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Product Liability Cases: Cannabis Products

As an increasing number of states legalize and regulate the recreational and medical use of cannabis products, manufacturers of those products have become the subjects of state product liability actions. The Food and Drug Administration ("FDA") has yet to issue a formal rule or regulation governing the manufacture, sale, and labelling of cannabis-derived compounds. This article explores two defenses that cannabis product manufacturers may employ against product liability lawsuits involving the rules, or lack thereof, promulgated by the FDA: (1) the doctrine of "primary jurisdiction," in which a court defers its power to hear a case pending the determination of various issues within the FDA's competence; and (2) the doctrine of preemption, in which a state product liability claim is preempted by any rule ultimately promulgated by the FDA or by Congressional statute.

1. Brief Overview of the FDA's Actions

"Cannabis" refers to a plant of the *Cannabaceae* family and contains more than eighty biologically active chemical compounds. FDA Regulation of Cannabis and Cannabis-Derived Products, including Cannabidiol ("CBD"), U.S. Food & Drug Admin., https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#farmbill (last visited Nov. 30, 2020). Two well-known compounds derived from this plant are delta-9-tetrahydrocannabinol ("THC") and cannabidiol ("CBD"). "Hemp" refers to the plant or any part of it that contains less than 0.3% THC by dry weight; by contrast, "marijuana," also derived from the same plant, contains a higher THC concentration. *See* FDA Regulation of Cannabis and Cannabis-Derived Products, including Cannabidiol ("CBD"), U.S. Food & Drug Admin., https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#farmbill (last visited Nov. 30, 2020); *see*7 U.S.C.A. § 1639*o*(1) (defining "hemp"); 7 C.F.R. § 990.1 (2019) (defining marijuana).

Congress recently enacted legislation relating to some, but not all, cannabis products. Under the Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 32 Stat. 4490 ("2018 Farm Bill"), hemp is no longer considered a controlled substance under federal law. FDA Regulation of Cannabis and Cannabis-Derived Products, including Cannabidiol ("CBD"), U.S. Food & Drug Admin.. The 2018 Farm Bill was silent, however, regarding cannabis products containing more than 0.3% THC or any concentration of CBD. *See* FDA Regulation of Cannabis and Cannabis-Derived Products, including Cannabidiol ("CBD"), U.S. Food & Drug Admin. Indeed, the FDA has stated that the 2018 Farm Bill "explicitly preserved [its] authority to regulate products containing cannabis or cannabis-derived compounds [including hemp] under the Federal Food, Drug, & Cosmetic Act ("FDCA") and … the Public Health Service Act." FDA Regulation of Cannabis and Cannabis-Derived Products, including Cannabidiol ("CBD"), U.S. Food & Drug Admin.

Since 2018, the FDA has issued warning letters and consumer updates providing informal guidance on the production and sale of cannabis products, but has yet to promulgate any formal rule or regulation governing such products. On May 31, 2019, the FDA held a public hearing to "obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds." Scientific Data and

Information about Products Containing Cannabis or Cannabis-Derived Products; Public Hearing (May 31, 2019), U.S. Food & Drug Admin., https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds (last visited Nov. 30, 2020). Six months later, on November 25, 2019, the FDA issued warning letters to fifteen CBD product sellers, indicating that they had violated the FDCA by espousing unproven medical claims in their marketing. FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns (November 15, 2019), U.S. Food & Drug Admin., https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details (last visited Nov. 30, 2020). The FDA further published a revised Consumer Update noting that certain "CBD products are being marketed with unproven medical claims and could be produced with unsafe manufacturing practices." What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD, U.S. Food & Drug Administration (November 15, 2019), https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis (last visited Nov. 30, 2020). The FDA also noted that it was "continuing to evaluate the regulatory frameworks for products containing cannabis and cannabis-derived compounds." What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD, U.S. Food & Drug Administration.

In July 2020, the FDA issued non-binding draft guidance relating to clinical research standards for the development of cannabis and cannabis-derived drug products. Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research Guidance for Industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cannabis-and-cannabis-derived-compounds-quality-considerations-clinical-research-guidance-industry (last visited Nov. 30, 2020). Comments to the guidance were received in September 2020. The guidance addresses manufacturing and testing issues for FDA regulatory submissions. Among other things, the guidance specifies the sources of cannabis that may be used in drug development, information of quality considerations, and recommendations regarding the proper calculation of THC levels. See FDA In Brief: FDA Issues Draft Guidance to Encourage Cannabis-Related Clinical Research, https://www.fda.gov/news-events/fda-brief/fda-brief-fda-issues-draft-guidance-encourage-cannabis-related-clinical-research (last visited Nov. 30, 2020).

2. Product Liability Lawsuits in the Context of Cannabis or Cannabis-Derived Compounds

As states continue to broadly legalize cannabis products, product liability claims against manufacturers of such products will likely increase. Under most state product liability laws, a product may be considered unreasonably dangerous and thus defective in three general ways: (1) when it contains a manufacturing defect that departs from the product's intended design; (2) when it contains a design defect, whereby the foreseeable risks of the product could have been reduced by use of a reasonable alternative design; or (3) when it is defective due to inadequate labels or warnings. *See, e.g.*, Restatement Third, Torts: Product Liability, § 2.

Plaintiffs may creatively assert any of these claims against manufacturers or distributors of cannabis products. For example, a plaintiff might allege that an edible cannabis product contains high concentrations of THC that render it defective in design or, if a certain batch of the product varies from the product's specified THC quantity, that it contained a manufacturing defect. If a manufacturer failed to warn of certain risks or side effects associated with its cannabis products, it could be subject to a claim for inadequate warnings or instructions. Plaintiffs may rely on non-binding guidance issued by the FDA in support of these claims.

The FDA's failure to, as yet, promulgate formal rules or regulations governing cannabis products presents the manufacturers with at least one defense against product liability claims, while any rules the FDA ultimately issues may present manufacturers with another.

3. Potential Defenses in Product Liability Case

A. The Doctrine of Primary Jurisdiction

In the absence of specific formal guidance from the FDA, a manufacturer or distributor of cannabis products can legitimately move to stay a product liability suit on the basis of primary jurisdiction. "Primary jurisdiction" refers to the "deferral by a court of its power to hear a case, pending administrative determination of issues particularly within agency competence." 5 Administrative Law § 47.01 (2019). Although the Supreme Court has said that "[n]o fixed formula exists for applying the doctrine of primary jurisdiction," courts have applied a variety of factors in determining whether application of the doctrine is appropriate. *See* United States v. Western Pac. R. R. Co., 352 U.S. 59, 64 (1956). These factors include, but are not limited to, whether there is a "substantial danger of inconsistent rulings;" whether the issue has "already been addressed by the agency;" whether "judicial economy is better served by having the agency decide the question;" whether referral will "result in substantial delay and added expense;" and whether the "defendant could be subject to conflicting orders." 5 Administrative Law § 47.01 (2019) (citing case law from different circuits).

Applying these factors, plaintiffs in cannabis product liability suits face the real possibility of a court's stay given the FDA's lack of formal guidance on production, distribution, and marketing of cannabis products. The Southern District of Florida recently relied upon primary jurisdiction to grant a motion to stay a lawsuit relating to the labelling of cannabis products. *See* Snyder v. Green Rds. of Fla. LLC, 2020 WL 42239 (S.D. Fla. 2020). In *Snyder*, the plaintiffs sued a manufacturer of CBD products, alleging that the labels misrepresented the amount of CBD contained in the products, and thus, that the plaintiffs were over-charged for the products purchased. *Snyder*, at *1. In granting the motion to stay, the court, among other things, noted that the 2018 Farm Bill "explicitly recognized the FDA's authority to regulate … hemp-derived products ….." *Snyder*, at *7. Importantly, "the FDA obviously has expressed an active interest in regulating the manufacture and marketing of CBD products." *Snyder*. at *7. Other manufacturers have already relied upon *Snyder* in seeking dismissal or stay of similar lawsuits. *See, e.g.*, Motion to Dismiss, *McCarthy v. Elixinol LLC*, 5:19-cv-07948 (N.D. Cal.), ECF No. 23 (motion to dismiss citing *Snyder*); ECF No. 45 (plaintiff's voluntary dismissal without prejudice); *Glass v. Global Widget, LLC*, 2020 WL 3174688 (E.D. Cal. 2020) (relying on the reasoning in *Snyder* to stay the lawsuit "until such time as the FDA completes its rulemaking regarding the marketing, including labelling, of hemp-derived ingestible products"); *Colette v. CV Scis*., Inc., 2020 U.S. Dist. LEXIS 93553, *18 (C.D. Cal. 2020) (staying consumer-protection lawsuit until "FDA completes its rulemaking regarding the marketing, including labelling, of CBD ingestible products"); *Ahumada v. Global Widget LLC*, case No. 1:19-cv-12005 (D. Mass.), ECF No. 34 (staying, in text order, class-action consumer protection case "pending imminent FDA regulation of CBD products").

Because courts apply the doctrine on a case-by-case basis, primary jurisdiction does not guarantee a stay for manufacturers or distributors of cannabis products. In Burton v. Hodgson Mill, Inc., 2017 WL 1282882, *1 (S.D. Ill. Apr. 6, 2017), for example—a non-cannabis case—a plaintiff sued a manufacturer of pancake mix for including the allegedly misleading label "all natural" on its packaging. In its motion to dismiss, the defendant argued that the court should stay the case under the doctrine of primary jurisdiction. *Burton*, at *8. The court was not persuaded, reasoning that "the FDA last issued a call for proposals on the topic in the fall of 2016 and has not yet issued any further timeframe or next steps … [M]ore importantly, the FDA's eventual formal definition has no bearing on a reasonable consumer's perception at the time this product was advertised and purchased." *Burton*, at *8. Applying this logic, a plaintiff could argue that because the FDA has provided no timeframe within which it will promulgate rules or regulations governing cannabis products, staying the case could prejudice a plaintiff's rights by delaying the suit indefinitely. Additionally, depending on the nature of the claims, a court may conclude that the expertise of the FDA is not even necessary to resolve the case. *See also Potter v. Potnetwork Holdings, Inc.*, 2020 WL 1516518, *6 (S.D.Fla. 2020) (declining to stay case because "[e]ven if new regulations change the requirements for CBD products' labels, such as by requiring a safety warning or information on the products' manufacturing, they seem unlikely to change the food labeling requirements at issue in this case"); *Ballard v. Bhang Corp.*, No. EDCV 19-2329 JGB (KKx), 2020 WL 6018939 (C.D. Cal. Sep. 25, 2020) (denying the stay, and noting that "Plaintiff in the instant case does not claim to have been defrauded or hoodwinked by the legal status of CBD; he simply got less CBD than he thought he was paying for."). Regardless, the doctrine of primary jurisdiction is a good-faith tool for practitioners defending cannabis product manufacturers to have in their toolkit. At a minimum, staying the case allows the parties to potentially negotiate a resolution to the dispute without the additional expense or risk of litigation.

B. The Doctrine of Preemption

If and when the FDA ultimately promulgates rules, defendants may be able to argue that state product liability claims are preempted by federal law. Under the Supremacy Clause of the U.S. Constitution, "state laws that conflict with federal law are without effect." Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 479–480 (2013) (citing U.S. Const., Art. VI, cl. 2) (internal quotation marks omitted). In the "absence of an express pre-emption provision, the [Supreme] Court has found state law to be impliedly pre-empted where it is impossible for a private party to comply with both state and federal requirements." *Bartlett*, 570 U.S. at 480. The preemption argument is beginning to appear in motions to dismiss in CBD cases. *See, e.g.*, Motion to Dismiss, *McCarthy v. Elixinol LLC*, 5:19-cv-07948, ECF No. 23 (defendant arguing that plaintiff's state claim, arising under state consumer-protection statute, was preempted by the 2018 Farm Bill); *Ballard v. Bhang Corp.*, No. EDCV 19-2329 JGB (KKx), 2020 WL 6018939 (C.D. Cal. Sep. 25, 2020) ("Plaintiff offers a convincing argument that the 2018 Farm Bill did not preempt state false advertising claims because it neither conflicted with nor is impeded by state false advertising laws, and because the Supreme Court has held that at least some FDA regulations do not preempt state tort law claims."). Depending on the nature of federal rules or statutes ultimately promulgated, manufacturers could foreseeably argue that state product liability claims are preempted by federal rules governing, for example, product labeling or manufacturing.

In recent years, the Supreme Court has addressed the preemption doctrine in the context of the rules promulgated by the FDA and the FDCA statute. The reasoning in those cases may reveal how any preemption defense relating to cannabis regulations will ultimately fare in courts. In one case, the Court held that federal law preempted a state product liability claim, resulting in the vacatur of a jury verdict that was in favor of a product liability plaintiff. *See* *Bartlett*, 570 U.S. at 476. In *Bartlett*, the plaintiff was prescribed a generic form of the drug "sulindac," which was manufactured by the defendant. *Bartlett*, 570 U.S. at 478. The drug had severe effects on the plaintiff, leading to a number of "physical disabilities." *Bartlett*, 570 U.S. at 478. She sued the manufacturer under New Hampshire's product liability statutes, prevailing on her design defect claim at trial. *Bartlett*, 570 U.S. at 479. The design-defect claim under New Hampshire law imposed a duty to strengthen warnings. *Bartlett*, 570 U.S. at 484. The First Circuit affirmed the verdict, but the Supreme Court reversed the decision, with a 5-4 majority. *Bartlett*, 570 U.S. at 479, 493. The defendant argued that the state claims were preempted by the FDA's rules because it was "impossible" to comply with both state and federal law. In making its argument, the manufacturer noted that state law would seemingly require the manufacturer to strengthen its warnings, but federal law prohibited the manufacturer from independently changing its labels. *Bartlett*, 570 U.S. at 485. Additionally, the defendant could not redesign the drug because, among other things, "the drug [was] chemically incapable of being redesigned." *Bartlett*, 570 U.S. at 484. For these reasons, the Supreme Court concluded that the state-law claims were preempted and reversed the judgment. *Bartlett*, 570 U.S. at 493; *see also* PLIVA, Inc. v. Mensing, 564 U.S. 604, 609 (2011) (holding "federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt … state-law claims"). Relying on *Bartlett*, a defendant may argue that it is "impossible … to comply with both state and federal requirements." *See* *Bartlett*, 570 U.S. at 480.

Notwithstanding *Bartlett*, the Supreme Court has held that the preemption defense was not available in other circumstances, especially in the absence of any express statutory language indicating an intent for federal law to displace state law. In Wyeth v. Levine, 555 U.S. 555, 558 (2009), a drug was injected into the plaintiff's arm, which subsequently had to be amputated. The Vermont jury decided that the defendant manufacturer of the drug "failed to provide an adequate warning of that risk" and awarded damages to the plaintiff. *Wyeth*, 555 U.S. at 558. The defendant argued that the state claims were preempted by the FDA regulations; the trial court disagreed, and the state supreme court affirmed. *Wyeth*, 555 U.S. at 563. The U.S. Supreme Court affirmed the state supreme court's decision. *Wyeth*, 555 U.S. at 581. In so doing, the Court rejected the manufacturer's argument that it was "impossible" to comply with both state and federal law. *Wyeth*, 555 U.S. at 573. In setting forth another basis for its preemption defense, the manufacturer argued that the FDCA "establishes both a floor and a ceiling for drug regulation: Once the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate." *Wyeth*, 555 U.S. at 573. The Supreme Court was not persuaded by this argument, reasoning:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But

> despite its 1976 enactment of an express pre-emption provision for medical devices, … Congress has not enacted such a provision for prescription drugs …. Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Wyeth, 555 U.S. at 574–75. Consequently, absent an "express pre-emption provision" for cannabis products, courts may find that Congress did not intend for "FDA oversight to be the exclusive means of ensuring [] safety and effectiveness" of cannabis products. *See* *Wyeth*, 555 U.S. at 574–75.

The *Wyeth* defendant also relied on a preamble to the FDA regulation, which expressly provided that the state law was preempted. *Wyeth*, 555 U.S. at 575. The Supreme Court was not persuaded by this purported preemption by the agency. *See* *Wyeth*, 555 U.S. at 575. It acknowledged that, in some circumstances, deference to an agency rule may be appropriate. *Wyeth*, 555 U.S. at 576. But deference is appropriate if an agency "ha[s] a unique understanding of the statutes [it] administer[s] and an attendant ability to make informed determinations about how state requirements may pose an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wyeth*, 555 U.S. at 577. In other words, even if the FDA issues a rule that purports to preempt state law, a court will scrutinize the rule to determine if preemption is appropriate. *See* *Wyeth*, 555 U.S. at 577; *see also* *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1676 (2019) (holding that "judge, not the jury, must decide the pre-emption question").

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In short, manufacturers and distributors of cannabis products can use an FDA regulation, or lack thereof, to their advantage in defending against state product liability claims. In the absence of formal rules or regulations on this subject, defendants can seek to stay state product liability claims under the primary jurisdiction doctrine. When and if the FDA promulgates such rules, defendants may be able to defend against state claims by showing that such claims are preempted and that it is "impossible" to comply with both state and federal law. *See* *Bartlett*, 570 U.S. at 480.

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