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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MICHELE MCCARTHY, individually and on behalf of all others similarly situated,

Plaintiff,

vs.

ELIXINOL LLC, a Colorado Limited Liability Company,

Defendant.

Case No. 5:19-cv-07948-SVK

DEFENDANT ELIXINOL LLC'S REPLY IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED CLASS ACTION COMPLAINT

Date: July 2, 2020
Time: 1:30 P.M.
Ctrm.: 8
Judge: Hon. Lucy H. Koh

Complaint Filed: December 4, 2019

Defendant ELIXINOL LLC ("Elixinol" or "Defendant") files its Reply in Support of Its Motion to Dismiss Plaintiff's First Amended Complaint ("Reply"). The Reply is submitted in response to the Opposition to Defendant's Motion to Dismiss (Dkt. No. 43) ("Opposition") filed by Plaintiff Michele McCarthy ("Plaintiff"). As noted herein, the Court should dismiss each of the claims asserted in Plaintiff's First Amended Complaint ("FAC") or, in the alternative, stay the matter in its entirety.

Dated: April 3, 2020.

FROST BROWN TODD LLC

By: */s/ Martin E. Rose*

Martin E. Rose
Sean M. Whyte

SHAW, KOEPKE & SATTER

By: */s/ John W. Shaw*

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I. INTRODUCTION

Plaintiff's First Amended Complaint ("FAC") bases every single cause of action on the premise that the Food and Drug Administration ("FDA") has deemed all hemp-derived cannabidiol ("CBD") products illegal. In stark contrast, the head of the agency—FDA Commissioner Stephen Hahn—said on February 26, 2020 "[p]eople are using these [CBD] products. ***We're not going to be able to say, 'You can't use these products***,' because . . . even if you did, it's a fools' game to even try to approach that."[1] A week later, on March 5, 2020, the FDA issued a Statement that, far from announcing the illegality of CBD products, concluded by stating that "[the FDA] recognize[s] the significant public interest in CBD and we must work together with stakeholders ***and industry*** to develop high-quality data to close the substantial knowledge gaps about the science, safety and quality of many of these products."[2] To be blunt, if CBD products were illegal, how could the FDA plan to work together with the billion-dollar CBD industry to develop high-quality data on the products? The FDA further announced in its March 5th Statement that it was re-opening its public docket that was initially opened to facilitate the public "shar[ing] new data with the agency."[3] The FDA stated that the "docket provides a valuable conduit for submission of scientific data on CBD to the agency, so we have decided to extend the comment period ***indefinitely*** to allow the public to comment and to share relevant data with the agency."[4] In short, the FDA has not engaged in the final, formal rulemaking process that establishes a regulatory structure that carries the force of law. Rather, the FDA is at a much earlier stage in the process. The FDA is working with the industry and other stakeholders to gather data and determine how it should regulate the industry. Thus, the foundation of all of Plaintiff's causes of action—the claim that the FDA has deemed CBD products "illegal"—is completely inaccurate and the reason why her amended complaint should be dismissed with prejudice. Alternatively,

[1] *See* Defendant's Motion to Dismiss (Dkt. No. 34) at 7 fn.9 (emphasis added).

[2] FDA STATEMENT, https://www.fda.gov/news-events/press-announcements/fda-advances-work-related-cannabidiol-products-focus-protecting-public-health-providing-market (last visited April 2, 2020).

[3] *Id.*

[4] *Id.* (emphasis added).

this action should be stayed pending finalization of the FDA's rulemaking on CBD products.

II. PLAINTIFF'S CLAIMS REST ON THE FAULTY PREMISE THAT ELIXINOL'S PRODUCTS ARE ILLEGAL.

The Opposition begins with the same incorrect premise underlying the FAC: that "the sale of CBD products is illegal." Opp. at 1. This is not true. Because even though the FDA has made numerous statements regarding CBD and its addition to human and pet food products, none of these statements—regardless of whether they appear in agency-issued warning letters, online Q&A statements, speeches, or some other format—represent law. Instead, by its own admission, the FDA's position regarding CBD and CBD products has been, and remains, in a state of flux. As recently as last month, the current FDA Commissioner stated, "We are trying to formulate what our stance is going to be on [CBD]."[5] He continued by acknowledging that, "[p]eople are using these [CBD] products. We're not going to be able to say, 'You can't use these products,' because . . . even if you did, it's a fools' game to even try to approach that."[6]

And in September 2019, a bipartisan group of twenty-six Members of Congress reached out to the FDA urging action, noting that "FDA's current regulatory posture on CBD has created significant regulatory and legal uncertainty" and expressing discouragement "by FDA's estimation that a rulemaking process could span 3 to 5 years" while asserting their belief that "more expeditious measures" could be taken.[7] It is impossible to say that the law is settled when Congress and the FDA, three months before Plaintiff filed her lawsuit, anticipated the regulatory rule-making process to last another *three to five years*. With this letter, Congress expressly requests "an interim final rule, pending issuance of a permanent final rule, to establish a clear regulatory framework for CBD as a dietary supplement and food additive," thus acknowledging that *no regulatory framework currently exists* relating to CBD products.[8] Congress has instructed the FDA to act, but it has not.

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[5] *See* Defendant's Motion to Dismiss (Dkt. No. 34) at 7 fn.9.

[6] *Id.*

[7] Letter from Members of Congress, to Acting FDA Commissioner Ned Sharpless (Sept. 19, 2019), https://pingree.house.gov/uploadedfiles/pingree_comer_cbd_letter_to_fda_9.19.19.pdf (last visited Apr. 2, 2020).

[8] *Id.*

And Congress is not alone. A district court in Florida, when presented with similar issues, has found that "the rulemaking process [regarding CBD products] at the federal level is active," and 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 . . . ." *Snyder v. Green Roads of Fla. LLC*, Case No. 0:19-cv-62342-UU, 2020 WL 42239, at *7 (S.D. Fla. Jan. 3, 2020).

Since there has been no final—or even interim—rule establishing a regulatory framework, Plaintiff's FAC relies entirely on an unfounded "illegality" premise that has no support in the law. Thus, the primary issue before the Court is whether to: (1) dismiss Plaintiff's FAC with prejudice in its entirety because Plaintiff has no basis upon which to bring her claims; or (2) issue a stay as to Plaintiff's FAC pending further, final action by the FDA.

A. Not every statement by a regulatory body carries the force and weight of law.

Judicial deference to an agency's interpretation of a statute is appropriate when that interpretation is not unreasonable, if Congress has not spoken directly to the specific issue in question. *Chevron U.S.A. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-45 (1984). Under this *Chevron* deference standard, agency interpretations such as "opinion letters . . . policy statements, agency manuals, and enforcement guidelines" may "lack the force of law" and instead are merely persuasive. *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000). Instead, such interpretations are only afforded "a measure of deference proportional to [their] power to persuade, in accordance with the principles set forth in *Skidmore v. Swift Co.*" *GCIU-Emp'r Ret. Fund v. Quad/Graphics, Inc.*, 909 F.3d 1214, 1218-19 (9th Cir. 2018) (citing *Skidmore v. Swift Co.*, 323 U.S. 134 (1944)). *Skidmore* review requires the court to consider "the interpretation's thoroughness, rational validity, consistency with prior and subsequent pronouncements, the logic and expertness of an agency decision, the care used in reaching the decision, as well as the formality of the process used." *Id.* (quotation omitted). Unquestionably, the FDA's statements related to CBD products should not be afforded *Chevron*, or even *Skidmore* deference.

While the FDA has issued statements related to CBD products, these statements are not the result of a "logical and rational" process, as they are inchoate. Plaintiff's claims are based on

a question-and-answers section of the FDA's website ("Q&A"),[9] warning letters sent to some CBD companies (but *not* Elixinol) ("Warning Letters"), [10] and a press announcement ("Statement").[11] But far from being definitive rule-making, these statements reference actions that the FDA intends to take, such as "we intend to hold a public meeting *in the near future*" and the intent "to pursu[e] an efficient regulatory framework." *See supra* fn. 2 (emphasis added). Further, the current FDA Commissioner has specified that the FDA has not formulated its stance, and that further study is required.[12] None of these opinions—the foundation of Plaintiff's claims—should be accorded deference under either *Chevron* or *Skidmore*. While Plaintiff's claims rely on these statements as if they were law, under the *Chevron* and *Skidmore* guidelines, not only do they fall short of being afforded the weight of law, they are not even persuasive. *Chevron* would require that the FDA's interpretation be reasonable. But as the Agency's position is in development, it cannot be described as reasonable. And under a *Skidmore* analysis, the court must consider "the interpretation's thoroughness, rational validity, consistency with prior and subsequent pronouncements, the logic and expertness of an agency decision, the care used in reaching the decision, as well as the formality of the process used." *GCIU*, 909 F.3d at 1218-19 (citing *Skidmore*, 323 U.S. 134). The interpretations upon which Plaintiff relies fails on every single one of these considerations. The thoroughness aspect is plainly incomplete. By its own admission, the Agency's consideration of CBD products is ongoing and is not finalized. *See supra* fn.2. As noted by the current FDA Commissioner, there are "information gaps" that must be filled.[13] Further, the

[9] FDA REGULATION OF CANNABIS AND CANNABIS-DERIVED PRODUCTS, INCLUDING CANNABIDIOL (CBD), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd (last visited Jan. 29, 2020).

[10] Warning letters are "informal and advisory," and the FDA does not consider them to be "final agency action." U.S. F.D.A. REGULATORY PROCEDURES MANUAL, Ch. 4, pg. 3, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual (last visited April 1, 2020).

[11] STATEMENT FROM FDA COMMISSIONER SCOTT GOTTLIEB, M.D., ON THE SIGNING OF THE AGRICULTURE IMPROVEMENT ACT AND THE AGENCY'S REGULATION OF PRODUCTS CONTAINING CANNABIS AND CANNABIS-DERIVED COMPOUNDS, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys (last visited Jan. 29, 2020).

[12] *See* Defendant's Motion to Dismiss (Dkt. No. 34) at 7 fn.9.

[13] *See* Defendant's Motion to Dismiss (Dkt. No. 34) at 7 fn.9.

formality of the interpretations on which Plaintiff relies—website posts, press announcements, and warning letters *to other companies*—does not approach the requisite notice-and-comment process through which an agency exercises its rule-making authority. Congress—and the industry—needs this as-yet-provided regulatory certainty.[14] And there is no aspect of the FDA's process that can be described as "consistent" between prior and subsequent pronouncements. Because these interpretations are not subject to either *Chevron* or *Skidmore* deference, they are not to be afforded the weight of law. Since the whole of Plaintiff's claims rely on this premise, Plaintiff's claims must be dismissed with prejudice.

B. The interpretative rules do not carry the weight of law.

Beyond just the *Chevron* (and *Skidmore*) tests, "[f]ederal administrative agencies are required to engage in reasoned decisionmaking." *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2706 (2015) (internal quotation omitted). This means that an agency's decree must be the result of a process that is "logical and rational." *Id.* Plaintiff asserts that the FDA's statements are "interpretative rules" that explain existing law or regulations. Opp. at 11-12. But "interpretive rules" are not entitled to *Chevron* deference; they are afforded "some weight on judicial review," as the reviewing court can consult them "to determine whether the Secretary has consistently applied the interpretation embodied in the citation." *Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 157 (1991). There is no argument to be made that the FDA has "consistently applied" the interpretation that Plaintiff relies upon. And an agency's action "is lawful only if it rests 'on a consideration of the relevant factors.'" *Michigan*, 135 S. Ct. at 2706. Here, even if the FDA has considered the relevant factors in dealing with CBD products, it has issued not a clear action, but a muddled series of communications without a formal determination.

Plaintiff's Opposition rebuts none of this. In fact, Plaintiff admits further action is needed, stating in her Opposition that "action by the FDA regarding CBD will require the enactment of new regulations or amendment of existing regulations." Opp. at 9. These things have not happened. The FDA—far from enacting regulations or amending existing ones—has merely

[14] *See supra* fn.2 ("Regulatory certainty will allow the legal hemp industry to flourish while opening up exciting new economic opportunities for farmers and entrepreneurs in a way that protects consumers.").

made public comments through its website, its Commissioner(s), and warning letters targeted to companies other than Elixinol. Because Plaintiff's claims require that the FDA's statements be treated as law, and they are not, Plaintiff's claims fail and must be dismissed with prejudice.

C. California has not taken independent action that regulates CBD products.

Plaintiff also asserts that her claims are reliant on California's Sherman Law, but this only incorporates and enforces federal law. CAL. HEALTH & SAFETY CODE § 110100(a); Opp. at 6, fn.1 & 7. But California has not taken independent action to regulate CBD products, and California law does not support Plaintiff's assertion that the FDA's statements create binding law. Per the California Supreme Court, while a court "must give great weight and respect to an administrative agency's interpretation of a statute," the significant factors to consider "include whether the administrative interpretation has been formally adopted by the agency or is instead in the form of an advice letter . . . and whether the interpretation is long-standing and has been consistently maintained." *Ste. Marie v. Riverside Cnty. Reg'l Park & Open-Space Dist.* (2009) 46 Cal. 4th 282, 292-93. And courts are not bound by "interpretative bulletins" that were "not adopted in accordance with the [California's Administrative Procedure Act]." *Alvarado v. Dart Container Corp. of Cal.* (2018) 4 Cal. 5th 542, 558. Further, California courts do not recognize opinion letters as binding authority, and instead accord "great weight" to "[c]onsistent administrative construction of a statute." *Drumm v. Morningstar, Inc.*, No. C08-03362 TEH, 2009 WL 3721356, at *4 (N.D. Cal. Nov. 5, 2009). This requires an interpretation that is "long-standing" and "consistently maintained," as in *Drumm*, where the Northern District court accorded only "some weight" to opinion letters that had remained "in place for more than two decades." *Id.* at *5 & fn.1 (citing *Christensen*, 529 U.S. at 587).

Here, neither the FDA nor any California agency has produced any interpretations remotely close to meeting that standard of "long-standing" and "consistent" administration or maintenance. In the span of a few years, the FDA has issued numerous statements while not making a formal determination, and Plaintiff's FAC relies on only those statements that support her claims. This does not represent any form of stabile, consistent regulation, and thus California law does not bind the Court to the FDA statements upon which Plaintiff relies. Plaintiff's claims

that Elixinol's Products are "illegal" are not based on mere clarifications of existing law, and they are not supported by a binding, formal rule-making process under either federal or California caselaw. Thus, Plaintiff's claims must be dismissed with prejudice.

III. PLAINTIFF MISUNDERSTANDS THE PRIMARY JURISDICTION STAY REQUIREMENT.

The Ninth Circuit looks to four factors when applying the primary jurisdiction doctrine: "(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, 780 (9th Cir. 2002). The Court should invoke the primary jurisdiction doctrine here.

A. The FDA has not completed its rule-making process, so Plaintiff's claims that Elixinol's Products are illegal is incorrect.

Plaintiff's entire FAC relies on the premise that Elixinol's products and labeling is "illegal." But, as noted previously, the FDA has not completed its rule-making process regarding CBD products, leaving the issue unresolved and fulfilling the first factor of the primary jurisdiction doctrine. Further, this unresolved issue is squarely within the purview of the FDA, as admitted by Plaintiff in her Opposition. Opp. at 9 ("Here, action by the FDA regarding CBD will require the enactment of new regulations or amendment of existing regulations."). The 2018 Farm Bill "explicitly recognized the FDA's authority to regulate products containing cannabis-derived products, including hemp-derived products under the FDCA." *Snyder*, 2020 WL 42239, at *7.

Here, Plaintiff invites the Court to create the regulations that Congress charged the FDA to create. It is a long-standing, fundamental premise of our system of government that "it is for Congress, not the courts to write the law." *Stanard v. Olesen*, 74 S. Ct. 768, 771 (1954). The FDA has not conducted enough scientific testing of CBD products to issue a final determination regarding their use or legality—and Plaintiff invites the Court to make a blind determination without the testing that the FDA believes is needed.[15] The FDA has not finished holding public hearings or receiving comments from the public and industry regarding CBD products—and

[15] *See* Defendant's Motion to Dismiss (Dkt. No. 34) at 7 fn.9.

Plaintiff invites the Court to decide before that process is complete. The FDA has, by its own admission, not had adequate time to develop and issue a final determination regarding CBD products—and Plaintiff seeks a judicial end-run around this rulemaking process through this action.[16] Plaintiff asks the Court to do what the FDA has not done: make a final determination regarding CBD products without access to any of the tools provided to federal regulatory bodies. Plaintiff should wait until the FDA has issued final, or even interim, rules that have the force of law before suing. A federal judge,[17] more than two dozen bipartisan Members of Congress,[18] and even the head of the FDA himself[19] all recognize that no formal, binding guidance exists. Plaintiff should not be permitted to convert non-binding, informal FDA statements into law and use that as a basis for a lawsuit.

The evidence before the Court shows that the FDA has not completed its rule-making process and has not instituted any final, formal rules or regulations. While the FDA has issued warning letters to a limited number of companies, these are "informal and advisory" in nature—the FDA has not shut down a single CBD company, has not pulled a single CBD product off the shelves, and has not taken a single further action. Instead, the FDA is stalling to allow itself time to do the things it must for rulemaking: analyze scientific testing, initiate notice-and-comment processes, hold public hearings with consumers and the industry, and completing the aspects of the rule-making and approval process mirroring the legislative process, as it is authorized (and required) to do by Congress. As more than two dozen, bipartisan Members of Congress have made clear, the FDA has been charged by Congress with issuing regulatory framework, and it has not done that. And, despite Plaintiff's wishes otherwise, it is the FDA—not the Court—who has been given that charge, so it must be completed by the FDA. Plaintiff's claims are premature, because there is no underlying law to support them and they must be dismissed with prejudice.

B. Plaintiff's claims on retroactive application of law are misdirected because, by application of Plaintiff's logic, her FAC must be dismissed with prejudice.

[16] *See* Defendant's motion to Dismiss (Dkt. No. 34) at 1 fn.1 & at 7 fn.9.

[17] *See Snyder*, 2020 WL 42239, at *7.

[18] *See supra* fn.2.

[19] *See* Defendant's Motion to Dismiss (Dkt. No. 34) at 7 fn.9.

Generally, "courts disfavor retroactivity," and there is a long-standing principle that "a court is to apply the law in effect at the time it renders its decision." *Covey v. Hollydale Mobilehome Estates*, 116 F.3d 830, 835 (9th Cir. 1997). Plaintiff, relying primarily on caselaw from other circuits, asserts that future action cannot be retroactively applied to her claims, so action by this Court must be based on the status of the law as it stands today. But this reasoning only serves to heighten the justification for dismissing Plaintiff's claims with prejudice. As thoroughly discussed already, there is no current law expressly identifying Elixinol's products as illegal, and Plaintiff's reliance on non-binding authority does not make it so. Since Plaintiff's claims have no legal support, any future action by the FDA would either maintain the status quo (allowing the sale of CBD products) or make them illegal. By Plaintiff's logic, this would not apply retroactively, and Plaintiff's claims still must be dismissed with prejudice.

C. The Court must rely on FDA guidance regarding the legality of CBD Products.

As noted by the court in *Snyder*, "[r]egulatory oversight of CBD ingestible products, including labeling, is currently the subject of rulemaking at the FDA," and "the rulemaking processes at the federal level is active." *Snyder*, 2020 WL 42239 at *6-7. "FDA regulations currently provide little guidance" regarding CBD ingestibles and their labeling. *Id.* at *7. Because of this rampant instability, the *Snyder* court invoked the primary jurisdiction doctrine, staying the case pending the completion of the FDA's rulemaking regarding hemp-derived products. *Id.*

If this Court does not dismiss Plaintiff's claims outright with prejudice, then it should do the same. Plaintiff's claims rely on the assertion that the FDA has determined Elixinol's products as "illegal." But the inconsistent messaging from the FDA renders this conclusion inaccurate. The FDA ultimately must decide, through its rule-making process, how CBD and hemp-derived products will be regulated, and at that point Elixinol's products either will, or will not, be definitively labeled as legal. But this determination can *only* come from the FDA.

Plaintiff notes that "primary jurisdiction is not required" if referral to the agency would postpone a decision when the court is otherwise competent to rule. *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 761 (9th Cir. 2015). But the analysis goes further – as primary jurisdiction is not required "when the case must eventually be decided on a controlling legal issue wholly

unrelated" to the ultimate issue before the agency. *Id.* (citing *Amalgamated Meat Cutters & Butcher Workmen of N. Am. v. Jewel Tea Co.*, 381 U.S. 676, 686 (1965)). Indeed, the *Astiana* court held that the district court did not err in invoking primary jurisdiction, because the issue before it was "a particularly complicated issue that Congress has committed to' the FDA." *Id.* (citation omitted). Here, the matter before the Court is not wholly unrelated to the agency issue. Despite Plaintiff's protestations, it is decidedly more complicated than "adjudicate[ing] the amount of trans fat in margarine, or the amount of protein in a protein powder." Opp. at 11. Rather, the matter before the Court is entirely encompassed by the agency issue—the legality of CBD products. The Court is not otherwise competent to make this determination, as the FDA has thus far issued insufficient uniform guidance, as required by Congress in the 2018 Farm Bill. Since the Court must rely on the FDA, it should invoke the primary jurisdiction doctrine and stay this matter pending further FDA action.

IV. PLAINTIFF MISUNDERSTANDS THE PREEMPTION ISSUE.

Federal preemption of state law occurs when there is explicit statutory text requiring it, but it can also be inferred "where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation" or when there is "actual conflict" between state and federal law. *Ting v. AT&T*, 319 F.3d 1126, 1135-36 (9th Cir. 2003) (citations omitted). "The purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (internal quotations omitted). Under the Food, Drug, and Cosmetic Act ("FD&C" or "FDCA"), "all such proceedings for the enforcement, or to restrain violations, of [the Act] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Further, Congress expressly allows the FDA discretion to decline to prosecute "minor violations" of the FD&C when it "believes that the public interest will be adequately served by a written notice or warning." 21 U.S.C. § 336.

A. Plaintiff asserts that her claims are based on California regulation of the sale of hemp, but the California law merely incorporates and enforces federal law.

Private enforcement of the FD&C is barred. *Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013). The U.S. Supreme Court has held that state-law claims not based on "traditional state

tort law which had predated the federal enactments in question," but rather on "violations of FDCA requirements" were in conflict with, and thus "impliedly pre-empted by, federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 352-53 (2001). Thus, a state-law claim that is nothing more than an action to enforce the FD&C is preempted. *Perez*, 711 F.3d at 1119-20. To escape preemption, a state-law claim must fit through a "narrow gap," namely, "the plaintiff must be suing for conduct that *violates* the FDCA . . . but the plaintiff must not be suing *because* the conduct violates the FDCA." *Id.* at 1120 (citation omitted) (emphasis in original).

As admitted by Plaintiff, California's Sherman Laws incorporate and adopt the FD&C regulations. CAL. HEALTH & SAFETY CODE § 110100(a); Opp. at 6, fn.1 & 7. And the entire reasoning behind Plaintiff's claims is that Elixinol's Products are "illegal" *because* they violate the FD&C. *See* FAC at ¶¶ 2, 6, 16, 17, 21-22. For example, Plaintiff claims the Products "do not meet the definition of a dietary supplement under section 201(ff) of the FD&C," "fail to bear adequate directions for use," and that Elixinol's "use of CBD in animal foods . . . is a prohibited act under section 301(ll) of the FD&C." FAC at ¶¶ 19, 21-23; Opp. at 6-7. Absent the FD&C, these requirements would not exist. This means that "the existence of [the FD&C] is a critical element" of Plaintiff's claims, and therefore they are preempted. *Perez*, 711 F.3d at 1119.

B. The 2018 Farm Bill requires deference to the FDA.

The 2018 Farm Bill states that "[n]o State . . . shall prohibit the transportation or shipment of hemp or hemp products . . . through the State." 2018 Farm Bill, Pub. L. No. 115-334 § 10114, 132 Stat. 4490, 4914 (2018). This type of "explicit statutory command" displaces state law. *Ting*, 319 F.3d at 1135. And nothing in the 2018 Farm Bill serves to affect or modify the FD&C. 132 Stat. 4490, 4914. But again, Plaintiff's claims rely on FDA statements that do not bear the weight of law. So, while the 2018 Farm Bill requires deference to the FD&C and, by extension, the FDA who enforces the FD&C, there is no existing law that would support Plaintiff's claims. Thus, they must be dismissed with prejudice.

V. PLAINTIFF'S FAC FAILS TO STATE A CLAIM FOR EACH OF ITS CAUSES OF ACTION.

A claim is only plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the conduct alleged." *Ashcroft v.*

Iqbal, 556 U.S. 662, 678 (2009). Conclusory statements and legal allegations, unwarranted inferences, and threadbare recitals of a claim's elements are not sufficient. *Id.*; *Adams v. Johnson*, 355 F.3d 1179, 1183 (9th Cir. 2004).

A. Plaintiff alleges inadequate facts to support each of her claims under the *Iqbal/Twombly* standard.

Plaintiff's initial response to Elixinol's first motion to dismiss was to amend her complaint. But in doing so, Plaintiff did not make *any* factual additions to her Complaint in the FAC. If a plaintiff does not allege adequate facts to state a facially plausible claim for relief, the defendant is entitled to dismissal of that claim. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A plaintiff's legal conclusions and unwarranted inferences are not sufficient to defeat a motion to dismiss. *Iqbal*, 556 U.S. at 680; *Adams*, 355 F.3d at 1183. Here, each of Plaintiff's claims relies on such legal conclusions and unwarranted inferences.

1. Plaintiff does not allege adequate facts for her UCL claim.

Plaintiff asserts that she properly alleges a UCL claim, but once again the entirety of her support relies on her incorrect legal conclusion that Elixinol's Products are illegal. Opp. at 13-14. The Opposition claims the FAC sufficiently pleads facts for an unlawful business practices claim but is merely reasserting the "illegality" argument that is based on non-binding FDA statements.

And in supporting her claim of unfair business practices, Plaintiff cites caselaw stating that the purchase of a product that should not have been on the market is satisfactory to establish standing under the UCL. *Franz v. Beiersdorf, Inc.*, 745 F. App'x 47, 48 (9th Cir. 2018). But Plaintiff does not allege facts adequate to show Elixinol's Products should not have been on the market and instead asserts the legal conclusion that Elixinol's Products are "illegal to sell." This failing to plead adequate facts dooms her unfair business practices claim.

Finally, acknowledging the heightened pleading standard for fraud claims, Plaintiff presents the "who, what, when, where, and how" of her fraudulent conduct claim. But rather than identifying the facts with particularity—like the names of persons who made allegedly fraudulent representations, their authority to speak, what was said, and who they said it to—Plaintiff merely falls back on the "illegality" argument. *See Moss v. Infinity Ins. Co.*, 197 F. Supp. 3d 1191, 1198 (N.D. Cal. 2016). This renders her pleading insufficient, and it must be dismissed with prejudice.

2. Plaintiff does not allege adequate facts for her FAL claim.

Plaintiff's assertion that her FAL claim is adequately pleaded also rests on the "illegality" argument. Opp. at 15. By relying solely on the FDA's advisory statements, Plaintiff's allegations constitute mere legal conclusions and combined with a recitation of the claim's elements.

3. Plaintiff does not allege adequate facts for her CLRA claim.

To prove her CLRA claim is adequately pleaded, Plaintiff begins by asserting that her failure to plead that she read the allegedly inadequate labels is incorrect. But Plaintiff does not point to any portion of the FAC that makes such an assertion. To allege a CLRA claim, a consumer must show that she was exposed to the unlawful business practice. *Sciacca v. Apple, Inc.*, 362 F. Supp. 3d 787, 796 (N.D. Cal. 2019). Plaintiff's Opposition represents that "omissions contrary to a defendant's representation are actionable," citing *Wilson v. Hewlett-Packard Co.* 668 F.3d 1136, 1141 (9th Cir. 2012). But Plaintiff's only support evidence of omissions was the omission of the fact that Elixinol's Products are illegal. Since this is inaccurate, Plaintiff's CLRA claim fails.

Plaintiff asserts that her CLRA notice letter was sufficient because it repeated statements from the FAC. Opp. at 17-18. However, Plaintiff's "illegality" argument is null, and her FAC pleads that she only purchased one product, never alleged she used it, and never identified what induced her to "purchase and use" the Products. Furthermore, she does not identify specific statements or advertisements by Elixinol that support her claim. Plaintiff's CLRA claim is inadequately pleaded and should be dismissed with prejudice.

4. Plaintiff alleges inadequate facts for her breach of express warranty claim.

Plaintiff asserts that she adequately pleaded her breach of express warranty claim simply because she purchased Elixinol's Product "because Defendant warranted that the products are legal." Opp. at 18. But a plaintiff must prove the seller "made an affirmation of fact or a promise, or otherwise described the goods . . . [that] formed part of the basis of the bargain." *Stearns v. Select Comfort Retail Corp.*, 763 F. Supp. 2d 1128, 1142 (N.D. Cal. 2010). But product representations do not automatically create a warranty—they "must be specific and unequivocal." *Maneely v. Gen. Motors Corp.*, 108 F.3d 1176, 1181 (9th Cir. 1997). Plaintiff does not identify a single specific, unequivocal statement that she relied on as the basis of the bargain. This

constitutes a failing to plead adequate facts and as a result Plaintiff's breach of express warranty claim should be dismissed with prejudice.

5. Plaintiff alleges inadequate facts for her breach of implied warranty claim.

To plead a breach of implied warranty claim, Plaintiff must allege adequate facts to show that the product was not the same quality as those generally acceptable in the trade or not fit for the ordinary purposes for which the product is used. *Andrade v. Pangborn Corp.*, No. C 02-3771 PVT, 2004 WL 2480708, at *23 (N.D. Cal. Oct. 22, 2004) (citing CACI 1231; CAL. COM. CODE § 2314). But Plaintiff once again merely asserts the inaccurate legal conclusion that Elixinol's Products are illegal, mislabeled, and misbranded. These are not adequate facts—they are conclusory statements and legal allegations. Thus, Plaintiff's claim for breach of implied warranty must be dismissed with prejudice.

6. Plaintiff fails to rebut Elixinol's assertion that she did not allege adequate facts to support her claim for declaratory judgment, and thus the claim must be dismissed with prejudice.

"[A] plaintiff's failure to oppose a defendant's [motion to dismiss] argument [is] a concession that such claims should be dismissed," since failing to oppose a dispositive motion "may be construed as abandoning the subject claims." *Narang v. Gerber Life Ins. Co.*, Case No. 18-CV-04500-LHK, 2018 WL 6728004, at *4 (N.D. Cal. Dec. 21, 2018) (citations omitted). Though Elixinol's Motion alleges that Plaintiff's declaratory judgment claim should be dismissed, Plaintiff's Opposition does not address this claim and offers no rebuttal. Since Plaintiff failed to oppose Elixinol's motion to dismiss the declaratory judgment claim, it should be found to be abandoned, and thus must be dismissed with prejudice.

7. The caselaw is clear: Plaintiff cannot plead equitable claims in the alternative here because she relies on identical factual predicates.

Defendant moved to dismiss Plaintiff's equitable claims because, in this District, if there is an adequate remedy at law a plaintiff cannot assert both legal and equitable claims. To support her claim that she may plead equitable claims in the alternative, Plaintiff relies on caselaw from the Eastern District of California. The reason for this is simple—Northern District caselaw does not follow similar reasoning on this matter. A plaintiff who seeks equitable relief "must establish that there is no adequate remedy at law available," even if that plaintiff has no other remedy if

those claims fail. *Munning v. Gap, Inc.*, 238 F. Supp. 3d 1195, 1203 (N.D. Cal. 2017) (citation omitted). As more fully briefed in footnote 18 of Elixinol's Motion, this is not an outlier—numerous district courts in the Northern District have applied this reasoning to claims under the UCL, FAL, CLRA, and breach of warranty claims.

Further, despite Plaintiff's assertion that dismissal at the motion-to-dismiss stage is premature, Northern District courts have routinely held the opposite to be true. "[S]everal courts in this district have barred claims for equitable relief—including claims for violations of California consumer protection statutes—at the motion to dismiss stage . . . ." *Munning*, 238 F. Supp. 3d at 1203; *see also Zapata Fonseca v. Goya Foods Inc.*, Case No. 16-CV-02559-LHK, 2016 WL 4698942, at *7 (N.D. Cal. May 17, 2018) (holding that plaintiff's CLRA, UCL, FAL, and unjust enrichment claims must be dismissed because they relied on the same factual predicates as plaintiff's legal causes of action). Plaintiff's equitable claims—which rely on the exact factual predicates as her legal claims—must be dismissed with prejudice.

CONCLUSION

For these reasons, Plaintiff's First Amended Complaint should be dismissed with prejudice in its entirety. Alternatively, Plaintiff's claims are subject to primary jurisdiction as the underlying issues await FDA action, and if the Court does not dismiss Plaintiff's claims, it should stay this action pending that ultimate FDA action.

Plaintiff's Opposition includes a request that, in the event any of her claims are dismissed, she be granted leave to amend. But Plaintiff has already amended her Complaint once as a matter of course, as permitted by FED. R. CIV. P. 15(a)(1). And while leave to amend should be freely given, "the district court may exercise its discretion to deny leave to amend due to . . . repeated failure to cure deficiencies by amendments previously allowed . . . [and] futility of amendment." *Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 892-93 (9th Cir. 2010). Having already amended her Complaint in response to Elixinol's previous motion to dismiss, any claims that are dismissed now are due to a failure to cure previously identified deficiencies, meaning further amendment would be futile. Elixinol requests that each of Plaintiff's claims that are dismissed be dismissed with prejudice and that the Court not grant Plaintiff further leave to amend.

Dated: April 3, 2020.

Respectfully submitted,

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