Legal Backgrounder

Vol. 35 No. 12 May 8, 2020

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

FDA's Ongoing Review of CBD and its Impact on Class Action Litigation

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Shortly after the signing of the Farm Bill in December 2018,[1] the Food and Drug Administration (FDA) acknowledged the "growing public interest" in hemp-derived cannabidiol (CBD) dietary supplement and food products and committed to "take steps to make the pathways for the lawful marketing of these products more efficient."[2] One year and 22 Warning Letters later—not including those issued prior to December 2018—the FDA has yet to provide any clarity about the lawful marketing of CBD, or even indicate a proposed timeline for such action. In the meantime, states have moved forward with their own rules for CBD products, creating an inconsistent patchwork of requirements for these products. More recently, class action plaintiffs have targeted the industry in what is arguably an attempt to privately enforce the Federal Food, Drug, and Cosmetic Act (FD&C Act) and in violation of the well-established primary jurisdiction doctrine.

Continued FDA Inaction

The 2018 Farm Bill removed hemp and its constituents (including CBD) from the federal controlled substances list, meaning the botanical would no longer be classified as a Schedule I substance under the Controlled Substances Act. Hemp is now distinguished from its counterpart—marijuana—based on THC levels and hemp must contain no more than 0.3% THC on a dry-weight basis. Many in the dietary supplement and food industries, as well as Members of Congress, presumed this action permitted the sale of CBD in ingestible form as supplements and food.

The Farm Bill, however, includes language that expressly preserves FDA's authority to regulate hemp products under the current FD&C Act provisions. These provisions contain a lesser-known limitation on the use of an ingredient in supplements and food based on prior drug approval or significant investment in research and development. Sometimes called "drug preclusion" or "IND preclusion," under §201(ff)(3)(B) of the FD&C Act,[3] a substance may not be used as a dietary ingredient if it includes "an article" that was first (1) approved as a new drug or (2) approved as an investigational new drug (IND) "for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public." FDA can, however, through notice-and-comment rulemaking, enact regulations allowing the substance to be used in dietary supplements and food, despite its use first as a drug. FDA has taken the position that the CBD drug Epidiolex was an investigational new drug that meets the requirements to preclude CBD use in dietary

[1] Agriculture Improvement Act of 2018, Pub. L. 115-334.

[2] Statement of FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds, December 20, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys (December 2018 Gottlieb Statement).

[3] 21 U.S.C. § 321(ff)(3)(B). A similar provision governs the relationship between food and approved drug ingredients or those ingredients subject to substantial clinical investigation. FD&C Act § 301(ll) (21 U.S.C. § 331(ll)).

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supplements and food.

Prior to the CBD debate, the most notable FDA application of §201(ff)(3)(B) involved the monacolin K content of red-yeast rice and whether it was the same "article" as a substance (called lovastatin) found in a drug approved to treat high cholesterol. In 1997, FDA took action against a manufacturer for allegedly engineering a product to have lovastatin levels similar to those found in the approved drug and which marketed the product to pharmacists based on those similarities.[4] FDA suggested that red-yeast rice could still be a legal supplement as long as the substance monocalin K was found at naturally occurring levels. FDA has neither provided clarity on how a company would determine a "naturally occurring level" nor has it offered any other parameters to help companies interested in selling similarly-situated substances (*e.g.,* hemp-extract products that contain naturally-occurring CBD) distinguish their product from a drug article.

FDA is also reading additional requirements into the statute that Congress arguably did not intend. The IND preclusion language was intended to protect drug companies' investment in research and development—nowhere in the provision's statutory language or legislative history did Congress indicate preclusion should be premised on ingredient safety.[5] Yet, FDA has indicated that the agency will not move forward with rulemaking "[i]f we don't think we'll have the data to say that some level of CBD can be safely added to a food or dietary supplement."[6] This position also ignores the current FDA regulatory framework for supplements and food. An FDA decision to remove the preclusion barrier does not mean an ingredient can be used in dietary supplements or food regardless of safety or other regulatory requirements; rather, CBD would then be considered a dietary supplement or food subject to all other FDA regulatory requirements for these products (*e.g.,* safety determinations, labeling, manufacturing requirements, etc.).

Class Action Fallout

The continued uncertainty around CBD has stimulated a significant increase in consumer class action lawsuits. Following the most recent statements and Warning Letters FDA issued in November 2019, private plaintiffs filed a wave of class actions against CBD product marketers. CBD lawsuits filed before FDA's 2019 actions targeted "THC Free" or "No THC" claims where the products contained trace levels or low amounts of THC and their consumption allegedly caused plaintiffs to fail employer-mandated drug tests. Other initial lawsuits involved label-content claims in which the plaintiffs alleged the products did not contain the amount of CBD listed on the label.

This latest round of class actions focus on CBD products that plaintiffs claim are illegally labeled and marketed as dietary supplements or food (among other allegations), based on FDA's statements and its position outlined in Warning Letters.[7] Defendants in such federal-law and state consumer-fraud and deceptive-practices lawsuits can make primary-jurisdiction and preemption arguments. Courts could apply one of those defenses to stay or dismiss CBD-related claims—something one court has already done.

In that case, *Snyder v. Green Roads*, the plaintiffs alleged that the defendant misrepresented the amount of CBD contained in various CBD products. The court stayed the case pursuant to the primary

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[4] Letter from William B. Schultz, FDA to Stuart Pape re: Pharmanex, Inc., Docket No. 97P-0441 (May 20, 1998). The manufacturers of the product in question challenged FDA's interpretation of "article" in a case that went up to the Tenth Circuit. *Pharmanex, Inc., v. Shalala*, 221 F.3d 1151 (10th Cir. 2000). That case focused on the scope of the term "article" and whether an "article" could be considered a single-drug active ingredient or was meant to refer to the approved drug itself. The court determined that "article" could refer to either but gave no guidance on the issue of when a substance was the same as a single-drug active ingredient.

[5] *See e.g.*, S. Rep. 103-410, Part V, § 3 (1994); 140 Cong. Rec. S11,709 (daily ed. Aug. 13, 1994).

[6] Remarks by Lowell Schiller, JD at the Council for Responsible Nutrition Conference (Nov. 7, 2019), https://www.fda.gov/news-events/speeches-fda-officials/remarks-lowell-schiller-jd-council-responsible-nutrition-conference-1172019-11072019

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[7] *See*, *e.g.*, *McCarthy v. Elixinol, LLC,* Case No. 5:19-cv-07948 (N.D. Cal).

jurisdiction doctrine after finding that the plaintiff's claims implicate FDA's expertise on a regulated product.[8] The court specifically cited FDA's active and ongoing review of CBD and the need for uniform, consistent guidance from the agency, which is a key primary-jurisdiction-doctrine factor. Notably, however, one court recently rejected a defendant's request for a stay in a case based on similar allegations, agreeing with the plaintiff that any potential new FDA regulations would not change the requirements for disclosing ingredient content.[9]

Unlike cases targeting CBD content claims, the primary jurisdiction doctrine is even more relevant in the cases alleging that manufacturers are falsely advertising CBD products as dietary supplements or food. *Snyder v. Green Roads* will likely be instructive, with courts staying or possibly dismissing these cases as well given CBD's uncertain regulatory status. Despite the numerous FDA Warning Letters and statements on the illegality of CBD supplements and foods, courts and even FDA itself have recognized that Warning Letters are not considered legally binding final agency actions.[10] FDA's informal public policy statements also have no force of law. In addition, FDA has yet to articulate the scope of the IND preclusion and to what types of CBD-containing hemp products it applies, which further underscores the need for FDA to provide clear regulatory guidance for this product category. To be sure, even the court in the *Green Roads* case noted that "FDA regulations currently provide little guidance with respect to whether CBD ingestibles, in all their variations are food supplements, nutrients or additives and what labelling standards are applicable to each iteration."[11]

One could also argue that plaintiffs' "false advertising" cases are nothing more than impermissible private enforcement of the FD&C Act in violation of 21 U.S.C. § 337(a).[12] The IND prelusion and the definition of "dietary supplement" central to the allegations are contained solely in the FD&C Act and not in the state laws plaintiffs in which plaintiffs cloaked their claims. FDA has sole authority to enforce the FD&C Act, and courts have dismissed cases that attempt to side-step FDA's enforcement powers.[13] For instance, one California federal district court found that §337(a) impliedly preempted a lawsuit under California's Sherman Food, Drug & Cosmetic Law alleging that a dietary ingredient was an adulterated "new" dietary ingredient. The court reasoned that the lawsuit constituted private enforcement of the federal law because only the FD&C Act sets forth rules for "new" dietary ingredients.[14] Likewise, the plaintiffs' state-law false advertising relate to the classification of products as a "dietary supplement," a question that only FDA can resolve through its application of the FD&C Act.

The States and Congress

Notably, FDA inaction has also led many states to develop their own regulatory frameworks for hemp and CBD products, in some instances expressly legalizing the use of CBD in dietary supplements and food despite FDA's position. As states continue to view the growth of the industry alongside a perceived federal vacuum, state regulators are stepping in to provide clarity where FDA has not. The result is a patchwork of state rules for testing, labeling, and registering hemp and CBD products, creating logistical challenges for industry and confusion especially for consumers. Even if FDA were to clarify the pathways for CBD in food and supplements, it appears unlikely that states would roll back these comprehensive regulatory schemes absent express preemption at the federal level.

Congress is also carefully watching FDA's next steps and the growing class action threat. Federal

[8] *Snyder et al. v. Green Roads of Florida LLC*, Case No. 0:19-cv-62342 (S.D. Fla.).
[9] *Potter v. PotNetwork Holdings Inc. et al.*, Case No. 1:19-cv-24017 (S.D. Fla.).
[10] FDA Regulatory Procedures Manual § 4-1-1, Warning Letter Procedures.
[11] *Id.* at 15.
[12] This provision provides, in part, that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."
[13] *See*, *e.g.*, *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013).
[14] *Dabish v. MusclePharm Corp*., 2016 U.S. Dist. LEXIS 191885 at 15 (S.D. Cal 2016).

ISBN 1056 3059

legislation to amend the IND preclusion and allow the use of a hemp-derived CBD as a food or dietary-supplement ingredient is currently under consideration.[15] However, some Members of Congress have expressed reservations about deciding the course of CBD ahead of FDA, especially in light of the agency's safety concerns. Such action would also be unprecedented, as Congress has never legislated about a particular ingredient this manner. If FDA inaction continues—along with more lawsuits—Congress could possibly step in and dictate the regulatory pathways for CBD.

Some insight from FDA may be on the way, although the timing remains unclear. FDA recently provided Congress with a progress report on its review of CBD, as Congress directed in report language accompanying a FY2020 Appropriations bill, with another report on the CBD marketplace due later this year.[16] The report, which arrived about two weeks after Congress's deadline, sheds some light on the agency's ongoing efforts to further study the potential uses of CBD outside the drug context, but did not provide a much-needed timeline.[17] Therefore in the continued absence of clear direction from FDA, class action litigation may continue—along with increased and varying state regulation of CBD products creating more uncertainty for both industry and consumers.

[15] H.R. 5587, 116th Congress (2019-2020).

[16] "Within 60 days of enactment of this Act, the FDA shall provide the Committees with a report regarding the agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion and the process in which CBD meeting the definition of hemp will be evaluated for use in products. The FDA is further directed to perform a sampling study of the current CBD marketplace to determine the extent to which products are mislabeled or adulterated and report to the Committees within 180 days of enactment of this Act." Division-Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2020, Congressional Directives (Dec. 16, 2019), https://docs.house.gov/billsthisweek/20191216/BILLS-116HR1865SA-JES-DIVISION-B.pdf.

[17] Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations, Cannabidiol (CBD), (Mar. 5, 2020), https://hempsupporter.com/assets/uploads/FDA-CBD-Report.pdf.

  ISBN 1056 3059