The CBD problem: searching for a legal pathway for CBD in foods and supplements

Product Liability Alert

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When the 2018 Farm Bill removed hemp from the definition of marijuana − and thus from the list of Schedule I drugs under the Controlled Substance Act (CSA) – it unlocked an industry ripe for expansion. Sales of products containing cannabidiol (CBD), are booming – indeed, analysts predict that CBD sales could become a $15-$20 billion industry by 2025.[1]

However, CBD companies are still faced with a regulatory quagmire, struggling to understand how to legally promote, label, and distribute CBD consumables in light of the FDA gridlock, inconsistent state laws, and uncertainty as to which pathway will result in a viable resolution.

Current regulatory landscape: Farm Bill, FDA, and state laws

The 2018 Farm Bill

On December 20, 2018, President Donald Trump signed into law the Agriculture Improvement Act of 2018, Pub. L.

No. 115-334 (2018 Farm Bill), which included a number of actions related to defining and removing hemp from the CSA First, the 2018 Farm Bill defined "hemp" as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." Section 12619 of the 2018 Farm Bill lays out conforming changes to the CSA, with the most significant change being the explicit removal of "hemp" from the term "marihuana." [2] That same section also excluded THC in hemp from the term "tetrahydrocannabinols" in Schedule I. [3] By making these amendments to the CSA, Congress effectively declassified hemp (as well as THC in hemp) as a Schedule I drug. These changes to the CSA removed any doubt as to Congress' intent to remove hemp from the purview of the CSA.[4]

Under the 2018 Farm Bill, "hemp and hemp products" produced in accordance with the 2018 Farm Bill – *ie,* pursuant to a USDA-approved hemp plan – are expressly permitted to be sold in interstate commerce. However, the 2018 Farm Bill does not define "hemp products," and thus it does not expressly address the ability to add substances like hemp-derived CBD to specific consumer products, such as conventional foods and dietary supplements.

Congressional intent appears to be in favor of hemp-derived CBD being permissible in consumer products, including consumables (as to do otherwise would effectively undermine the ability to sell hemp-derived CBD, defeating much of the purpose of the Bill) − but the Farm Bill does not expressly (or implicitly) contemplate the regulatory complexities and the impact of FDA regulations associated with adding CBD as a new ingredient into the food supply.

Of particular significance is that the 2018 Farm Bill did not address or acknowledge FDA regulations that prohibit substances that have been subject to drug trials and/or approved as a drug from being added to foods or supplements (the "prior drug exclusion"). The prior drug exclusion prohibits adding an active pharmaceutical ingredient to foods, or marketing a product containing an active pharmaceutical ingredient as a dietary supplement, unless the drug was marketed in foods or dietary supplements before the drug was approved and before it was subject to substantial clinical investigations.[6]

At present, the FDA is unaware of any evidence that CBD was marketed in foods or dietary supplements prior to it being subject to substantial clinical investigations.[7] As a result, even though the Farm Bill removes hemp from the CSA and permits hemp products to be sold in interstate commerce, foods and supplements are still prohibited from using CBD as an ingredient due to the FDA prior drug exclusion.

2. FDA landscape

The Farm Bill explicitly **preserves FDA's authority to regulate products containing cannabis or cannabis-derived compounds** under the FD&C Act and section 351 of the Public Health Service Act (PHS Act).[8] This means that FDA still treats hemp and hemp-derived CBD as subject to the same regulatory and safety requirements as any other ingredient.

In June 2018, the agency approved Epidiolex, the first drug with CBD derived from the cannabis plant. Of note: as a result of this approval, the prior drug exclusion precludes hemp-derived CBD from being added to conventional foods or dietary supplements.[9] Unless Congress or FDA creates a workaround to the prior drug exclusion, CBD remains impermissible in conventional foods and dietary supplements at the federal level, and thus there is potential risk that any such product containing CBD could be deemed adulterated.

FDA publications and commentary, including from FDA's former Commissioner Scott Gottlieb and current Principal Deputy Commissioner Amy Abernethy, have clearly articulated FDA's position that the prior drug exclusion makes it illegal to include CBD in dietary supplements or foods.[10] At the same time, the FD&C Act provides, and FDA clearly acknowledges, that FDA has authority, in its discretion, through notice-and-comment rulemaking, to issue a regulation exempting a substance from the prior drug exclusion and approving the use of such substance in food or finding that it would be lawful in dietary supplements.[11] This process, FDA estimates, could take three to five years.[12] To date FDA has never issued such a regulation for any substance,[13] nor does the legislative history provide guidance on how such a process would work.[14]

There is an equal lack of interpretation of the prior drug exclusion to be found in regulatory enforcement or litigation involving other products and ingredients. Such matters have only increased the level of confusion, raising questions about the significance of the comparative molecular composition, concentration, and dose of CBD for

introduction into the consumables market as compared to the composition, concentration, and dose found in Epidiolex.[15] Do these questions form the basis for a distinction between the current ingredient and the prior drug such that the exclusion would not apply?

And of course, even if FDA did create an exemption to the prior drug exclusion, that would not obviate the need to determine safety. As Principal Deputy Commissioner Abernethy stated in her testimony, "If [FDA] were to create an exception under one provision of the FD&C Act, but other provisions of the statute still barred products from coming to market, our action could end up generating additional confusion in the marketplace."[16] Former FDA Commissioner Gottlieb has indicated one potential alternative approach could be for FDA to exercise enforcement discretion (perhaps only temporary) with respect to certain CBD products under specified conditions while FDA assesses the safety of CBD through New Dietary Ingredient Notifications (NDINs) or food additive petitions.[17] In other comments, he has also indicated that Congress could help alleviate the administrative burden by passing legislation to the effect that FDA need not undertake rulemaking to create the exemption from the prior drug exclusion; instead, it could address the safety of CBD through its assessment of NDINs or food additive petitions.[18]

To date, FDA has not committed to any particular path for resolution.

3. State laws

To complicate matters, individual states have begun implementing their own state-specific hemp laws. These approaches, predictably, are inconsistent. (And, at this writing, bills are pending in several state legislatures).

As a general trend, states that have passed hemp laws tend to permit use of hemp in both foods and supplements.[19] For example, Florida, Oregon, New Jersey, Indiana, Colorado, Kentucky, New Hampshire, Nevada, Ohio, and Virginia have passed laws and/or regulations regarding hemp consumables, and these states permit (or appear to permit where language is otherwise gray) hemp-derived CBD in both foods and dietary supplements.

However, each individual state's regulations may differ on key issues, such as retailer licensing and product labeling. States have adopted varying approaches when it comes to hemp and hemp products processed in another state, with at least one state (Maine)[20] only allowing hemp-derived CBD consumables that are produced and sold within that state, whereas other states allow hemp products processed in a different state where the hemp and hemp products are processed lawfully under another state's hemp laws or in a manner that is generally consistent with the state's hemp requirements.[21] In some cases, even states that appear to contemplate the use of hemp in food may still impose unique state-specific restrictions by guidance. Vermont, for example, prohibits the use of hemp in meat, milk, and dairy products.[22]

In states where no hemp regulations have yet been issued, the general trend is for the state to take a position (often through a guidance statement) clarifying that hemp is not permitted in foods or supplements and typically aligning with FDA's position regarding the prior drug exclusion pending formal amendments to FDA regulations. For example, Washington, New York, California, Massachusetts, Pennsylvania, Michigan, North Carolina, and Minnesota have implemented no formal hemp regulations, but have issued guidance indicating alignment with FDA.[23] However, notably, several of the same states that do not currently permit hemp-derived CBD in foods and supplements (including New York, California, Massachusetts, Pennsylvania, and North Carolina) have pending bills that would likely permit such use upon passage and implementation.

Overall, the state-specific landscape is changing constantly, on an almost weekly basis, and the clear trend is toward states permitting CBD in consumables – this despite FDA's clearly articulated position that hemp is not permitted in foods and supplements pending issuance of regulations that would permit such use.

Potential pathways for resolution

While it appears both Congress and FDA are committed to finding a solution to the CBD problem, the answer is not straightforward. In the meantime, both the industry and individual states are pushing forward. Many agree that something must change, but the real question is: specifically what?

To recap, the challenge in finding the regulatory pathway forward for CBD arises from the intersection of these issues:

A. The 301(ll) and 201(ff) drug exclusions, which FDA has concluded apply to CBD
B. The provision in each of those sections authorizing the Secretary of HHS – in reality, the FDA – at its discretion to issue a regulation that creates an exception from the drug exclusion, given that there is no precedent for the issuance of such a regulation, and
C. FDA's statutory obligations to ensure the safety of food and dietary supplements through the application of the statutory and regulatory regimes governing GRAS substances, food additives, and new dietary ingredients.

The intersection of these issues has given rise to widespread uncertainty as to how the agency should go about fulfilling both (B), establishing an exemption from the drug exclusions, and (C), evaluating the safety of CBD for use in foods and dietary supplements.

Based in part on FDA guidance and commentary from former Commissioner Gottlieb and Principal Deputy Commissioner Abernethy, along with existing regulatory parameters, the use of CBD in foods and dietary supplements could come about in several potential ways, including:

1. Congress passes a law that allows FDA to effectively bypass the prior drug exclusion, leaving FDA to conduct the safety assessment (*ie,* FDA would still have to determine that CBD satisfies the NDI, GRAS, or food additive requirements).
2. FDA undertakes a formal notice-and-comment rulemaking process to create an exemption to the prior drug exclusion (this could take three to five years), while also conducting the safety assessment.
3. FDA exercises temporary enforcement discretion with respect to CBD products that meet specific parameters, while also conducting the safety assessment. Notably, while former Commissioner Gottlieb raised this possibility, it would merely be a temporary fix; ultimately, the prior drug exclusion would have to be addressed through (1) or (2).

Regardless of the avenue, **the lynchpin in all scenarios is determining that CBD is safe for use in conventional foods and dietary supplements**. Public statements by Principal Deputy Commissioner Abernethy, by former Commissioner Gottlieb, and in FDA's April 3, 2019, Federal Register announcement suggest that for FDA to approve the use of CBD in food or to find that it would be lawful in dietary supplements, the agency would have to be satisfied that CBD is safe for such use under the existing statutory/regulatory regimes that govern GRAS substances, food additives, and new dietary ingredients. FDA will have to address this foundational requirement regardless of any other legislative or regulatory fixes. As a result, it seems likely that, if FDA were to undertake the formal notice-and-comment rulemaking process, the agency would first need to be satisfied that CBD is safe for use in order to justify creating an exclusion to the prior drug exclusion. Even if Congress expedited the process by enacting legislation that relieved FDA from notice-and-comment rulemaking, FDA would still have to be persuaded that CBD would be safe for use in foods and dietary supplements under the existing statutory/regulatory regimes.

The ongoing struggle for clarity

The federal regulatory pathway to CBD being permitting in foods and dietary supplements has yet to be determined. While several potential pathways can be identified, there is currently no clear conclusion as to which pathway is favored or which provides the most beneficial outcome for all parties. At the least, safety will be a critical requirement and industry will play an important part in developing the necessary body of evidence. In the interim, we can expect states to continue passing their own laws in an attempt to create a regulatory structure that allows CBD products to be commercialized.

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[1] New York-based investment bank Cowen & Co estimates that the CBD market could be $16 billion by 2025 (*Cowen's Collective View of CBD* (Feb. 25, 2019), available here), while Boulder-based BDS Analytics estimates the CBD market could be $20 billion by 2024 (*U.S. CBD Market Anticipated to Reach $20 Billion in Sales by 2024* (May 9, 2019), available here).

[2] The CSA uses the spelling "marihuana" when referring to the otherwise common term, marijuana. *See also* 21 U.S.C. § 802(16) (CSA Definition of "Marihuana"). This article uses the common term "marijuana" except when referring specifically to the CSA term as noted here.

[3] *See* Sec. 12619 of the 2018 Farm Bill

[4] In addition, on August 27, 2019, the Drug Enforcement Agency (DEA) published a federal register notice (84 FR 44920) affirming that as a result of the 2018 Farm Bill, hemp, including hemp plants and CBD preparations at or below the 0.3 percent THC threshold, does not require a DEA registration to grow or research it. *See* DEA, Press Release, *DEA announces steps necessary to improve access to marijuana research* (Aug. 27, 2019), available here.

[5] *See* Sec. 10114(b) of the 2018 Farm Bill.

[6] *See* Sec. 301(ll) of the FD&C Act, 21 U.S.C. § 331(ll), and Sec. 201(ff)(3)(B), 21 U.S.C. § (ff)(3)(B).

[7] *See* FDA Q&A, Abernethy Testimony.

[8] *See* Sec. 297D of the 2018 Farm Bill.

[9] *See* Sec. 301(ll) of the FD&C Act, 21 U.S.C. § 331(ll), and Sec. 201(ff)(3)(B), 21 U.S.C. § (ff)(3)(B).

[10] FDA, *Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers*, at Nos. 9 and 10 (Apr. 2, 2019), available here (hereinafter, FDA Q&A). In FDA's July 2019 consumer update, FDA again stated that "We are aware that there may be some products on the market that add CBD to a food or label CBD as a dietary supplement. Under federal law, it is currently illegal to market CBD this way." FDA, *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD* (July 17, 2019), available here. *See* FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to advance agency's continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products* (Apr. 2, 2019), available here; *see also* Testimony of Amy Abernethy, Principal Deputy Commissioner, Office of the Commissioner, FDA, Department of Health And Human Services before the Senate Committee on Agriculture, Nutrition, and Forestry, *Hemp Production and The 2018 Farm Bill*, (July 25, 2019), available here ("CBD cannot be marketed as a dietary supplement, and foods to which CBD has been added cannot be introduced into interstate commerce under the FD&C Act.") (hereinafter, Abernethy Testimony).

[11] *See* 21 U.S.C. § 331(ll)(2) (applying to foods) and 21 U.S.C. § 321(ff)(3)(b) (applying to dietary supplements)

[12] *See* Abernethy Testimony, at 3-4 ("It is important to note that it can take three to five years to complete even an expedited notice and comment rulemaking process that complies with the Administrative Procedure Act and other requirements.").

[13] *See* FDA Q&A Nos. 9 & 10.

[14] See, *eg*, *Pharmanex v. Shalala*, 221 F.3d 1151, 1158 (10th Cir. 2000) ("Turning to the legislative history, we find that the intended application of § 321(ff)(3)(B) is not elucidated, but rather becomes less clear. First of all, the Senate Report upon which the district court relied, and which Pharmanex now invokes, was explicitly disclaimed as a source of legislative intent. *See* Statement of Agreement, 140 Cong. Rec. S14801 (Oct. 7, 1994), *reprinted in* 1994 U.S.C.C.A.N. 3523 ('It is the intent of the chief sponsors of the bill ... that no other reports or statements be considered as legislative history for the bill.').").

[15] An argument could also be made that when hemp and hemp-derived CBD, when added to foods or supplements in naturally occurring levels, does not even fall within the prior drug exclusion.

[16] Abernethy Testimony, at 3-4.

[17] Scott Gottlieb, *Opinion: The CBD craze is getting out of hand. The FDA needs to act*, Washington Post (July 30, 2019), available here.

[18] *Id.*

[19] Based on a sampling of 25 states and the District of Columbia − New York, California, Illinois, Florida, Massachusetts, Texas, Oregon, New Jersey, Washington, Indiana, Colorado, Kentucky, Pennsylvania, Vermont, New Hampshire, Arizona, Nevada, Ohio, Michigan, Georgia, Virginia, North Carolina, Minnesota, Maryland, and Tennessee.

[20] Earlier this year, Maine passed a bill clarifying that food, food additives and food products containing hemp-derived CBD are allowed only if such products are produced and sold within the state of Maine. *See* LD 360, *An Act To Clarify That Food, Food Additives and Food Products Containing Hemp-derived Cannabidiol Produced and Sold within the State Are Not Adulterated and To Match the State's Definition of "Hemp" to the Definition in Federal Law* (approved by Governor on March 27, 2019), available here.

[21] *See, eg*, Texas (Sec. 443.206 of HB 1325), and New Jersey (Section 9(e) of A5322/S3686).

[22] *See* Vt. Stat. Ann. tit. 6, c. 34 § 562 ("'Hemp products' or 'hemp-infused products' means all products made from hemp, including cloth, cordage, fiber, food, fuel, paint, paper, construction materials, plastics, seed, seed meal, seed oil, and certified seed for cultivation."); *see also* Vermont Agency of Agriculture, Food & Markets, *Hemp, CBD, Cannabinoids as ingredients in foods and feeds in Vermont*, available here (clarifying that the Vermont Agency of Agriculture is responsible for regulating additives and adulterants in Meat and Dairy/Milk Products, and cannabinoids are not permitted in either category of product).

[23] We note that Georgia is an outlier in that it has implemented hemp regulations, which expressly state that hemp may not be used in "food products" unless approved by FDA. Georgia Hemp Farming Act, HB 213, § 2-23-3(6), available here.

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