.9(g)(2).

24 21 C.F.R. 101.13(i)(3); 21 U.S.C. 343(a).

AB 45 leaves CBD manufacturers without a preemption defense that other food companies often employ.

A. When CBD Companies Fail to Include AB 45's Required Labeling

One scenario likely to instigate litigation is when CBD companies fail to include AB 45's required labeling on their products sold in the state of California. This could cause the government to bring enforcement actions or private plaintiffs to bring Unfair Competition Law, California Consumers Legal Remedies Act, or other claims based on violations of AB 45's labeling requirements.

As discussed above, however, the FDCA does not require food labeling to include AB 45's warnings or a link to a certificate of analysis detailing CBD and contaminant content. This means that, because AB 45's requirements are not identical to the FDCA's, CBD companies can argue these requirements are "without effect"—*i.e.* they are unenforceable in court. This presents significant issues for those seeking to enforce AB 45's labeling requirements against companies that fail to include them. In fact, to the extent CBD companies leave these items off their labels, it is arguable that these labeling requirements may not be enforceable in court at all.

Similarly, should CBD companies fail to provide a publicly viewable certificate of analysis (as opposed to only failing to provide a link to it on their products' labels), CBD companies also have the ability to argue that this requirement is unenforceable in court. In the Ninth Circuit, "'[l]abeling' is construed broadly under the Food, Drug, and Cosmetic Act ('FDCA') and includes any article that 'supplements or explains' the product even if the article is not physically attached to it."[25] Given that the certificate of analysis is meant to "supplement[] or explain[]" CBD products, it can arguably be defined as "labeling" under the FDCA. Thus, because the FDCA does not require a certificate of analysis in connection with food labeling, AB 45's certificate of analysis labeling requirement is "not identical" to the FDCA. Accordingly, CBD companies can argue that AB 45's requirement for a publicly viewable certificate of analysis is "without effect" and unenforceable in court.

In conclusion, to the extent CBD companies leave AB 45's required items off their product labels, an argument can be made that attempts to enforce AB 45's labeling requirements in court are preempted.

B. When CBD Companies Include Inaccurate CBD Content or Contaminant Measurements on Product Labels

Another scenario likely to generate litigation is when CBD companies include inaccurate CBD content or contaminant measurements on their product labels. Just as in the previous scenario, this could cause the California government to bring enforcement actions or private plaintiffs to bring claims based on violations of AB 45's labeling requirements.

However, unlike lawsuits based on failure to include AB 45's required labeling, which FDCA preemption would arguably block, here the FDCA arguably has the opposite effect of permitting litigation. This is because, while the FDCA does not require CBD or contaminant content to be listed on food labeling, it nonetheless prohibits any voluntarily listed items from being "false or misleading

[25] *Sandoval v. Pharmacare US, Inc.*, 730 F. App'x 417, 420 (9th Cir. 2018).

in any particular."[26] Thus, if a private plaintiff or the government were to bring a claim based on inaccurately labeled CBD or contaminant content in violation of AB 45, such a claim would arguably not be seeking to enforce a requirement that is "not identical"' to the FDCA because the FDCA also prohibits "false or misleading" food labels.[27] In other words, because a claim for inaccurate labeling in violation of AB 45 targets a practice that is also a violation of the FDCA, plaintiffs may argue that the claim would not be preempted.[28]

In fact, when it comes to inaccurately labeled CBD or contaminant content, AB 45 may amplify the risk of labeling litigation against CBD companies. This is because it imposes several new requirements for labeling, including the listing of approximately 100 different contaminant levels, which otherwise would not be required on product labels. And, a misstatement of any of these contaminant levels has the potential to lead to lawsuits alleging the labeling was "false or misleading."

In short, due to the interplay between AB 45 and FDCA preemption, plaintiffs have the ability to argue that claims for inaccurately stated CBD and contaminant content are allowed.

C. A Preemption Defense Is Arguably Unavailable Against Claims Based on Inaccurately Stated CBD or Contaminant Content

Given that the FDCA likely does not bar all labeling litigation based on AB 45, it bears mentioning that the interplay between AB 45 and the FDCA also arguably deprives CBD companies of a preemption defense against claims based on inaccurately stated CBD or contaminant content.

Normally, food manufacturers faced with suits alleging they mislabeled the amount of calories or vitamins in a food can mount a preemption defense by showing the actual amounts of calories or vitamins in the food are within the allowable ranges set by the FDCA.[29] This is because the FDCA specifies the degree to which actual nutrient contents can vary from the labeled amounts, and any claim to the contrary would be "not identical" to the FDCA's requirements and thus preempted.[30] Accordingly, food manufacturers can use preemption as a potent shield against labeling litigation based on inaccurate nutrient-content claims.

However, if CBD companies are sued for "false or misleading" CBD or contaminant-content labeling, plaintiffs may argue that CBD companies cannot defend against these suits by showing the actual CBD or contaminant content levels in their products are within AB 45's allowable ranges. This is because, unlike the FDCA, AB 45 does not contain a provision stating contrary laws are preempted

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[26] 21 U.S.C. § 343(a); *see* 21 C.F.R. 101.13(i)(3)("the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if. . . The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (*e.g.*, '100 calories' or '5 grams of fat').").

[27] *See Reid v. Johnson & Johnson*, 780 F.3d 952, 962-63 (9th Cir. 2015).

[28] *Reid v. Johnson & Johnson*, 780 F.3d 952, 959 (9th Cir. 2015) (The FDCA's labeling provisions do not "preempt state law-based causes of action that are identical to the federal labeling requirements."); *Hawkins v. Kroger Co.*, 906 F.3d 763, 771-72 (9th Cir. 2018) (permitting UCL, CLRA, and other state law claims to proceed based on a label claiming a product contained "0g Trans Fat," given that the FDCA similarly prohibited statements that were "false or misleading in any way," and the FDCA did not otherwise authorize the "0g Trans Fat" statement on the label.).

[29] *Reyes v. McDonald's Corp.*, Nos. 06 C 1604, 06 C 2813, 2006 U.S. Dist. LEXIS 81684, at *23 (N.D. Ill. Nov. 8, 2006); *Chavez v. Church & Dwight Co.*, No. 17 C 1948, 2018 U.S. Dist. LEXIS 82642, at *12 (N.D. Ill. May 16, 2018); s*ee also CreAgri, Inc. v. USANA Health Scis., Inc.*, 474 F.3d 626, 631 n.11 (9th Cir. 2007); *Clay v. Cytosport, Inc.*, No. 15-cv-165 L (DHB), 2015 U.S. Dist. LEXIS 110447, at *11 (S.D. Cal. Aug. 19, 2015).

[30] 21 C.F.R. 101.9(g)(4)-(6).

or that compliance with its terms provides a defense against such suits. Hence, CBD companies arguably cannot dispatch with labeling suits just by showing they complied with AB 45's labeling requirements. Further, because the FDCA arguably does not set forth acceptable ranges for CBD or contaminant levels, plaintiffs may argue that CBD companies also cannot avail themselves to a preemption defense under the FDCA.

Thus, although AB 45 imposes several additional labeling requirements on CBD companies, it may leave them without the preemption defense that is usually available to food companies.

IV. Where Does This Leave CBD Companies?

The dynamic between AB 45 and the FDCA leaves CBD companies in a peculiar place. On one hand, leaving CBD content and contaminant claims off their labels may reduce their exposure to labeling litigation because the FDCA arguably preempts claims seeking to enforce these requirements. CBD companies that do this, however, run the risk of irking the Department of Public Health, which may result in their CBD products getting embargoed[31] or their authorization to manufacture hemp products getting revoked.[32] On the other hand, CBD companies that include AB 45's required CBD content and contaminant labeling on their products may risk increased exposure to litigation and loss of the ability to raise a preemption defense by pointing to compliance with the FDCA.

This outcome likely was not intended by the California Legislature when drafting and passing AB 45 given that FDCA preemption was not addressed in the bill's official analyses.[33] However, because of the interplay with the FDCA, AB 45 creates opportunity for lawsuits over CBD product labeling. Thus, once litigation begins to arise, it will be important to monitor how courts treat the preemption issues that result.

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If you have any questions about the issues addressed in this Client Alert, or if you would like a copy of any of the materials we reference, please do not hesitate to contact us:

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31 CAL. HEALTH & SAFETY CODE §§ 111860, 111927.
32 CAL. HEALTH & SAFETY CODE §§ 111923.5, 111927.2.
33 *E.g.* SENATE COMMITTEE ON AGRICULTURE, INDUSTRIAL HEMP PRODUCTS 6-7 (July 1, 2021), https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=202120220AB45#.