UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Michelene Colette et al,

Plaintiff,

v.

CV Sciences, Inc.,

Defendant.

2:19-cv-10227-VAP-JEM(x)

Order GRANTING IN PART Defendant's Motion to Dismiss and STAYING Remaining Causes of Action (Dkt. 39).

Before the Court is Defendant CV Sciences, Inc.'s Motion to Dismiss (the "Motion"). (Dkt. 39). Plaintiffs Michelene Colette and Leticia Shaw filed opposition on April 6, 2020 (Dkt. 43), and Defendant replied on April 20, 2020 (Dkt. 44). The Court deems the Motion suitable for resolution without oral argument pursuant to Local Rule 7-15. After considering all papers filed in support of, and in opposition to, the Motion, the Court GRANTS IN PART the Motion and STAYS the remaining causes of action.

I. BACKGROUND

This lawsuit is one of several in the vanguard of consumer class actions relating to the marketing and sale of cannabidiol ("CBD") products. Just in the Central and Northern Districts of California, the Court is aware of four similar cases, each filed around the same time and each now facing a pending motion to dismiss. *See DaSilva v. Infinite Product Co.*, No. 2:19-cv-10148, Dkt. 48 (C.D. Cal. Mar. 17, 2020); *Davis v. cbdMD, Inc.*, No. 2:19-cv-10241, Dkt. 40 (C.D. Cal Mar.

15, 2020); *McCarthy v. Elixinol, LLC*, 5:19-CV-07948, Dkt. 34 (N.D. Cal. Mar. 13, 2020); *McCarthy v. Charlotte's Web Holdings, Inc.*, 5:19-cv-07836, Dkt. 33 (N.D. Cal. Mar. 16, 2020).

Defendant here, a California corporation with its principal place of business in San Diego (Dkt. 35 ¶ 15), produces and sells a range of CBD products, including sprays, oil drops, gummies, capsules, and softgels (*id.* ¶ 1). Plaintiff Colette is an Arizona citizen who alleges she purchased Defendant's CBD spray approximately two years ago for $60. (*Id.* ¶ 13). Plaintiff Shaw is a California citizen who alleges that she purchased six of Defendant's products between May and December 2018 for a total of $377.73. (*Id.* ¶ 14). Each Plaintiff claims that, had she known CBD products are "not legally sold in the United States," she would not have purchased them. (*Id.* ¶¶ 13–14).

The crux of this lawsuit is Plaintiffs' allegations that Defendant's products are illegal under the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301, *et seq* ("FDCA"). Plaintiffs claim the products run afoul of the FDCA in two ways: first, they "are mislabeled as Dietary Supplements or contain the illegal dietary ingredient CBD," and second, Defendant's CBD spray is intended for sublingual use and, therefore, "does not meet the definition of a dietary supplement." (*See generally id.* ¶¶ 18–24). The Food and Drug Administration ("FDA") is actively considering the regulation of CBD products, including the "manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived products." *See* U.S. Food & Drug Admin., *Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds;*

Extension of Comment Period, 84 Fed. Reg. 28822, 28823 (June 20, 2019). Currently, the FDA's position is that it is illegal under federal law to "add CBD to a food or label CBD as a dietary supplement." *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD* (May 5, 2020), https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis.

Citing the FDA's statements on CBD products, Plaintiffs' First Amended Complaint ("FAC") brings claims for (1) violation of California's Unfair Competition Law ("UCL"), (2) violation of California's false advertising law, (3) violation of California's Consumer Legal Remedies Act ("CLRA"), (4) breach of express warranty under California law, (5) breach of implied warranty of merchantability under California law, (6) breach of express warranties under Arizona law, (7) breach of implied warranty of merchantability under Arizona law, (8) violation of the Arizona Consumer Fraud Act ("ACFA"), and (9) declaratory judgment. (Dkt. 35 ¶¶ 43–132). Plaintiffs seek to represent a class of "all persons in the United States who purchased [Defendant's products] during the class period," as well as California and Arizona subclasses. (*Id.* ¶ 31–33). Defendant moves to dismiss the FAC for failure to state a claim or, in the alternative, stay the case under the primary jurisdiction doctrine. (*See generally* Dkt. 39-1).

II. LEGAL STANDARD

A. Motion to Dismiss

Federal Rule of Civil Procedure 12(b)(6) allows a party to bring a motion to dismiss for failure to state a claim upon which relief can be granted. Rule 12(b)(6)

is read along with Rule 8(a), which requires a short, plain statement upon which a pleading shows entitlement to relief. Fed. R. Civ. P. 8(a)(2); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). When evaluating a Rule 12(b)(6) motion, a court must accept all material allegations in the complaint—as well as any reasonable inferences to be drawn from them—as true and construe them in the light most favorable to the non-moving party. *See Doe v. United States*, 419 F.3d 1058, 1062 (9th Cir. 2005).

"While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citations omitted). Rather, the allegations in the complaint "must be enough to raise a right to relief above the speculative level." *Id.*

To survive a motion to dismiss, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *Ashcroft v. Iqbal*, 556 U.S. 662, 697 (2009). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556).

The Ninth Circuit has clarified that (1) a complaint must "contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to

defend itself effectively" and (2) "the factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011).

B. Motion to Stay

It is well-established that "[a] district court 'has broad discretion to stay proceedings as an incident to its power to control its own docket' in an effort to promote judicial economy." *DeMartini v. Johns*, 693 F. App'x 534, 538 (9th Cir. 2017) (quoting *Clinton v. Jones*, 520 U.S. 681, 706–07); *see also Landis v. N. Am. Co.*, 299 U.S. 248, 254–55 (1936) ("[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants. How this can best be done calls for the exercise of judgment, which must weigh competing interests and maintain an even balance.").

III. DISCUSSION

A. Declaratory Relief

The Court addresses Plaintiffs' final cause of action first. In Count Nine, "Plaintiffs seek a declaration that Defendant has misrepresented the nature, ingredients and effectiveness of the Products and that its actions are unlawful." (Dkt. 35 ¶ 131). This claim for relief arises under the Declaratory Judgment Act, 28 U.S.C. § 2201 ("DJA"), which permits a court to "declare the rights and other legal relations of any interested party seeking such declaration."

The DJA authorizes declaratory relief only in "a case of actual controversy." 28 U.S.C. § 2201. "[T]he phrase 'case of actual controversy' in the Act refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citation omitted). "In a class action, the plaintiff class bears the burden of showing that Article III standing exists." *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 978 (9th Cir. 2011). Standing requires that (1) "the plaintiff suffered an injury in fact," (2) "the injury is fairly traceable to the challenged conduct," and (3) "the injury is likely to be redressed by a favorable decision." *Id.* (internal quotation marks omitted). "Standing exists if at least one named plaintiff meets the requirements." *Id.* "Basically, the question is whether there is a 'substantial controversy, between parties having adverse legal interests, *of sufficient immediacy and reality* to warrant the issuance of a declaratory judgment.'" Phillips & Stevenson, Rutter Group Prac. Guide Fed. Civ. Proc. Before Trial (Nat Ed.) § 10:24 (2020) (quoting *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 US 270, 273 (1941) (emphasis added).

Defendant argues Plaintiffs lack standing to pursue declaratory relief, "because they do not allege that they intend to purchase CVSI's CBD products in the future." (Dkt. 39-1 at 21). Plaintiffs counter that they "face [a] threat of future harm because, while they desire to purchase CBD products in the future, they cannot be certain that Defendant's representations are true when they see the products on the store shelves." (Dkt. 43 at 23). This contention is unpersuasive and, indeed, strains credulity. Plaintiffs make it clear they believe Defendant's products are illegal and mislabeled, and they do not allege they expect to be repeat customers as things stand now. If they did, it would be with full knowledge of Defendant's alleged misconduct. Under these circumstances, Plaintiffs fail to

establish standing for declaratory relief. *See Campion v. Old Republic Home Prot. Co.*, 861 F. Supp. 2d 1139, 1150 (S.D. Cal. 2012) ("Plaintiff's UCL claim is based entirely on a past transaction. . . . Furthermore, . . . [Plaintiff] now has knowledge of Defendant's alleged misconduct. Thus, Plaintiff cannot show he is realistically threatened by a repetition of the alleged violation."); *Snyder v. Green Roads of Fla. LLC*, 2020 WL 42239, at *4 (S.D. Fla. Jan. 3, 2020) ("Plaintiffs simply have not alleged a likelihood of future injury. In fact, Plaintiffs allegations make clear that they will not purchase more of Defendant's products so long as the labelling does not meet their standards. Accordingly, Plaintiffs lack standing to assert a claim for injunctive relief.").

B. Primary Jurisdiction Doctrine[1]

"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). It "is a prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *GCB Commc'ns, Inc. v. U.S. S. Commc'ns, Inc.*, 650 F.3d 1257, 1263–64 (9th Cir. 2011) (internal quotation marks omitted). "It is useful . . . in instances where the federal courts do have jurisdiction over an issue, but decide that a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Id.* at 1264 (internal quotation marks omitted).

[1] Having concluded a stay is appropriate, the Court does not reach the remainder of Defendant's Motion to Dismiss.

"Not every case that implicates the expertise of federal agencies warrants invocation of primary jurisdiction. Rather, the doctrine is reserved for a limited set of circumstances that requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Astiana v. Hain Celestial Group, Inc.*, 783 F.3d 753, 760 (9th Cir. 2015) (internal quotation marks omitted); *see also Clark*, 523 F.3d at 1114 (stating the doctrine applies in "limited circumstances" and is "not designed to secure expert advice from agencies every time a court is presented with an issue conceivably within the agency's ambit." (internal quotation marks omitted)). The Ninth Circuit has stated that "even when agency expertise would be helpful, a court should not invoke primary jurisdiction when the agency is aware of but has expressed no interest in the subject matter of the litigation[,]" or when "referral to the agency would significantly postpone a ruling that a court is otherwise competent to make." *Astiana*, 783 F.3d at 761.

Defendant asks the Court to "stay the case under the primary jurisdiction doctrine until the FDA concludes ongoing rulemaking on CBD products." (Dkt. 39-1 at 19–20). Regulatory oversight of CBD ingestible products, including labelling, is currently the subject of rulemaking at the FDA. The FDA recently has conducted a public hearing and instituted an agency task force on CBD regulation. 84 Fed. Reg. 12969. In its Notice of Public Hearing, the FDA stated: "Regulatory oversight of products containing cannabis or cannabis derived compounds is complex and involves multiple Federal and State agencies." *Id.* at 12970. It also made clear that it was concerned with labelling of products containing cannabis-derived, including hemp-derived, compounds. *Id.* at 12971–72. Although the FDA rulemaking

process is ongoing, the FDA is under considerable pressure from Congress and the industry to expedite the publication of regulations and policy guidance regarding CBD products. *See Snyder*, 2020 WL 42239, at *6 n.2.

Courts consider the following non-exhaustive factors in deciding whether the primary jurisdiction doctrine applies: "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek Semiconductor Co., Ltd. v. Microchip Tech., Inc.*, 307 F.3d 775, 781 (9th Cir. 2002).

The Court finds the relevant factors here require applying the primary jurisdiction doctrine. This lawsuit raises issues of first impression surrounding how the FDA intends to classify and regulate CBD products; to the Court's knowledge, the only federal court to confront similar issues also invoked the primary jurisdiction doctrine. *See generally Snyder*, 2020 WL 42239. Although Plaintiffs rely heavily on the FDA's November 22, 2019 issuance of warning letters to certain CBD retailers to establish the illegality of Defendant's actions, "regulatory letters do not constitute final agency action," *Dietary Supplemental Coal., Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992) (citations omitted). The fact remains that the FDA has not formally established its position. Moreover, the "[r]egulatory oversight of products containing cannabis or cannabis derived compounds is complex and involves multiple Federal and State agencies." 84 Fed. Reg. 12970. As discussed earlier, Congress has committed regulation of CBD products to the FDA and expects the agency to publish guidance as soon as possible. Finally, the

number of CBD class actions currently pending in the federal district courts makes clear the danger of inconsistent adjudications.

The *Snyder* court thoughtfully applied the primary jurisdiction factors in a similar case, and the Court adopts its analysis here:

> First, it appears to the Court that the FDA is exercising regulatory authority over ingestible and other CBD products, but there is uncertainty with respect to whether the FDA will conclude that some or all CBD products are food additives, supplements or nutrients that can be safely marketed to the public and, if nutrients, whether the labelling standards and requirements for CBD products will be different or the same as for other nutrients. Thus, there appears to be a need for consistent guidance. Second, the FDA appears to be properly exercising their regulatory authority; the FDA regulates, among other matters, food additives, supplements and nutrients, and because ingestible CBD products could be deemed to fall into any of these categories, they are within the FDA's jurisdiction. Third, the Agriculture Improvement Act of 2018 (the "2018 Farm Bill"), Pub. L. No. 115-334, 132 Stat. 4908–11, explicitly recognized the FDA's authority to regulate products containing cannabis-derived compounds, including hemp-derived products under the FDCA. 7 U.S.C. §§ 1639(o)–(s). Fourth, the exercise of regulatory authority by the FDA over the labelling of ingestible CBD products requires both expertise and uniformity in administration. The need is well-illustrated by the fact that, among other issues with which the FDA is concerned, are whether CBD products pose safety risks, how the mode of delivery affects safety, whether there are dosage considerations related to safety, whether there is a need for manufacturing standards, and whether there are standardized definitions for the ingredients in, for example, hemp oil. U.S. Food & Drug Admin., FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol

> (CBD) (content current as of Dec. 31, 2019), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd. Lastly, the FDA obviously has expressed an active interest in regulating the manufacture and marketing of CBD products. *Id.* ("FDA continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by the FDA."); 84 Fed. Reg. 12969 (notice of public hearing).

2020 WL 42239, at *7.

Plaintiffs offer two reasons the primary jurisdiction doctrine is inapposite here. First, they argue "[a]ny forthcoming regulatory action by the FDA cannot be retroactively applied to class claims accrued prior to enactment of the rule." (Dkt. 43 at 17). Plaintiffs concede, however, that the presumption against retroactivity may be overcome by statutory authorization. (*Id.* at 18). Whether cannabis regulations will apply retroactively is unknown, but given the widespread use and sale of CBD products—and particularly the large number of states that have legalized their sale—Congress may conclude that fairness, practicality, and comity require retroactive legislation.

Second, Plaintiffs assert "[t]he Court does not need the FDA's guidance to determine whether the CBD products are illegal," because "consumer class actions based on unlawful, misleading, or deceptive labeling and advertising are areas the courts can address without the need to 'secure [the FDA's] expert advice.'" (Dkt. 43 at 20 (citing *Reid v. Johnson & Johnson*, 780 F.3d 952, 967 (9th Cir. 2015))). The cases they cite, however, are distinguishable. In *Reid*, for instance, the

plaintiff's "claims present[ed] no issues of first impression, as the FDA ha[d] already addressed the substantive issues raised [t]here." 780 F.3d at 966. The facts showed the FDA had published an interim final rule that covered some of the plaintiff's claims and was unlikely to announce any other, relevant guidance. *Id.* at 966–67. Here, the FDA has yet to issue rules and is working feverishly to do so. In another case cited by Plaintiffs, *Zakaria v. Gerber Prod. Co.*, the court stated, "Plaintiff raises neither an issue of first impression nor a complex one" and found adjudication did "not present a 'substantial danger of inconsistent rulings.'" 2015 WL 3827654, at *6 (C.D. Cal. June 18, 2015) (quoting *Brown v. MCI WorldCom Network Servs., Inc.*, 277 F.3d 1166, 1173 (9th Cir.2002)). As noted above, there are several CBD-related lawsuits currently making their way through the court systems; inconsistent rulings are likely to follow in the absence of FDA guidance.

"If a court determines that the doctrine of primary jurisdiction applies, it must either stay the case pending an administrative ruling or dismiss the case without prejudice." *Capaci v. Sports Research Corp.*, 2020 WL 1482313, at *8 (C.D. Cal. Mar. 26, 2020) (citing *Astiana*, 783 F.3d at 761). "When the purpose of primary jurisdiction is for parties to pursue their administrative remedies, a district court will normally dismiss the case without prejudice. However, when a court invokes primary jurisdiction but further judicial proceedings are contemplated, then jurisdiction should be retained by a stay of proceedings, not relinquished by a dismissal." *Astiana*, 783 F.3d at 761 (internal quotation marks and citation omitted). "In either circumstance, the district court must be attuned to the potential prejudice arising from the dismissal of claims." *Id.* The Court anticipates further judicial proceedings in this lawsuit. Accordingly, the case will be STAYED until

the FDA completes its rulemaking regarding the marketing, including labelling, of CBD ingestible products.

IV. CONCLUSION

The Court therefore DISMISSES Plaintiff's request for declaratory relief and STAYS the remaining causes of action. The parties are directed to file joint status reports with the Court every 90 days, beginning on September 1, 2020.

IT IS SO ORDERED.

Dated: 5/22/20

Virginia A. Phillips
Chief United States District Judge