NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: BAYER PHILLIPS COLON HEALTH PROBIOTICS SALES PRACTICES LITIGATION	Civil Action No. 11-03017 **OPINION**

John Michael Vazquez, U.S.D.J.

I. INTRODUCTION

This matter comes before the Court on Defendant Bayer Healthcare LLC's ("Bayer" or "Defendant") motion for summary judgment. D.E. 157. Also pending before the Court is Plaintiffs Troy Yuncker and Dino Rikos' (collectively "Plaintiffs") motions for class certification (D.E. 143) and motion to strike portions of Defendant's expert's opinion (D.E. 165). Plaintiffs allege that Bayer made false and misleading claims regarding one of its dietary supplements. The Court considered the written submissions of the parties[1] and considered the motion without oral argument pursuant to Federal Rule of Civil Procedure 78(b) and Local Civil Rule 78.1(b). For the reasons that follow, Bayer's motion for summary judgment is granted. Because the Court grants Bayer's motion, Plaintiffs' pending motions (D.E. 143, 165) are denied as moot.

II. BACKGROUND

[1] Bayer's brief in support of its motion for summary judgment will be referred to as "Def. Br." Plaintiffs opposition brief will be known as "Pl. Opp." Bayer's reply brief will be referred to as "Def. Rep."

The facts of this matter are derived from the record, and they are reviewed in the light most favorable to the non-moving party, Plaintiff. *See Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) (noting that in motion for summary judgment "a court must view the evidence in the light most favorable to the opposing party" (internal quotation marks omitted)).

A. The Dietary Supplement

Plaintiffs filed this action on their own behalf and on behalf of all others similarly situated who purchased Phillips' Colon Health ("PCH"), a probiotic dietary supplement sold by Bayer. Defendants Statement of Material Facts not in Dispute ("DSOF") ¶ 1.[2] The supplement is provided to Bayer from another company, Wakunaga of America Co., Ltd.[3] ("Wakunaga"). Plaintiffs allege that Bayer made "false and misleading" representations in the marketing of PCH. *Id.* PCH's product label stated as follows:

3 strains of good bacteria to promote

OVERALL DIGESTIVE HEALTH

Helps Defend Against Occasional:

CONSTIPATION

DIARRHEA

GAS AND BLOATING

Id. ¶ 2. Plaintiffs allege that these "statements are false and misleading and reasonably likely to deceive the average consumer." *Id.* At all relevant times, the PCH label contained the statement

[2] The Court cites to Bayer's Statement of Material Facts not in Dispute only when Plaintiffs have admitted that such facts are undisputed.

[3] The parties do not make clear the actual corporate name of Wakunaga in their moving papers or the Complaint. The Court derives the name Wakunaga of America Co., Ltd. from the exhibits that the parties submitted.

that "[t]his product is not intended to diagnose, treat, cure, or prevent any disease." DSOF ¶ 28. The disclaimer was required by law.

B. Probiotics

A probiotic is defined by the World Health Organization as "[l]ive microorganisms which, when administered in adequate amounts, confer a health benefit on the host." D.E. 145-7 at 8. Probiotics are commonly used to "prevent overgrowth of potential pathogens in the gastrointestinal tract." *Id.* Probiotics can lead to better "host defense and nutritional benefits by increasing indigenous beneficial bacteria and decreasing harmful bacteria." *Id.* There are many other benefits of probiotics and scientists are just beginning to understand all of the functions they perform in the overall health of human beings. Declaration of Dr. Stefano Guandalini, M.D. ("Guandalini Dec.") ¶ 14 (D.E. 160-3). Bacteria are categorized by their genus, species, and strain. Pl. Opp. at 5. The genus, species, and strain for the three PCH bacteria are (1) *Lactobacillus* (genus) *gasseri* (species) KS-13 (strain); (2) *Bifidobacterium bifidum* G9-1; and (3) *Bifidodbacterium longum* MM-2. *Id.* The parties do not dispute that PCH is regulated as a dietary supplement, as opposed to a drug.

Pursuant to the Dietary Supplement Health & Education Act of 1994 ("DSHEA"), the approval process for dietary supplements is less onerous than that required for drugs. The DSHEA permits the label on dietary supplements "to bear, among other types of statements, a statement that describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." *Stanley v. Bayer Healthcare LLC*, No. 11-862, 2012 WL 1132920, at *7 (S.D. Cal. Apr. 3, 2012) (internal quotation marks omitted). These statements, known as "structure/function claims, are not required to be pre-approved by the FDA."

Id. Drugs, however, are held to a higher standard requiring pre-approval from the Food and Drug Administration, 21 U.S.C. §§ 331(d), 355(a), and generally "must be supported by randomized, placebo-controlled, double-blind clinical trials," *United States v. Bayer Corp.*, No. 07-01, 2015 WL 5822595, at *3 (D.N.J. Sept. 24, 2015) (the "*FTC Opinion*") (citing 21 C.F.R. § 314.126). Dietary supplements need not meet these requirements. *Id.* Instead, "the only substantiation requirement is that claims must be 'truthful and not misleading,'" *id.* (quoting 21 U.S.C. § 343(r)(6)(B)), and a statement "prominently displayed and in boldface type" which says, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease," 21 U.S.C. § 343(r)(6)(C). "As long as the supplement is not marketed as a drug -- i.e., it is not claimed to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases, -- it is not regulated like a drug." *FTC Opinion*, at *3 (internal quotation marks and citations omitted).

C. Plaintiffs Troy Yuncker and Dino Rikos

Plaintiff Troy Yuncker alleges that he purchased one package of 30-count PCH in May 2011 at a Walgreens store in Chicago, Illinois based on "the digestive health representations" on the package. *Id.* ¶ 7. Yuncker was shopping for a probiotic because he "was having bad gas and digestive problems" due to consuming fast food. *Id.* ¶ 11. In particular, Yuncker testified that he had been suffering from "gastrointestinal problems," which he later identified as acid reflux, for at least ten years prior to using PCH. *Id.* ¶ 12. Yuncker consumed one pill of PCH per day for a period of nine days and then stopped taking the supplement. *Id.* ¶¶ 13-14. Yuncker believed that PCH was ineffective because his "gas and constipation [had not] changed." Deposition of Troy Yuncker ("Yuncker Dep.") at 85:3-7.

Plaintiff Dino Rikos purchased PCH six to seven times over a six-month period in 2010 at "various retail drug store chains" in California and Illinois. DSOF ¶ 16. Rikos claims to have chosen PCH based on the "digestive health representations" on the label. *Id.* ¶ 17. In particular, Rikos purchased PCH to combat chronic diarrhea, gas, and bloating that he suffered subsequent to a diagnosis of colon and rectal cancer, chemotherapy, radiation, and colon resection surgery. *Id.* ¶ 20. Rikos believed that PCH "wasn't doing anything" to cure his symptoms, and as a result, decide to file suit against Bayer for false advertising. Deposition of Dino Rikos ("Rikos Dep.") 48:18 to 49:6.

D. The Scientific Studies

There are three scientific studies that both Plaintiffs and Defendant claim play a significant role in the outcome of this motion. Each study was a double-blind, placebo randomized controlled trial ("RCT").[4] RCTs are known in the scientific community as the "gold standard" for scientific studies. *Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867, 882 (N.D. Cal. 2016) ("Randomized clinical trials are 'the gold standard for determining the relationship of an agent to a health outcome.'" (quoting Federal Judicial Center, *Reference Manual on Scientific Evidence* 555 (3d ed. 2011))).

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[4] An RCT is defined as

> [a]n experimental study to assess the effects of a particular variable (e.g., a drug or treatment) in which subjects are assigned randomly to an experimental, placebo, or control group. The experimental group receives the drug or procedure; the placebo group's medication is disguised to resemble the drug being investigated. The control group receives nothing. Laboratory tests or clinical evaluations are performed on the groups (usually using the double-blind technique) to determine the effects of the drug procedure.

Taber's Cyclopedic Medical Dictionary 1847-48 (20th ed. 2006).

The first RCT was conducted with approval from the Research Ethics Board of the Canadian College of Naturopathic Medicine in March 2010 and approval from the Natural Health Product's Directorate in May 2010 (the "Canada I Study"). Declaration of James E. Cecchi ("Cecchi Dec."), Ex. 55 (D.E. 145-27). The purpose of the study was "to investigate the effects of an investigational Probiotic on Irritable Bowel Syndrome." *Id.* The study used the same three-strain bacteria that make up Bayer's PCH. *Id.* at Ex. 54. The results of the Canada I Study indicated that the active group[5] and placebo group both experienced "significant improvements" in Irritable Bowel Syndrome ("IBS").[6] *Id.* at Ex. 54. The study found that "the greatest difference in effect between active and placebo groups [was] seen in the [d]iarrhea subtype." *Id.* The greatest effect regardless of whether the participant was in the active or placebo group was seen in the constipation subtype. *Id.* However, despite these positive trends, the Canada I Study concluded that the "difference between the groups is not statistically significant" and the "sample size amongst the subtypes is not large enough to draw a definite conclusion." *Id.*

The second RCT took place in 2013 and "was performed to test the effect of [PCH] on the severe sufferers of [IBS]." *Id.*, Ex. 58 (the "Canada II Study"). The analysis of the Canada II Study was conducted by the Centre for Quantitative Analysis and Decision Support at Carleton University. *Id.* The study concluded that the use of PCH on severe IBS participants did not "reveal a statistically significant treatment effect." *Id.* at 2. The Canada II Study acknowledged that the differences in improvement between the active and placebo groups "were nearly significant," but ultimately found that "the large placebo effect and high fluctuating nature of IBS on a day-to-day

[5] The "active group" designates the participants that took the three bacteria strains.

[6] IBS is a "chronic, reoccurring gastrointestinal disorder . . . characterized by abdominal pain, bowel dysfunction and bloating in the absence of any structure abnormalities." Cecchi Dec., Ex. 54.

basis make it very difficult to control for the uncertainty of the data." *Id.* at 2. In sum, the study found that "there is simply not enough evidence to conclude that [PCH] is effective against IBS . . . [or that it] provides a practically significant improvement in the average participant's quality of life." *Id.* at 20-21.

The third RCT, known as the "Florida Study," was conducted by researchers at the University of Florida and published in 2015. *Id.*, Ex. 59. The Florida Study used the same three-strain bacteria contained in PCH. *Id.* at 1. The objective of the study was to determine "whether older adults who consumed a probiotic mixture would have a greater proportion of circulating CD4+ lymphocytes, altered cytokine production, and a shift in intestinal microbiota toward a healthier microbial community." *Id.* The study consisted of 32 healthy adults between the ages of 65 and 80. *Id.* at 5. It was designed not to detect changes in clinical symptoms, but in "biomarkers." *Id.* at 1. Biomarkers are defined as a "detectable cellular or molecular indicator of exposure, health effects, or susceptibility, which can be used to measure the absorbed, metabolized, or biologically effective dose of a substance, the response to the substance including susceptibility and resistance, idiosyncratic reactions, and other factors or conditions." *Stedman's Medical Dictionary* 221 (28th ed. 2006).

The Florida Study concluded that the probiotic mixture "maintained CD4+ lymphocytes and produced a less inflammatory cytokine profile in healthy older adults." D.E. 145, Ex. 59 at 9. The study found that the "changes may have been due to changes in the microbial communities, which more closely resemble those observed in healthy younger populations." *Id.* While the Florida Study concluded that "healthy older adults may benefit from ingesting this probiotic mix," it suggested that "future studies should explore inflammatory changes and health-related outcomes in an at-risk population." *Id.*

E. Plaintiffs' Expert

Plaintiffs' expert Dr. Stefano Guandalini, M.D. is a Professor of Pediatrics and Director of the Division of Gastroenterology, Hepatology and Nutrition of the Department of Pediatrics at the University of Chicago. Guandalini Dec. ¶ 1. Dr. Guandalini has engaged in extensive clinical research testing probiotics, authored more than 200 peer-reviewed publications, and presented more than 300 invited lectures. *Id.* ¶ 3-5.

In his deposition, Dr. Guandalini opined that PCH "has been clinically proven to be ineffective" for people with IBS. Deposition of Dr. Stefano Guandalini, M.D. ("Guandalini Dep.") at 69:14-16; 176:13-18. Dr. Guandalini explained that for a claim about a dietary supplement, such as PCH, to be true it must be supported by "competent and reliable scientific evidence," which requires "well conducted clinical trials." *Id.* at 68:17-21; 150:2-12. Dr. Guandalini defined "well-conducted clinical trial" to mean, among other things, that the study should not be initiated by the industry, possibly be conducted "in a multi-center fashion, be double blind and placebo controlled, consist of a sufficient number of sufficient participants to reach statistically significant results, be carefully analyzed, and be subject to peer review. *Id.* at 137:6 to 138:1; *see also id.* at 161:4-8 (stating that an RCT would be required to state that a product "helps promote digestion"). Dr. Guandalini stated that the reason he believes "well-conducted clinical trials" are necessary is because doing so is "good clinical practice." *Id.* at 140:9-19. According to Dr. Guandalini, the testing required to determine the efficacy of a product is the same whether the product is classified as a drug or a dietary supplement. *Id.* at 61:6-10. Dr. Guandalini also testified that he did not "have enough authority to express a judgment on" the difference between the Food and Drug Administration's regulations on drugs compared to dietary supplements. *Id.* at 62:24 to 63:5.

To support his conclusion that PCH is ineffective, Dr. Guandalini relied on two RCTs, the Canada I Study and the Florida Study.[7] *Id.* at 69:10-11; 164:3-7. Dr. Guandalini explained that these were the only two studies on which he based his opinion to conclude that PCH's claims of "defend[ing] against occasional constipation, diarrhea, gas, and bloating" are false. *Id.* at 164:3-7. However, Dr. Guandalini recognized some limitations in the results of the Canada I and Florida Studies. In regard to the Canada I Study, Dr. Guandalini noted that the study's results were limited to showing that PCH did not cause a statistically significant improvement in adults with symptoms of IBS, as opposed to less severe gastrointestinal issues or general health maintenance. *Id.* at 163:22 to 164:9. Dr. Guandalini agreed that PCH's effect on IBS symptoms and its effect on overall digestive health are distinct inquiries:

> Q. Okay. Now, whether a therapy shows significant changes in IBS symptom severity does not necessarily tell us whether or not a therapy supports overall digestive health in a healthy population, right?
>
> A. Yeah, right.

Id. at 165:10-14. Additionally, as to the Florida Study, Dr. Guandalini explained that its results of PCH's ineffectiveness were limited to the particular patient population of "70 years and older." *Id.* at 158:9-14.

Dr. Guandalini was asked whether he believed that PCH effectively promoted overall digestive health in adults who do not have IBS, to which he provided inconsistent responses. First, he opined that there was sound scientific evidence that PCH is ineffective for adults with IBS, while leaving open the possibility that PCH could be effective for someone without IBS:

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[7] In his deposition, Dr. Guandalini said he relied only on these two studies. Guandalini Dep. at 69:10-11; 164:3-7. It appears, however, that Dr. Guandalini subsequently considered the Canada II study as it was discussed in his declaration submitted in connection with this motion. *See* D.E. 160-3 ¶ 35.

> Q. Okay. So then your opinion leaves open the possibility that PCH may work for someone without IBS, right?
>
> A. Well, yeah.
>
> . . . .
>
> Q. You are not opining that PCH is incapable of helping to promote overall digestive health, you just don't know one way or the other?
>
> A. I don't know.

Id. at 175:18-21; 177:2-5. Then Dr. Guandalini clarified that he would "be surprised if [PCH promoted overall digestive health] considering the small amount of bacteria contained in the preparation." *Id.* at 177:2-9. Next, Dr. Guandalini stated that he believed that PCH was "incapable of protecting against" symptoms of occasional constipation, diarrhea, gas, and bloating. *Id.* at 178:7-23. The colloquy took place as follows:

> Q. Okay. Let's go back. My original question was, you are not opining that PCH is incapable of helping to defend against occasional constipation, diarrhea, gas, and bloating?
>
> A. In my opinion, it is incapable of protecting against those symptoms as well, based on the fact that is was so clearly negative in the population of IBS sufferers, which, once again, are a population closely resembling, overlapping those that the claims are made for. I hope I made myself clear. So the strong evidence of lack of efficacy, clinical proven ineffective to treat patients with irritable bowel syndrome, on that I stand firm. I want to add, in addition, my opinion is that given this proof of inefficiency, it's extremely likely that we'll also not be able to protect from the occasional onset of symptoms. I really see no evidence to support that.

Id. Finally, Dr. Guandalini was asked:

> Q. Can you completely rule out that PCH provides health benefits to some people?
>
> A. No, I cannot.

> Q. Okay. In fact, there's no study finding that PCH has no benefits for anyone, correct?
>
> A. There is no study -- yes . . . I'm not aware of any study showing that there is a complete lack of health benefit.

Id. at 180:23 to 181:7.

F. Defendant's Expert

Defendant's Expert, Dr. Daniel J. Merenstein, M.D. is a tenured associate professor at Georgetown University where he focuses his research on probiotics and sinusitis and also teaches in both the undergraduate and medical schools. Declaration of Daniel J. Merenstein, M.D. ("Merenstein Dec.") ¶¶ 1, 3, 5. (D.E. 157-9). In the past six years, Dr. Merenstein was the principal investigator on seven probiotic clinical trials. *Id.* ¶ 6. Dr. Merenstein also works as a family physician with specialties in pediatrics and infectious and gastrointestinal diseases. *Id.* ¶ 4.

Dr. Merenstein opined that PCH helps alleviate diarrhea, constipation, gas, and bloating. Deposition of Daniel J. Merenstein, M.D ("Merenstein Dep.") 180:13 to 182:19. (D.E. 160-1). In particular, Dr. Merenstein "believe[s] that PCH can effectively help individuals who are generally healthy but suffer from occasional constipation, diarrhea, gas, and bloating." Merenstein Dec. ¶ 50. However, Dr. Merenstein acknowledged that although PCH promotes overall digestive health for some users, it may not do so for all people. Dr. Merenstein explained his position as follows:

> Q. Does Phillips Colon Health promote overall digestive health for everyone?
>
> A. No. We talked about that I think in the last hour, that there is nothing out there that does it for everyone. People can exercise and have a heart attack. People can get a flu vaccine and get the flu. And people can take Phillips Colon Health and have diarrhea.
>
> Q. Okay. Does PCH promote overall digestive health at least for some users?

A. Oh, yes, no question about it.

Q. Okay. And, similarly, does PCH help defend against occasional constipation, diarrhea, gas, and bloating for everyone that uses it?

A. No, it does not for everyone.

Q. But it does for some users, correct?

A. It does for some users.

Id. at 337:7 to 338:2.

Dr. Merenstein was asked for his opinion regarding the results of the Canada I, Canada II, and Florida Studies. Dr. Merenstein described the two Canada Studies as "null studies." *Id.* at 237:5-11. Dr. Merenstein found them to be "null studies" because they did not support the theory that PCH had a different effect on the active participants when compared to those who took the placebo. *Id.* at 237:18-21. Dr. Merenstein opined that although the two Canada Studies did not demonstrate that PCH "helps defend against occasional diarrhea, constipation, gas, or bloating," *id.* at 237:5-11; 239:19 to 240:4, the testing in these studies was targeting PCH's effect on participants with IBS as opposed to its effect on digestive health outcomes, *id.* at 237:22 to 238:4. In other words, Dr. Merenstein believed that each of the Canada Studies "tell us nothing about the cause and effect between probiotic use and helping to promote overall digestive health (as opposed to IBS), which is what the PCH label claims." Merenstein Dec. ¶ 55. As to the Florida Study, Dr. Merenstein stated that it "support[ed] Bayer's claims as part of the totality of scientific evidence . . . and proved PCH to be beneficial for the maintenance of gut homeostasis." Merenstein Dec. ¶ 56.

G. Procedural History

Plaintiffs filed a six-count Amended Complaint against Bayer alleging the following causes of action: (1) violation of the New Jersey Consumer Fraud Act (on behalf of Plaintiffs Rikos, Yuncker and all class members), (2) violation of the Consumers Legal Remedies Act -- California Civil Code Section 1750 et seq. (on behalf of Plaintiff Rikos and the California subclass), (3) unlawful business acts and practices in violation of California Business & Professions Code Section 17200, et seq. (on behalf of Plaintiff Rikos and the California subclass), (4) violation of Illinois' Consumer Fraud Act, 815 ILCS 505/1, et seq. (on behalf of Plaintiffs Rikos, Yuncker, and the Illinois subclass), (5) breach of implied warranty of merchantability,[8] (6) unjust enrichment (on behalf of Plaintiffs Rikos, Yuncker, and all class members). D.E. 94.

Defendant filed a motion to dismiss the complaint, which the Court granted in part and denied in part. D.E. 114. The Court denied the motion as to Counts Two through Six, but dismissed Plaintiffs' claim under the New Jersey Consumer Fraud Act. *Id.* Then, after discovery, Bayer moved for summary judgment on the remaining counts, which Plaintiffs oppose.

III. LAW AND ANALYSIS

A. Standard of Review

A moving party is entitled to summary judgment where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" when a dispute over that fact "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Importantly, "[f]actual disputes that are irrelevant or unnecessary will not be counted." *Id.* A material fact raises a "genuine" dispute "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Williams v. Borough of W. Chester*, 891 F.2d 458, 459 (3d

[8] In Plaintiffs opposition brief, they clarified that they are not seeking certification of this claim.

Cir. 1989) (quoting *Liberty Lobby*, 477 U.S. at 248). "Where the record taken as a whole could not lead a reasonable trier of fact to find for the non-moving party, there is no genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (internal quotation marks omitted). "When analyzing the sufficiency of the evidence, the court must view the facts and any reasonable inferences drawn therefrom in the light most favorable to the party opposing summary judgment." *InterVest, Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 159-60 (3d Cir. 2003) (citing *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 456 (1992)).

Summary judgment is appropriate "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Under those circumstances, "there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Id.* at 322-23. However, to withstand a motion for summary judgment, the nonmoving party need only "come forward with evidence which, if believed, would support a finding in its favor." *In re Bressman*, 327 F.3d 229, 237 (3d Cir. 2003).

B. The Federal Trade Commission Opinion

In September 2015, Judge Linares issued an opinion relevant to the issues arising in this case. *See United States v. Bayer Corp.*, No. 07-01, 2015 WL 5822595 (D.N.J. Sept. 24, 2015) (the "*FTC Opinion*"). In particular, the *FTC Opinion* analyzed (1) the different regulatory standards applicable to a dietary supplement as opposed to a drug, (2) the type of scientific evidence necessary to demonstrate that a dietary supplement, such as PCH, is "truthful and not misleading," and (3) the significance of the Canada I and Florida Studies.

In the *FTC Opinion*, Judge Linares addressed whether the United States of America (the "Government") had demonstrated by clear and convincing evidence that Bayer violated a consent decree thereby warranting a finding of contempt. *Id.* at *1. The consent decree, which had been entered into in 2007, applied to all of Bayer's dietary supplements. The consent decree provided that Bayer was barred "from making any representation, directly or by implication, concerning the need for or benefits to be derived from consumption of such [dietary supplements], unless, at the time such representation is made, [Bayer] possesses and relies upon a reasonable basis consisting of competent and reliable scientific evidence to substantiate the representation." *Id.* At issue was whether Bayer possessed adequate substantiation for its claims that PCH "promote[s] overall digestive health" and that it "helps defend against occasional constipation, diarrhea, gas, and bloating." *Id.* at *2, 5.

Judge Linares first recognized the regulatory differences between a dietary supplement and a drug. He explained that drugs are held to a higher standard requiring pre-approval from the FDA and usually must be supported randomized, placebo controlled, double-blind clinical trials, while dietary supplements do not. *Id.* at *3. Judge Linares determined that Bayer did not market PCH as a drug because it never made claims that PCH treats, prevents, or cures any diseases. The court noted that "[e]very package of PCH and every advertisement contains a disclaimer that that PCH is 'not intended to diagnose, treat, cure or prevent any disease.'" *Id.* at *12. Additionally, there was no evidence that the language on PCH's packages and advertisements would expressly or impliedly make a consumer believe PCH was making a disease claim. *Id.* at *13. Therefore, the court concluded that substantiation of PCH was evaluated by the lower standard used for dietary supplements. *Id.*

In order for a supplement to be "truthful and not misleading," Judge Linares noted that the FTC requires "competent and reliable scientific evidence," which is defined as: "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.* (quoting PX–1 *Dietary Supplements: An Advertising Guide for Industry* at 3). The FTC makes clear that RCTs are not required to meet the standard of "competent and reliable scientific evidence." *Id.* "Instead, competent and reliable scientific evidence is a flexible standard, and there is no fixed formula for the number or type of studies required." *Id.* In short, dietary supplements are evaluated by looking to the "totality of the evidence." *Id.* at *4. The court noted that the FTC's requirement of "competent and reliable scientific evidence," was the same level of proof required by the consent decree for Bayer to substantiate its claims regarding PCH. *Id.* at *3.

Judge Linares also discussed many of the studies Bayer relied upon to substantiate its claims about PCH. Two of those studies were the Canada I and Florida Studies. The court explained that the Florida Study "showed a positive impact in its primary outcome" and that PCH "was proven to be beneficial for maintenance of gut homeostasis" such as "digestive health and the absence of symptoms like constipation, diarrhea, gas and bloating." *Id.* at *9 (internal quotation marks omitted). As to the Canada I Study, Judge Linares found that it was a "primarily neutral study but showed results that trended positive for digestive health benefits." *Id.* (internal quotation marks omitted). The court noted that "the study was underpowered meaning there were not enough people to show a statistically significant benefit," but that Bayer's substantiation of PCH was not undercut "because many successful products, including FDA-approved drugs have neutral studies." *Id.*

Judge Linares concluded that the Government had failed to prove by clear and convincing evidence that Bayer had violated the consent decree. *Id.* at *19. One of the primary deficiencies in the Government's case concerned its expert evidence vis-à-vis the standards applicable to dietary supplements. The Government's expert opined that to meet the competent and reliable standard, Bayer needed to subject PCH to a double-blind, placebo controlled RCT. *Id.* at *9. The Government's expert admitted that "his study design did not distinguish between drugs or supplements." *Id.* Significantly, the Government's expert was not familiar with the regulations for dietary supplements nor was he familiar with FTC guidance concerning the "substantiation necessary for dietary supplement claims." *Id.* at *10.

Judge Linares concluded that Bayer did not violate the consent decree by failing to rely upon RCTs to support its claims about PCH. *Id.* at *14. Judge Linares explained that, contrary to the opinion of the Government's expert, proof of "competent and reliable scientific evidence" does not require RCTs pursuant to the regulations and FTC guidance. *Id.* Moreover, nothing in the consent decree required Bayer to conduct RCTs to support its claims concerning PCH. *Id.* at *16. Judge Linares also ruled that the Government's expert's opinion failed to satisfy the Government's burden. *Id.* at *15-16. The court criticized the Government's expert for "'not paying attention to the law or regulations about the difference between dietary supplements and drugs' in formulating his opinion." *Id.* at *16. Judge Linares explained that the Government's expert opinion that an RCT was necessary was "directly contrary" to the legal requirement as well as contrary to FTC guidance. *Id.* Judge Linares further concluded that Bayer possessed and relied upon competent and reliable scientific evidence in support its claims about PCH. *Id.* at *18-19. Bayer's medical lead for PCH "reviewed and relied upon [relevant] scientific studies in the public domain." *Id.* at *18.

The *FTC Opinion* is not dispositive in the current matter. There, the standard was different, specifically, the Government had to prove by clear and convincing evidence that Bayer violated the consent decree by making false and misleading claims concerning PCH. Here, the burden of proof is preponderance of the evidence. Moreover, the issue is whether there is a genuine issue of material fact to preclude summary judgment. However, the *FTC Opinion* is instructive. Like the Government's expert in the *FTC Opinion*, Plaintiffs' expert testified that a double-blind, placebo controlled RCT was necessary. Not only does this testimony misstate the correct legal requirements for dietary supplements, it also confuses the burden of proof. Plaintiffs must prove that Defendant's claims concerning PCH are false and misleading. Significantly, Plaintiffs did not conduct their own double-blind, placebo controlled RCT to support their position. In addition, like the Government's expert in the *FTC Opinion*, it does not appear that Plaintiffs' expert was aware of the different legal standards that govern dietary supplements as opposed to drugs.

C. California and Illinois Consumer Protection Statutes

Plaintiffs allege causes of action under the Consumers Legal Remedies Act, California Civil Code § 1750, et seq. ("CLRA"), false or deceptive advertising in violation of California Business and Professions Code, Cal. Bus. & Prof. Code § 17200 et seq. ("UCL"), and violation of the Illinois Consumer Fraud Act, 815 ILCS 505/1, et seq. ("ICFA").

California's CLRA generally prohibits "unfair methods of competition and unfair or deceptive acts or practices." Cal Civ. Code § 1770. California's UCL prohibits any "unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200. In evaluating a claim under the CLRA and UCL, the court must determine whether a reasonable consumer is likely to be deceived by the defendant's unlawful conduct. *Williams v. Gerber Prod. Co.*, 552 F.3d 934, 938 (9th Cir. 2008). When

alleging false advertising under the UCL and CLRA, "the plaintiff 'bears the burden of proving the defendant's advertising claim is false or misleading.'" *Stanley*, 2012 WL 1132920, at *3 (quoting *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharms., Inc.*, 107 Cal. App. 4th 1336, 1342 (2003)). Importantly, a plaintiff must put forth affirmative evidence of *falsity* "and cannot prevail by arguing that the defendant's claims are *unsubstantiated* and therefore misleading." *Mullins*, 178 F. Supp. 3d at 892 (emphasis added); *see also Aloudi v. Intramedic Research Grp., LLC*, 2015 WL 4148381, at *4 (N.D. Cal. July 9, 2015) (dismissing UCL and CLRA claims averring that defendant failed "to provide adequate substantiation" that its advertising claims were true); *Stanley*, 2012 WL 1132920, at *3 ("Private individuals may not bring an action demanding substantiation for advertising claims . . . only prosecuting authorities may require an advertiser to substantiate its advertising claims.").

The third consumer protection statute at issue, the ICFA, "protects consumers against 'unfair or deceptive acts or practices,' including 'fraud,' 'false promise,' and the 'misrepresentation or the concealment, suppression or omission of any material fact.'" *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 574 (7th Cir. 2012) (quoting 815 ILCS 505/2). The elements of a claim under the ICFA are "(1) a deceptive or unfair act or practice by the defendant; (2) the defendant's intent that the plaintiff rely on the deceptive or unfair practice; and (3) the unfair or deceptive practice occurred during a course of conduct involving trade or commerce." *Siegel v. Shell Oil Co.*, 612 F.3d 932, 934 (7th Cir. 2010). Similar to the UCL and CLRA, to demonstrate a deceptive act or practice under the ICFA, the plaintiff has the burden to show that the defendant's alleged misrepresentations were actually false. *Baldwin v. Star Sci., Inc.*, 78 F. Supp. 3d 724, 738 (N.D. Ill. 2015) (concluding that plaintiff failed to state a claim under the ICFA when he failed to allege "how [d]efendant's alleged misrepresentations were false"); *see also*

Spector v. Mondelēz Int'l, Inc., 178 F. Supp. 3d 657, 665 (N.D. Ill. 2016) ("Plaintiff's unsupported, conclusory allegation here regarding the falsity of the [defendant's] representation does not suffice to state a cause of action under the ICFA.").

Thus, Plaintiffs' claims under the CLRA, UCL, and ICFA depend on whether they have presented proof of falsity regarding Bayer's claims that PCH "promotes overall digestive health" and "helps defend against occasional constipation, diarrhea, gas, and bloating." Merely proving that the claims are unsubstantiated is insufficient. Two cases from the Southern and Northern Districts of California illustrate the necessary level of proof to defeat summary judgment in a claim for false advertising.

In *Mullins*, the court addressed claims under the UCL and CLRA alleging that the defendant made false or misleading representations in selling its product "Joint Juice." 178 F. Supp. 3d at 875. Joint Juice was a liquid dietary supplement that was marketed to remedy pain and stiffness in arthritic joints, but according to the plaintiff, was actually nothing more than "snake oil." *Id.* The active ingredients in Joint Juice were glucosamine hydrochloride ("glucosamine") and chondroitin sulfate ("chondroitin").

The court in *Mullins* concluded that the plaintiff "advanced evidence which directly supports the contention that certain of [the defendant's] representations are false or misleading." *Id.* at 876. The plaintiff presented evidence of Joint Juice's inefficacy through numerous RCTs in the form of randomized double-blind, placebo-controlled studies. *Id.* at 882-84. The plaintiff also produced meta-analyses[9] clinical treatment protocols, and bioavailability studies in support of her theory. *Id.* at 884-887. Among various types of medical evidence, meta-analyses are "considered

[9] "Meta-analyses pool the results of clinical trials to arrive at a single figure to represent the totality of the studies reviewed." *Mullins*, 178 F. Supp. 3d at 884 (internal quotation marks omitted).

the strongest." *Id.* at 884 (citation omitted). Clinical treatment protocols look to see if medical guidelines recommend using a particular substance to treat a condition or its symptoms. *Id.* at 885. No clinical treatment protocol recommended either glucosamine or chondroitin for plaintiff's condition. *Id.* The bioavailability studies showed that active ingredients in Joint Juice never reached the targeted joint cartilage and, even if they did, the amount was too small to have any meaningful effect on the joints. *Id.* at 886-87.

The district judge in *Mullins* acknowledged that the defendant's expert advanced some evidence, such as *in vitro* and preclinical animal studies, to refute the plaintiff's position, but that many of the sources relied upon by the defendant's expert could be deemed unreliable. *Id.* at 895. For example, the defendant's expert failed "to take into consideration the hierarchy of scientific evidence, which places meta-analyses and randomized clinical trials at the top" and also relied on certain studies "characterized by poor design" or industry bias. *Id.* The *Mullins* court found that due to the competent evidence presented by the plaintiff, and because the plaintiff "offered principled, supported critiques of the studies [the defendant's expert] used to form his opinions, and a jury may reasonably adopt those same views, [the plaintiff] may be able to convince a jury that [the defendant's] claims are literally false." *Id.* at 896. Therefore, the district court denied the defendant's motion for summary judgment.

In *Stanley*, the Southern District of California addressed claims under the CLRA and UCL, which alleged that Bayer made false and misleading statements regarding PCH, the same product at issue in the instant matter. 2012 WL 1132920, at *1-2. The plaintiff alleged that Bayer violated the CLRA and UCL by stating, among other things, that PCH "promote[s] overall digestive health" and "helps defend against occasional constipation, diarrhea, gas, and bloating." *Id.* at *5.

The plaintiff's experts believed that these statements were false and misleading due to a lack of substantiation. *Id.* at *5. One of the plaintiff's experts opined that "a majority of data generated in peer reviewed, double[-]blind, placebo controlled studies, relating to probiotics, largely suggests that probiotics have little effect on human digestive or immune health." *Id.* at *5 (internal quotation marks omitted). The *Stanley* court noted, however, that none of the plaintiff's experts actually opined that the claims about PCH were false or explained how the contested statements might mislead a reasonable consumer. *Id.* Instead, the plaintiff's experts repeatedly asserted that the statements were false or misleading due to a lack of substantiation. *Id.* For example, one expert was asked whether he could "rule out that probiotics do work for some people," to which he responded, "it's inconclusive." *Id.* at *6. Additionally, the plaintiff's experts were not aware of the different regulations for drugs and dietary supplements. *Id.* at *7. To the contrary, one expert opined that "he believe[d] [d]efendant should have the same support for its PCH claims as drug companies must have for their drug claims, i.e. proof of efficacy in placebo-controlled double-blind human studies." *Id.*

The district court held that the plaintiff had not met her burden in demonstrating that Bayer's statements about PCH were actually false or misleading. *Id.* In granting Bayer's motion for summary judgment, the court in *Stanley* concluded by noting that the plaintiff "cannot create a genuine issue of material fact regarding whether Defendant met the level of substantiation required under federal law by presenting opinions from experts who are not aware of the relevant regulatory standards." *Id.*

D. Analysis

Here, Plaintiffs failed to meet their burden of proof of showing that PCH's claims of promoting "overall digestive health" and "defend[ing] against occasional constipation, diarrhea,

gas, and bloating" are actually false. Although Plaintiffs argue that they have shown actual falsity, their expert's opinion is actually one of lack of substantiation. Plaintiffs' proofs are deficient for several reasons.

First, like the plaintiff's experts in *Stanley* and the Government's expert in the *FTC Opinion*, Dr. Guandalini does not recognize the difference in proof required to substantiate a dietary supplement as compared to a drug. As noted, drugs require pre-approval from the FDA and generally "must be supported by randomized, placebo controlled, double-blind clinical trials." *FTC Opinion*, at *3. Dietary supplements, in comparison, require only that the statements made regarding their properties are "truthful and not misleading." 21 U.S.C. § 343(r)(6)(B). To be "truthful and not misleading," the statements must be supported by "competent and reliable scientific evidence." *FTC Opinion*, at *3. Importantly, RCTs *may* be used to satisfy this standard, but they are not required. *Id.*

Dr. Guandalini testified that in order for Bayer's statements about PCH to be true, they must be supported by double-blind, placebo controlled "well conducted clinical trials," which he equates to RCTs. Guandalini Dep. at 68:17-21; 150:2-12; 161:4-8. Dr. Guandalini believes RCTs are necessary because they are "good clinical practice." *Id.* at 140:12-19. However, RCTs are not required for a dietary supplement. Further to the point, Dr. Guandalini testified that his opinion about a product's efficacy would not change regardless of whether it is a drug or a dietary supplement. *Id.* at 61:6-10. In his words, "[e]ither a compound works or it doesn't." *Id.* Dr. Guandalini candidly admitted that he did not have enough knowledge "to express a judgment" on the different types of regulations and requirements for drugs versus dietary supplements. *Id.* at 62:24 to 63:2. Dr. Guandalini was asked whether he was aware that in the *FTC Opinion*, the Court "already found that dietary supplements do not need to be supported by randomized, placebo-

controlled, double blind control trials." *Id.* at 147:21 to 148:10. Dr. Guandalini responded that he was "not aware and frankly [doesn't] care." *Id.*

Dr. Guandalini's lack of awareness and/or misunderstanding of the applicable legal standard required to prove that a statement about a dietary supplement is "true and not misleading" undercuts Plaintiffs' argument that "[t]his is not a lack of substantiation case because Plaintiffs present evidence that PCH does not work as advertised." Pl. Opp. at 26. Dr. Guandalini's opinion is nothing more than a lack-of-substantiation theory. In essence, Plaintiffs' expert opines that absent an RCT showing PCH's efficacy, Bayer's claims that PCH promotes digestive health are false. This lack-of-substantiation theory is not the legal standard. Without understanding the proper legal requirements to demonstrate whether Bayer's statements about PCH are false and misleading, Dr. Guandalini cannot offer an informed opinion as to whether that standard has been met. *See Stanley*, 2012 WL 1132920 at *7 ("Plaintiff cannot create a genuine issue of material fact regarding whether Defendant met the level of substantiation required under federal law by presenting opinions from experts who are not aware of the relevant regulatory standards."). Certainly, using RCTs to substantiate PCH may be a reliable scientific method to show its efficacy (or lack thereof), but such studies are not required as a matter of law. *See FTC Opinion*, at *3.

Second, Dr. Guandalini's interpretation of the Canada I & II and Florida Studies does not prove actual falsity. The purpose of the Canada Studies was to determine the effect of PCH on people who have IBS and severe IBS. The studies were not designed to test whether PCH "promote[s] overall digestive health" and "helps defend against *occasional* constipation, diarrhea, gas, and bloating." DSOF ¶ 2 (emphasis added). The difference in the symptoms of those with IBS and the symptoms that PCH purports to defend against are materially different in terms of severity. IBS is a "*chronic, reoccurring* gastrointestinal disorder . . . characterized by abdominal

pain, bowel dysfunction and bloating in the absence of any structure abnormalities." Cecchi Dec., Ex. 54 (emphasis added). These "chronic" and "reoccurring" symptoms are far more severe than the occasional constipation, diarrhea, gas and bloating that PCH claims to defend against.

In fact, Dr. Guandalini admitted that "whether a therapy shows significant changes in IBS symptom severity does not necessarily tell us whether or not a therapy supports overall digestive health in a healthy population." Guandalini Dep. 165:10-14. Dr. Guandalini implied multiple times that PCH could potentially be effective for someone without IBS:

> Q. So then your opinion leaves open the possibility that PCH may work for someone without IBS, correct?
>
> A. Well, yeah.

Id. at 175:18-21.

> Q. But for people who do not [have IBS] we do not have proof that the claims are false, correct?
>
> A. Neither that they are correct, yes, that's correct, but neither do we have proof that the statement is true.

Id. at 176:8-12.

> Q. You are not opining that PCH is incapable of helping to promote overall digestive health, you just don't know one way or the other?
>
> A. I don't know.

Id. at 177:2-5. In short, Dr. Guandalini did not offer a definitive opinion as to whether PCH's claims that it promotes overall digestive health and helps defend against occasional constipation, diarrhea, gas, and bloating were actually false.

Dr. Guandalini attempted to backtrack from his equivocal answers by claiming PCH is ineffective in treating occasional digestive problems. Dr. Guandalini stated that he "would be surprised" if PCH promoted overall digestive health "considering the small amount of bacteria

contained in the preparation." *Id.* at 177:7-10. He also explained that because IBS sufferers are a population closely resembling those with occasional constipation, diarrhea, gas, and bloating that "it's extremely likely that [PCH will] also not be able to protect from the occasional onset of symptoms" and that "[he] really *see[s] no evidence to support that.*" *Id.* at 178:11-23 (emphasis added).

Yet, even Dr. Guandalini's modified opinion is nothing more than a theory of lack of substantiation. At worse, it is pure speculation in light of the fact that he never clinically tested his views, and, at best, it is an educated guess. However, either is insufficient to carry Plaintiffs' burden of showing that the PCH's statements are actually false or misleading. Dr. Guandalini stated that he saw "no evidence to support" the statement that PCH helps promote digestive health. As discussed above, the question is not whether there is sufficient evidence to support PCH's claims, but rather whether Plaintiffs have presented proof that PCH's claims are in fact false or misleading. Moreover, Dr. Guandalini's testimony that "he would be surprised" if PCH was effective is a far cry from the scientific proof necessary to show actual falsity.

Dr. Guandalini's attempt to extrapolate the results of the IBS Canada Studies to those with occasional symptoms of constipation, diarrhea, gas, and bloating is unavailing. The Canada I Study concluded that it was conducted with too small of a sample size to draw a definite conclusion. Yet, there were indications of affirmative results for general digestive health. Cecchi Dec., Ex. 55; *see also FTC Opinion* at *9 (noting that Canada I Study was "primarily a neutral study but showed results that trended positive for digestive health benefits . . . [except that] the study was underpowered meaning there were not enough people to show a statistically significant benefit" (internal quotation marks omitted)). Dr. Guandalini offers no explanation why extrapolating from an inconclusive study about IBS to draw a conclusion about a different

population demonstrates that PCH's claims are false. As to the Canada II Study, Dr. Guandalini similarly does not provide a basis as to why a single study that did not conclude PCH improved the quality of life for those with "severe" IBS is indicative of PCH's efficacy in those with occasional digestive problems. For those reasons, the Canada Studies do not demonstrate that Bayer's claims about PCH fail to meet the standard of "truthful and not misleading."

The third and final RCT, the Florida Study, also does not show that the PCH claims are false or misleading. In the *FTC Opinion*, Judge Linares found that the Florida Study "showed a positive impact in its primary outcome" and that PCH "was proven to be beneficial for maintenance of gut homeostasis" such as "digestive health and the absence of symptoms like constipation, diarrhea, gas and bloating." *FTC Opinion*, at *9. But even assuming that the Florida Study showed that PCH was ineffective, its results nonetheless do not prove that Bayer's claims about PCH are in fact false. The Florida Study was limited to adults between the age of 65 to 80. Therefore, the study provides no basis to conclude that Bayer's claims about PCH are untrue for people who fall outside this age range.[10]

Lastly, Plaintiffs' reliance on *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013) is misplaced. In that case, the First Circuit held that where "numerous [double-blind randomized controlled trials] indicate that a drug is ineffective, that provides powerful scientific evidence of inefficacy." *Id.* at 49. Here, the only RCTs are the three studies discussed above. The Canada Studies tested PCH's effectiveness on individuals with IBS and

[10] Plaintiffs also cite a report from the European Food Safety Authority ("EFSA") which found there is no evidence that "PCH ingredients support respiratory tract defenses or resulted in a decrease in duration or severity of the common cold." Pl. Opp. at 12. Plaintiffs present no legal argument regarding the significance, if any, of this report to the claims at issue concerning overall digestive health. This matter concerns digestive health. The common cold and the respiratory tract are not the issue.

severe IBS and the Florida Study was limited to people aged 65-80. Plaintiffs have not directed the Court to an RCT where PCH's claims were tested on people younger than 65 and shown to be ineffective. Nor have Plaintiffs pointed to an RCT in which PCH was proven ineffective vis-à-vis Bayer's claims, *i.e.* promoting overall digestive health and providing relief from occasional symptoms. Therefore, *In re Neurontin Marketing & Sales Practices Litigation* is inapposite.

This matter is very similar to *Stanley*, not only because the same product is involved but also due to the nature of Plaintiffs' proofs. Moreover, Plaintiffs' case suffers from many of the same infirmities found by Judge Linares in the *FTC Opinion*. Plaintiffs' expert is incorrect as to the medical evidence necessary for a dietary supplement. Furthermore, and unlike *Mullins*, Plaintiffs have presented no meta-analyses or bioavailability studies.

Plaintiffs also argue that Bayer's internal documents indicate that Bayer marketed PCH toward women aged 35 or older who suffer from IBS and that Bayer anticipated that 15% of its customers would use PCH for IBS. PL. Opp. at 4. In *Mullins*, the court explained that evidence of targeting a specific group of consumers may be considered to show that a dietary supplement's *implied* claims are false or misleading, but it may not be used to substantiate the falsity of general health claims. 178 F. Supp. 3d at 896. There, the plaintiff hired an expert to analyze the defendant's marketing materials, advertisements, marketing research, and customer surveys to determine why consumers purchased Joint Juice. *Id.* at 880-82. The plaintiff's expert concluded that "the primary appeal and driving reason consumers purchase Joint Juice are joint health and joint pain" and that "consumers understand [the defendant's] implied claims about the palliative and structural benefits of drinking the product." *Id.* at 880-81 (internal quotation marks omitted). In other words, the plaintiff in *Mullins* presented evidence that the "vast majority of consumers

purchased Joint Juice because they suffered arthritis and joint pain and stiffness" -- ailments that Joint Juice did not explicitly claim to remedy. *Id.* at 891.

Here, unlike *Mullins*, Plaintiffs did not hire an expert to determine whether customers purchase PCH for a reason other than its explicit general health claims of promoting overall digestive health and helping to defend against occasional constipation, diarrhea, gas, and bloating. Instead, Plaintiffs point to Bayer's internal documents which indicate that Bayer targeted individuals with IBS and that it believed 15% of its customers would purchase PCH to alleviate IBS. This evidence is insufficient to overcome summary judgment for two reasons.

First, the fact that Bayer anticipates 15% of its customers will buy PCH to alleviate IBS symptoms does not prove what motivates those consumers to purchase PCH. More specifically, it is not clear whether Bayer's marketing of PCH conveys an implied message that the product alleviates IBS or whether consumers buy PCH believing that it helps with IBS for some other unknown reason. Unlike the plaintiff in *Mullins*, Plaintiffs here did not commission an expert to determine if PCH conveyed an implied message. Second, and more importantly, Plaintiffs do not argue that Bayer made any false *implied* claims about PCH. Therefore, Bayer's anticipation that IBS sufferers may purchase PCH, without more, is insufficient to overcome summary judgment.[11]

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[11] Plaintiffs also argue that Bayer admits in some of its internal documents that PCH "does nothing." Pl. Opp. at 12. Some examples are from a May 2009 presentation where Bayer stated, "[t]here is no information about [PCH's] subspecies and thus the product" and "[t]here is no clinical support for any of the claims that we make with regard to our specific subspecies." D.E. 144-32 at 197097. Another example is a May 2011 email where a Bayer representative asks the Chief Sales Officer from Wakunaga whether there is any additional information to substantiate the claims about PCH, to which the Chief Sales Officer replied, "I believe you have everything." D.E. 161-1 at 14359. Bayer also acknowledged that there was a "[w]eak scientific base for [PCH] bacteria strains." D.E. 150, Ex. 2 at 196802. These statements potentially support a lack-of-substantiation theory, but they fall short of acknowledging that Bayer's statements about PCH are actually false or misleading. Therefore, they do not provide a basis for Plaintiffs to overcome summary judgment.

In sum, Plaintiffs failed to present competent evidence to create a genuine issue of material fact that Bayer's claims that PCH promotes overall digestive health and helps defend against occasional constipation, diarrhea, gas, and bloating are actually false or misleading. Therefore, the Court grants summary judgment in favor of Bayer as to all counts.[12]

IV. CONCLUSION

For the reasons set forth above, Bayer's motion for summary judgment is granted. Plaintiffs' motions for class certification and to strike portions of Bayer's expert's opinion are denied as moot. An appropriate Order accompanies this Opinion.

Dated: April 17, 2017

John Michael Vazquez, U.S.D.J.

[12] Plaintiffs' claims for breach of the implied warranty of merchantability and unjust enrichment fail for the same reasons as the consumer protection statutes. *See Gaul v. Bayer Healthcare LLC*, No. 12-5110, 2013 WL 12181778 (D.N.J. Feb. 11, 2013) (dismissing New Jersey Consumer Fraud Act, unjust enrichment, breach of express warranty, and breach of implied warranty of merchantability claims because the complaint failed to properly allege that a product was falsely advertised).