UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
Miami Division

Case Number: 14-61909-CIV-MORENO

MARIO HERAZO, YANERIS ALMONTE,
DENIELE CHARUN & KENAN RASABI,

Plaintiffs,

vs.

WHOLE FOODS MARKET, INC.,

Defendant.
_____/

ORDER GRANTING IN PART MOTION TO DISMISS AND ORDER STAYING AND PLACING CASE IN CIVIL SUSPENSE FILE

Plaintiffs maintain that Defendant Whole Foods Market, Inc. used deceptive labels on their homeopathic products. Due to these deceptive labels, Plaintiffs filed a three-count complaint for unjust enrichment, a violation of the Florida Deceptive and Unfair Trade Practices Act, and negligent misrepresentation. Federal law mandates that Defendant include labels on their homeopathic products providing their indications for use – the stated purpose of the law is to achieve uniformity in regulations over nonprescription drugs. 21 U.S.C. § 379r. The Food and Drug Administration is charged with oversight over labeling of homeopathic products. In view of this regulatory scheme, the Court abstains from adjudicating this case under the primary jurisdiction and implied preemption doctrines. The Court also finds Plaintiffs lack standing to sue for injunctive relief and their unjust enrichment claim cannot survive as there is an adequate legal remedy.

THIS CAUSE came before the Court upon the Defendant's Motion to Dismiss **(D.E. No. 29)**.

THE COURT has considered the motion and the pertinent portions of the record, and being otherwise fully advised in the premises, it is

ADJUDGED that the motion is GRANTED in part and the case is STAYED pending review by the Food and Drug Administration.[1] It is also

ADJUDGED that the Clerk of this Court shall mark this cause as closed for statistical purposes and place the matter in a civil suspense file. The Court shall retain jurisdiction and the case shall be restored to the active docket upon motion of a party if circumstances change so that this action may proceed to final disposition. This order shall not prejudice the rights of the parties to this litigation. Plaintiffs SHALL notify the Court by October 30, 2015 and every 3 months thereafter of the current status of the proceedings and when this action is ready to proceed.

It is **ADJUDGED** that all other pending motions are DENIED as moot.

I. Background

Plaintiffs filed this purported class action against Defendant Whole Foods Market, Inc., a company that sells several homeopathic products under their "365 Be Well" brand to relieve medical symptoms. Plaintiffs claim that Defendant's products do not deliver the benefits promised to consumers. The named Plaintiffs, Mario Herazo, Yaneris Almonte, Deniele Charun, and Kenan Rasabi purchased products at Whole Foods. Specifically, they purchased "Cough Ease for Kids," "Cough Ease for Adults," "Flu Ease" and "Arnica Montana 30C" – none of which they claim

[1]Although the Court is abstaining from this matter pending agency review, the Court does find that Plaintiffs lack standing to seek injunctive relief and the claim for unjust enrichment is not tenable given there is an adequate remedy at law. Should the agency decline to administratively review this matter, the Plaintiffs' remaining claims are for monetary damages under the Florida Deceptive and Unfair Trade Practices Act and negligent misrepresentation.

delivered the promised benefits. Plaintiffs claim they relied on Defendant's deceptive and false labeling in purchasing these homeopathic products.

The three-count complaint is for unjust enrichment, a violation of the Florida Deceptive and Unfair Trade Practices Act, and negligent misrepresentation. Defendant has moved to dismiss on various grounds.

II. Legal Standard

"To survive a motion to dismiss, plaintiffs must do more than merely state legal conclusions," instead plaintiffs must "allege some specific factual basis for those conclusions or face dismissal of their claims." *Jackson v. BellSouth Telecomm.*, 372 F.3d 1250, 1263 (11th Cir. 2004). When ruling on a motion to dismiss, a court must view the complaint in the light most favorable to the plaintiff and accept the plaintiff's well-pleaded facts as true. *See St. Joseph's Hosp., Inc. v. Hosp. Corp. of Am.*, 795 F.2d 948, 953 (11th Cir. 1986). This tenet, however, does not apply to legal conclusions. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). Moreover, "[w]hile legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id.* at 1950. Those "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). In short, the complaint must not merely allege a misconduct, but must demonstrate that the pleader is entitled to relief. *See Iqbal,* 129 S. Ct. at 1950.

III. Legal Analysis

The motion to dismiss presents a myriad of arguments including whether the Defendant's offers of judgment to the named Plaintiffs moot their case, whether Plaintiffs have standing to pursue

injunctive relief, whether Plaintiffs' unjust enrichment claim can stand in the face of an adequate legal remedy, and whether this Court should abstain from adjudicating this case under the Florida Deceptive and Unfair Trade Practices Act's safe harbor provision, the primary jurisdiction doctrine, or principles of implied preemption.

A. Effect of the Offers of Judgment

The Eleventh Circuit in *Stein v. Buccaneers, Ltd., Partnership*, 772 F.3d 698 (11th Cir. 2014) addressed the issue of whether a defendant may moot a class action through an unaccepted offer of judgment under Federal Rule of Civil Procedure 68. The offers of judgment provided complete relief to the named plaintiffs, but not to class members, and were provided prior to the plaintiffs' filing of a motion to certify a class. Given the circumstances in *Stein*, the Eleventh Circuit found that the offers of judgment did not moot the case. *Id.*, 772 F.3d at 700.

In its reply brief, Defendant conceded that *Stein* is dispositive of its argument that the offers of judgment moot out the Plaintiffs' claims. Accordingly, the Court denies the motion to dismiss on this issue and finds the offers of judgment did not moot the named Plaintiffs' claims.

B. Unjust Enrichment (Count I)

"It is blackletter law that 'the theory of unjust enrichment is equitable in nature and is, therefore, not available where there is an adequate legal remedy.'" *In re: Managed Care Litig.*, 185 F. Supp. 2d 1310, 1337 (S.D. Fla. 2002) (quoting *Webster v. Royal Caribbean Cruises, Ltd.*, 124 F. Supp. 2d 1317, 1326 (S.D. Fla. 2000) (noting that under Florida law, "quantum meruit damages cannot be awarded when an enforceable contract exists.")). "An unjust enrichment claim can exist only if the subject matter of that claim is not covered by a valid and enforceable contract." *Id.* There

is an adequate remedy at law when monetary damages are available via an alternative claim. *Bule v. Garda CL Southeast, Inc.*, No. 14-21898-CIV, 2014 WL 3501546, *3 (S.D. Fla. July 14, 2014).

Plaintiffs have not alleged there is an express contract nor have they alleged there is a lack of an adequate legal remedy. Defendant argues the adequate legal remedy in this case stems from the express contract between the parties for the retail purchase of the homeopathic products –the facts of which are pled in the complaint and underlie the Florida Deceptive and Unfair Trade Practices Act claim, which is a claim for monetary damages and injunctive relief. Because the complaint provides factual allegations supporting an adequate remedy of law and a cause of action to recoup that remedy, the Defendant argues for dismissal of the unjust enrichment claim.

Plaintiffs argue that they should be allowed to plead the unjust enrichment claim in the alternative. An unjust enrichment claim can only be pled in the alternative if one or more of the parties contest the existence or validity of an express contract governing the subject of the dispute. *In Re: Managed Care Litig.*, 185 F. Supp. 2d at 1337-38; *Martorella v. Deutsche Bank Nat. Trust Co.*, 931 F. Supp. 2d 1218, 1228 (S.D. Fla. 2013). When an agreement is arrived at by words or in writing, the contract is said to be "express." *In re Standard Jury Instructions--Contract & Bus. Cases*, 116 So. 3d 284, 308 (Fla. 2013). In *Prohias v. Pfizer Inc.*, 490 F. Supp. 1228, 1236 (S.D. Fla. 2007) (Jordan, J.), the court found the purchase of a cholesterol-reducing drug sufficient to establish the requisite contractual relationship and dismissed the unjust enrichment claim. The *Prohias* court wrote: "Unjust enrichment 'cannot exist where payment has been made for the benefit conferred.'" *Id.* (quoting *N.G.L. Travel Assoc. v. Celebrity Cruises, Inc.*, 764 So. 2d 672, 675 (2000)). Here, the Court finds the Plaintiffs' purchase of the homeopathic products, which is not in dispute, forms

the basis of an express contract and dismisses the unjust enrichment claim.

C. Florida Deceptive and Unfair Trade Practices Act Claim[2]

As to the statutory claim for injunctive relief, Defendant challenges the Plaintiffs' standing under Article III. Plaintiffs' complaint indicates that the products were worthless. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 ("Past exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief ... if unaccompanied by any continuing, present adverse effects.'")(citing *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983), quoting *O'Shea v. Littleton*, 414 U.S. 488, 495-96 (1974)) . In the context of consumer protection claims challenging product labeling, the court has applied the *Lujan* standing maxim. *Marty v. Anheuser-Busch Co., LLC*, 43 F. Supp. 3d 1333, 1358 (S.D. Fla. 2014) ("There is no likelihood of injury in the future if a plaintiff has no interest in purchasing the product at issue again because it does not work or does not perform as advertised.") (quoting *Mason v. Nature's Innovation, Inc.*, No. 12-CV-3019 BTM (DHB), 2013 WL 1969957 (S.D. Cal. May 13, 2013)). In *Marty*, the court emphasized

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[2]The Florida Deceptive and Unfair Trade Practices Act states as follows:

> In any action brought by a person who has suffered a loss as a result of a violation of this part, such person may recover actual damages, plus attorney's fees and court costs as provided in s. 501.2105. However, damages, fees, or costs are not recoverable under this section against a retailer who has, in good faith, engaged in the dissemination of claims of a manufacturer or wholesaler without *actual knowledge* that it violated this part.

§ 501.211(2), Fla. Stat. (emphasis added). As a retailer of the subject homeopathic medicine, the statute engrafts a requirement that Defendant violated the act with actual knowledge. The complaint lacks an allegation that Defendant had actual knowledge it was violating the act. In view of the Court's abstention of this case on other grounds, the Court declines to grant Plaintiffs leave to amend this claim to incorporate that allegation. The Court, nevertheless, notes that the claim is not properly pled under the statute.

that where the complaint only contains allegations of past injury, those allegations do not support a finding of standing where injunctive relief is sought. *Id.*, 43 F. Supp. 3d at 1359. Similarly, the amended complaint here details past injury regarding the product labeling. It contains an allegation that but for the misleading labeling, Plaintiffs would not have purchased the homeopathic medication. It also describes the products as "worthless." The only logical deduction from these allegations is that the Plaintiffs will not be purchasing the homeopathic medication in the future. Consistent with the principles enunciated in *Lujan*, the Court dismisses the claim for injunctive relief for lack of standing pursuant to Federal Rule of Civil Procedure 12(b)(1).

D. Abstention under the Safe Harbor, Implied Preemption and Primary Jurisdiction Doctrines

Defendant Whole Foods seeks to have the Court abstain from hearing Plaintiffs' claims based on the safe harbor, implied preemption, and primary jurisdiction doctrines. The underlying premise for this argument stems from the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, 321(g)(1), which mandates that homeopathic medicine be treated as "drugs" under federal law. The Act generally prohibits misleading labeling. 21 U.S.C. § 331 ("The following acts and the causing thereof are prohibited: (a) [t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is . . . misbranded."); *see also* 21 U.S.C. § 321(n) (defining "misbranded" to include misleading labeling or advertising); 21 U.S.C. § 352 (titled "Misbranded Drugs and Devices"). A regulatory scheme requires sellers of homeopathic products to include "Indications for Use" or "Directions for Use" on their products as required by federal statute. *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. §§ 201.61(b), 201.66(c)(4) (providing regulatory scheme for formatting and content requirements for over-the-counter drug product

labeling); Compliance Policy Guide § 400.400 (providing the U.S. Food and Drug Administration's conditions under which homeopathic drugs may be marketed). Sellers are also required to include a "Statement of Identity" for their products that provide an "accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug. In the case of an over-the-counter drug that is a mixture and that has no established name, this requirement shall be deemed to be satisfied by a prominent and conspicuous statement of the general pharmacological action(s) of the mixture or of its principal intended action(s). . .." *See* 21 C.F.R. § 201.61; Compliance Policy Guide § 400.400.

1. Safe Harbor

At issue in the motion to dismiss is whether the Florida Deceptive and Unfair Trade Practices Act's safe harbor provision precludes liability. The Act explicitly precludes liability for "[a]n act or practice *required* or specifically permitted by federal or state law." § 501.212(1), Fla. Stat.; *Prohias*, 490 F. Supp. 2d at 1234. An act, however, does not need to violate a specific rule or regulation to be considered deceptive. *Prohias*, 490 F. Supp. 2d at 1233. The relevant inquiry for the Court is whether Whole Foods, as the moving party, has shown that a specific federal or state law affirmatively authorized it to engage in the conduct alleged in the complaint, not whether Whole Foods violated a specific rule or regulation. *Id.*, 490 F. Supp. 2d at 1234. To fall within the purview of the safe harbor, the *Prohias* court wrote that the defendant had to show the Food and Drug Administration viewed and approved the misleading advertising. *Id.*

In this case, Whole Foods has generally shown that it is required to provide labels on its homeopathic products and the products' Indications for Use. Whole Foods, however, has not met

its burden to show that the Food and Drug Administration specifically authorized the labels at issue in this case (exhibits A through D of the First Amended Complaint). The Court, therefore, cannot presume that the Food and Drug Administration viewed and approved the homeopathic product labels and declines to apply Florida's safe harbor provision absent that showing from Defendant.

2. Primary Jurisdiction

The primary jurisdiction doctrine applies where a case implicates a federal agency's expertise with a regulated product. *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956) (holding that primary jurisdiction doctrine applies 'whenever enforcement of [a] claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body."). "The doctrine enables a court to take advantage of an agency's expertise, protects the integrity of the regulatory scheme, and promotes uniformity." *Greenfield v. Yucatan Foods, L.P.*, 18 F. Supp. 3d 1371, 1375 (S.D. Fla. 2014) (quoting *Flo-Sun, Inc. v. Kirk*, 783 So. 2d 1029, 1037 (Fla. 2001)). The primary jurisdiction doctrine is a discretionary doctrine that 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." *Garrison v. Whole Foods Market Group, Inc.*, No. 13-05222-CV, 2014 WL 2451290, *2 (N.D. Cal. June 2, 2014). In this case, Defendant Whole Foods requests the Court defer this matter to the Food and Drug Administration.

Plaintiffs rely on *Garrison v. Whole Foods Market Group, Inc.*, No. 13-CV-05222, 2014 WL 2451290 (N.D. Cal. June 2, 2014) to argue the primary jurisdiction doctrine does not require abstention. In *Garrison*, the court declined to abstain because the Food and Drug Administration had repeatedly declined to adopt formal regulations regarding the meaning of the word "natural."

Id., at *2. It wrote: "[t]here is no clear indication the Agency intends to revisit this decision any time soon. There is, therefore, no 'resolution of [the] issue' pending before the Agency to which the Court could defer." *Id.* (quoting *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008)). The underlying facts of *Garrison*, however, are different than those present here. In *Garrison,* the plaintiffs were challenging food labels claiming the foods were "natural." Here, the Plaintiffs are challenging the Indications for Use that the Food and Drug Administration mandates for homeopathic medicine. In *Garrison*, the court specifically found the Agency had repeatedly declined to adopt a definition for "natural." In this case, there is no indication that the Agency is declining to oversee the indications for use that are at issue.

Courts consider four factors when applying the doctrine of primary jurisdiction: (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 scheme that (4) requires expertise or uniformity in administration. *Greenfield*, 18 F. Supp. 3d at 1376. The Food and Drug Administration has the necessary experience and expertise in regulating labeling of homeopathic medication and it is within the Agency's purview to decide whether the labels are compliant with federal law and the comprehensive regulatory scheme it has devised.

The Court is aware that the "primary jurisdiction doctrine is not designed to secure expert advice from agencies every time a court is presented with an issue conceivably within the agency's ambit." *In re Horizon Organic Milk Plus DHA Omega–3 Mktg. & Sales Practice Litig.*, 955 F.Supp.2d 1311, 1349 (S.D. Fla. 2013). In this case, however, given the extensive regulatory scheme

to oversee homeopathic drug marketing and the questions presented over the labels in this case, the Court finds abstention appropriate under the primary jurisdiction doctrine. *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 232 (3d Cir. 1990)(holding that the issue of whether an ingredient is properly labeled "active" or "inactive" under the Food and Drug Administration's standards is not properly decided by a district court).

Having found the doctrine of primary jurisdiction applies, the court has discretion either to stay the case and retain jurisdiction or to dismiss the case without prejudice if the Parties would not be unfairly disadvantaged. *See Reiter v. Cooper*, 507 U.S. 258, 269 (1993). Pending the referral to the Food and Drug Administration, the Court stays this case to avoid any prejudice to the parties. *Greenfield*, 18 F. Supp. 3d at 1377.

3. Implied Preemption

Implied preemption applies "when compliance with both state and federal law is impossible. . . or when the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699 (1984); *Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 790 (E.D. Tex. 2008) (noting claims were preempted because defendants could either "market their products in compliance with the FDA requirements, or they can refrain from marketing their products in order to comply with the requirements (and avoid the liability) imposed by Plaintiff's lawsuit. They cannot do both.") (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008)).

Defendant argues that when Congress enacted the "National Uniformity for Nonprescription Drugs" provision, 21 U.S.C. § 379r, it sought to achieve uniformity in regulations over

nonprescription drugs – not just allopathic drugs. It argues Plaintiffs' suit seeking to change the labeling requirements of Defendant's homeopathic medication conflicts with federal policy and should be impliedly preempted. Notwithstanding the Court's finding that Plaintiffs lack standing to bring a claim for injunctive relief, the Court additionally finds that allowing the claim for injunctive relief to go forward would undermine the purpose for which Congress enacted the uniformity provision and thwart the Food and Drug Administration's ability to carry out its oversight of marketing of homeopathic products.

DONE AND ORDERED in Chambers at Miami, Florida, this 23rd day of July, 2015.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Counsel of Record