NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. BAYER CORPORATION, Defendant.	Civil Action No. 07-01(JLL) **OPINION**

LINARES, District Judge**.**

This matter comes before the Court on the Government's Order to Show Cause why Defendant should not be held in Contempt for violating this Court's Order of January 3, 2007. At issue for this Court's determination is whether the Government has demonstrated by clear and convincing evidence that Defendant Bayer violated the 2007 Order issued by the Court. After careful review and consideration of the evidence presented at the contempt hearing, the Court finds that the Government has not met its burden of proof by clear and convincing evidence that Bayer failed to possess and rely upon competent and reliable scientific evidence to substantiate its specific claims about PCH's efficacy for constipation, diarrhea, and gas and bloating. This Opinion sets forth the basis for these conclusions.

I. FINDINGS OF FACT

A. BACKGROUND[1]

Defendant Bayer Corporation ("Bayer") manufactures and sells a variety of products, including vitamins, dietary supplements, and over-the-counter and prescription drugs. Bayer HealthCare, LLC, is a subsidiary of Bayer Corporation, and markets and sells One-A-Day brand vitamins and supplements, including One-A-Day WeightSmart, a multivitamin and dietary supplement. Between 2003 and 2007, Bayer advertised its One-A-Day WeightSmart product through television commercials, print advertisements in magazines, and on the Internet.

On January 3, 2007, the United States filed a complaint against Bayer alleging that the company violated a 1991 Federal Trade Commission ("FTC") administrative order to cease and desist certain advertising practices with respect to One-A-Day brand vitamins and mineral supplements. According to the Commission's Order, Miles Inc., a predecessor to Bayer, was to cease and desist "from making any representation, directly or by implication, concerning the need for or benefits to be derived from consumption of such product unless, at the time such representation is made, respondent possesses and relies upon a reasonable basis consisting of competent and reliable scientific evidence to substantiate the representation." As a successor to Miles, Inc., Bayer was subject to the Commission's Order. The United States claimed that Bayer violated the Order by making unsubstantiated representations that its One-A-Day WeightSmart products increased and enhanced metabolism, could help prevent weight gain associated with a decline in metabolism, and could help users control their weight by enhancing their metabolism.

[1] The facts set forth herein are the Court's findings of facts which are based on the Court's observations of the witnesses who testified and a thorough review of all the evidence admitted at trial.

Ultimately, the parties agreed to settle without adjudication of the merits of any issue of fact or law and Bayer agreed to pay a three million, two hundred thousand ($3,200,000.00) dollar civil penalty. Consent Decree § I.A, ECF No. 2. Additionally, Bayer was permanently enjoined from violating any provision of the Consent Decree and from making representations that any of its products:

> [I]ncreases metabolism; enhances metabolism through its . . . content; helps prevent some of the weight gain associated with a decline in metabolism in users over age 30; helps users control their weight by enhancing their metabolism; makes a material contribution to any program or system that promotes weight maintenance; can or will cure, treat, or prevent any disease; or have any effect on the structure or function of the human body.

Consent Decree §III.A-B, ECF No. 2. Additionally Bayer was enjoined from making any representation, express or implied, about the benefits, performance, or efficacy of any dietary supplement it markets or sells unless, at the time the representation is made, Bayer "possesses and relies upon competent and reliable scientific evidence that substantiates the representation." Consent Decree § III.B, ECF No. 2. The 2007 Consent Decree and 1991 Commission Order define "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has 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.* at 2. The Consent Decree was entered as the final order on January 3, 2007. *Id.* at 10.

The evidence presented to the Court at the contempt hearing proved that in 2008, Bayer began an extensive advertising campaign to promote PCH, a dietary supplement containing a proprietary blend of three specific strains of bacteria: *Lactobacillus gassieri* KS-13, *Bifidobacterium bifidum* G9-1, and *Bifidobacterium longum* MM-2. The Food and Drug Administration ("FDA") was notified of each of Bayer's label claims for PCH. Thereafter, in

2011, the FTC began investigating whether Bayer possessed adequate substantiation for its advertising claims regarding PCH. In 2011 and 2012, Bayer provided the FTC with documents, cover letters, and revenue information as "purported evidence for its advertising claims relating to constipation, diarrhea, and gas and bloating." After receiving production of these documents, cover letters, and revenue information, the FTC transferred the case to the U.S. Department of Justice for enforcement. On September 12, 2014, the United States filed a Motion for an Order to Show Cause as to why Bayer Corporation should not be held in civil contempt for violating the Consent Decree. The Government's contempt motion alleged a violation of Section III of the Consent Decree, which requires Bayer to "possess[] and rel[y] upon competent and reliable scientific evidence that substantiates" any dietary supplement claim.[2] On October 23, 2014, this Court granted the government's motion and ordered Bayer to show cause why it should not be held in civil contempt.

A contempt hearing was held over seven days from June 15, 2015 to June 30, 2015 in Newark, New Jersey. During the trial, the United States presented testimony from Dr. Pana Beke, Bayer's lead medical employee responsible for the substantiation of Bayer's PCH claims. Trial Tr. 1.52:11-1.53:24. The Government also presented testimony from FTC investigator Crystal Ostrum, PX-2 and PX-3, and Dr. Loren Laine, an expert in gastroenterology and clinical research. Trial Tr. 3.9:3-5. Bayer presented expert testimony from Dr. M. Brian Fennerty, an expert in gastroenterology and clinical trial design, and Dr. Daniel J. Merenstein, an expert in medicine, clinical trial design, and probiotics. Trial Tr. 5.10:11-15; Tr. 6.13:22-6.14:1. On July

[2] Originally, in its trial brief, the Government cited another provision of the decree (the recordkeeping provision), Dkt. No. 158. However, it has since disclaimed that this provision is "an independent ground[] for the contempt motion." Tr. 1.11:3-10.

30, 2015, the parties submitted their Joint Proposed Undisputed Findings of Fact, as well as their own Proposed Findings of Fact and Conclusions of Law.

B. REGULATORY FRAMEWORK

Bayer's Consent Decree adopted the substantiation standard— "competent and reliable scientific evidence"—that applies to the entire industry through agency guidance promulgated under the Dietary Supplement Health & Education Act of 1994 (DSHEA), Pub. L. No. 103-417, sec. 8, § 413(c) (codified at 21 U.S.C. § 350(b)); see PX-1 *Dietary Supplements: An Advertising Guide for Industry* at 3 ("FTC Guidance").

Recognizing the health benefits of dietary supplements, Congress enacted DSHEA to ensure that supplements can be marketed and sold without following the stringent requirements imposed on drugs. Although new drugs must be pre-approved by the Food and Drug Administration, *see id.* § 331(d); *id.* § 355(a), and traditionally must be supported by randomized, placebo-controlled, double-blind clinical trials, *see* 21 C.F.R. § 314.126, dietary supplements need not.

For dietary supplements, the only substantiation requirement is that claims must be "truthful and not misleading." 21 U.S.C. § 343(r)(6)(B); *see also id.* § 321(ff) (defining "dietary supplement" as any non-tobacco product "intended to supplement the diet"); *id.* § 343(r)(6)(A) (identifying types of dietary supplement claims, including structure/function claims). As long as the supplement is not marketed as a drug—i.e., it is "not claim[ed] to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," *id.* § 343(r)(6); id. § 343(r)(6)(C) (requiring disclaimer)—it is not regulated like a drug.

DSHEA does not specify what substantiation is necessary to render a claim "truthful and not misleading." Accordingly, in April 2001, the Federal Trade Commission provided

guidance, stating that the relevant standard is "competent and reliable scientific evidence." *See* PX-1 *Dietary Supplements: An Advertising Guide for Industry* at 3 ("FTC Guidance").

The FTC Guidance defines "'competent and reliable scientific evidence'" to mean: "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.* at 9. The FTC Guidance and Consent Decree therefore use the same definition of "competent and reliable scientific evidence." DX-278 No. 1 (Governments' Amended Response to Bayer's Requests for Admission). The FTC Guidance provides additional scientific and medical guidance regarding the evidence necessary to meet the "competent and reliable scientific evidence" standard embodied in both the FTC Guidance and Bayer's Consent Decree. PX-1.

First, the FTC Guidance makes clear that this standard is not the drug standard. Randomized clinical trials are not required. FTC Guidance at 9-18. Instead, "competent and reliable scientific evidence" is a "flexible" standard, and "[t]here is no fixed formula for the number or type of studies required." *Id.* at 8-9. Although "well-controlled human clinical studies are the most reliable form of evidence[,]" they are not necessary, and "[r]esults obtained in animal and in vitro studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible." *Id.* at 10. "[R]esearch explaining the biological mechanism underlying the claimed effect" will also be considered. *Id.* "[E]pidemiologic evidence may be an acceptable substitute for clinical data" in some circumstances. *Id.*

Second, the FTC Guidance states that one should look to "the totality of the evidence." *Id.* at 14. "The surrounding body of evidence will have a significant impact both on what type, amount and quality of evidence is required to substantiate a claim and on how that claim is presented." *Id.*

Third, studies on the precise formula used in the advertised product are not required. Rather, it can be "appropriate to extrapolate from the research to the claimed effect," even if there "are significant discrepancies between the research conditions and the real life use being promoted." *Id.* at 16.

The Food and Drug Administration (FDA) agrees in its guidance, recognizing that randomized, controlled clinical trials for dietary supplements may not be "possible, practical, or ethical." *See* FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act* (Dec. 2008), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm ("FDA Guidance").

C. PROCEDURAL HISTORY

In 2011, the FTC began investigating Bayer's marketing of Phillips Colon Health ("PCH"), a probiotic dietary supplement. See Dkt. No. 4-1 at 3. In response to the Government's investigation, Bayer produced nearly 100 scientific articles that supported its advertising claims for PCH. See June 15-30, 2015 Evid. Hr'g Tr. ("Tr.") 3.39:7-17; DX-254 (Sept. 30, 2013 Letter from M. Davis to L. Laine) at 4.

On September 12, 2014, the United States filed its contempt motion. In this motion, the Government disclosed the existence of its expert, Dr. Loren Laine, and the study design he opined was required to provide competent and reliable scientific evidence. Dkt. No. 4-8; PX-160.

Specifically, Dr. Laine opined that "competent and reliable scientific evidence" could only be met through "human clinical trials that (1) are randomized, placebo-controlled, and double-blind; (2) use the specific product for which the claims are made; (3) are performed in the population at which the claims are directed; and (4) use validated methods and appropriate statistical methods to assess 'outcomes.'" Dkt. No. 4-1 at 16; see also PX-160 ("Laine-Level RCTs"). On October 23, 2014, the Court directed Bayer to show cause why it did not violate the Consent Decree's requirement to "possess 'competent and reliable scientific evidence'" for dietary supplement claims as required in the Consent Decree. Dkt. No. 47 at 2.

Following further briefing and discovery, this Court held a seven-day contempt hearing that took place from June 15, 2015 until June 30, 2015.

D. PRODUCT: PHILLIPS' COLON HEALTH

Bayer launched its probiotic supplement PCH in 2008. Tr. 1.108:21-24, 1.130:18-21. "Probiotics are live microorganisms that, when administered in sufficient amounts, may improve health." DX-5 at 3. PCH contains three types of good bacteria: *Lactobacillus gasseri KS-13*, *Bifidobacterium bifidum G9-1*, and *Bifidobacterium longum MM2*. Tr. 1.76:12-18.

Probiotics, including PCH, are "a very safe intervention" with no risk of harm and "no down side." Tr. 5.50:11-12. No study on the bacteria in PCH has shown any adverse effect. Tr. 5.50:8-9. "The past thinking and the current thinking in the field is [that probiotics, including the species in PCH,] are perfectly safe." Tr. 5.77:22-25; *see also* Tr. 6.49:17-22 ("[F]or generally healthy people taking [probiotics including the PCH species], there is almost no side effect.").

E. CLAIMS AT ISSUE

Bayer makes the following claims for PCH:

• "To Promote Overall Digestive Health"

• "Helps Defend Against Occasional Constipation, Diarrhea, Gas and Bloating"

See, *e.g.*, PX-2; PX-3; PX-20; PX-21; PX-22; PX-29; PX-34; PX-125.

At trial, the Government's witness, FTC investigator Crystal Ostrum, agreed that "the digestive health claim is the same thing as the claim of relief, occasional constipation, diarrhea, gas and bloating." Tr. 2.99:9-13. *See also* Tr. 5.14:17-23 (looking at the PCH package, Dr. Fennerty understands the claims at issue to be the "singular claim of promoting overall digestive health" by "defend[ing] against the occasional constipation, diarrhea, gas and bloating that an individual or patient may have."); Tr. 6.9:22-6.10:2 ("gastrointestinal health" means "things like abdominal pain, diarrhea, constipation, gas, bloating, and straining.").

Ms. Ostrum also agreed that all of Bayer's labels and advertisements for PCH contain the FDA disclaimer stating: "This product is not intended to diagnose, treat, cure or prevent any disease." *See*, *e.g.*, PX-2; Tr. 2.91:15-17; Tr. 2.93:2-4; *see also* Tr. 2.42:16-19 (Dr. Beke noted that "[Bayer] regulatory ensures that every product label, every advertising and every promotional material that makes a structure function claim[ ] has a DSHEA statement on that page facing and linked to the claim."); PX-3; PX-7; PX-20; PX-29; PX-34; PX-125.

Ms. Ostrum further testified that "[n]one of [PCH's] advertisements show sick people." Tr. 2.98:4-6. "None of [them] shows anyone suffering from a disease." Tr. 2.98:7-9. Rather, they are humorous and lighthearted advertisements that show healthy and active individuals. Tr. 2.98:10-20 (Government witness affirming that the advertisements "made [her] laugh"); PX-157, -158 (advertisement showing PCH spokesperson speaking to active and healthy individuals on a safari); PX-34, -41 (ad showing PCH spokesperson speaking to active and healthy individuals on an airplane); PX-23, -25 (ad showing PCH spokesperson speaking to active and healthy individuals at a book reading).

Bayer's claims for PCH are all categorized as structure function claims under FDA regulations. Tr. 2.16; Tr. 2.40:22-25; *see* 65 Fed. Reg. 1000, 1006 (Jan. 6, 2000) ("a claim that a product 'helps promote digestion' would be a structure/function claim because it does not refer explicitly or implicitly to an effect on a disease state"); *id.* at 1026 ("for relief of 'occasional constipation' should not be considered [a] disease claim[]"); *id.* at 1031 (stating that "'[a]lleviates the symptoms referred to as gas'" and "'alleviates bloating'" are structure function claims "because the symptoms . . . are not sufficiently characteristic of specific diseases"); *see also id.* at 1033 ("'helps maintain regularity' is an acceptable structure/function claim"); *see also id.* at 1015, 1029.

Bayer does not make disease claims for PCH. The Government does not contend Bayer made disease claims, and the Government's witness, Ms. Ostrum, agreed that Bayer has "disclaim[ed]" any disease claim. Tr. 2.91:24; see PX-2; (FDA disclaimer stating: "This product is not intended to diagnose, treat, cure or prevent any disease").

Bayer has submitted "30-day notification letters" to the Food and Drug Administration notifying the agency of its claims for PCH. Tr. 2.41:10-15. The FDA has not responded to or rejected any of Bayer's FDA notifications regarding its claims. Tr. 2.41:16 – 2.42:6. If Bayer had made a disease claim for PCH, the FDA had authority to treat PCH as an unapproved drug subject to seizure and destruction under the Federal Food Drug and Cosmetic Act. 21 U.S.C. § 343(r)(6)(A).

The Government has suggested that Bayer made "implied" claims that PCH can help prevent, treat, or cure constipation, diarrhea, gas and bloating. Dkt. No. 4-1at 10. Government counsel conceded in closing that Bayer's "ads don't . . . use the terms 'cure, prevent, and treat.'" Tr. 7.41:21-25. Nonetheless, counsel asserted that the terms Bayer does use "are clearly

euphemisms for 'treat, cure and prevent.'" *Id.* That suggestion is irrelevant because the Government has not argued that Bayer has made any disease claims (either explicitly or implicitly), and the packaging and all advertisements for PCH expressly state that PCH is "not intended to diagnose, treat, cure or prevent any disease." *See*, *e.g.*, PX-2; Tr. 2.91:15-17. Moreover, these so-called "euphemisms" have been expressly permitted by the FDA. *See*, *e.g.*, 65 Fed. Reg. at 1006, 1015, 1026, 1029, 1031, 1033.

Therefore, the Court finds that the Government presented no clear and convincing evidence that Bayer made implied claims of any kind, let alone implied disease claims. It presented no consumer survey data, no customer impression testimony, and no expert marketing testimony of any kind. The suggestion of "implied" disease claims therefore is contrary to the record and rests solely on arguments of counsel. Furthermore, unlike other cases cited by the Government, the FTC made no agency findings that Bayer made any implied disease claims.

F. BAYER'S REVIEW PROCESS

At the hearing, evidence was presented that Bayer, in order to ensure that it complies with the Consent Decree, follows an extensive process known as the Legal, Medical, Regulatory (LMR) review. Tr. 2.34:6-8; Tr. 2.37:12-20; PX-73 (US-SOP-013-BPD); PX-74 (SOP-GRD-RA-201). LMR review and approval is required for every single piece of "promotional material" that "go[es] out the door as a public document." Tr. 2.37:12-20.

The LMR process consists of one representative each from the Legal, Medical, and Regulatory groups. Tr. 2.34:14-22. A standard operating procedure guides this process and requires the submission of all advertisements and promotional materials to the LMR board for approval. PX-73 at 3. Before promotional material may be published, unanimous approval of the LMR group must be obtained. Tr. 2.37:5-11; *see also* Tr. 2.39:16-21. If any member of the

LMR group does not agree that a piece of promotional material complies with legal, medical, and regulatory obligations, the material will not be published. PX-73 at 3; Tr. 2.37:18-21.

The LMR approval process is "ongoing" and applies to all "current and new products." Tr. 2.37:14-21. The process generally requires a one and a half hour meeting three times a week for gastrointestinal products. Tr. 2.34:8-11; Tr. 2.37:21-25. The "purpose of the LMR review is to . . . ensure that the claims . . . are not misleading to consumers . . . [and] from a medical perspective [] are based on adequate substantiation." Tr. 2.38:2-6. According to the evidence presented by Bayer, the role of "legal" in the LMR process is "to look at any claims or messaging in the document" and make sure they "are not misleading and are supported by evidence." Tr. 2.40:17-19. The role of "regulatory" is to ensure that "the claims . . . are acceptable structure function claims based on DSHEA." Tr. 2.40:22-25. If regulatory determines that a claim "is a disease claim," it rejects the promotional material and no one can override that determination. Tr. 2.41:3-7. The role of "medical" in the LMR process is to "look at dietary supplements and the claims [to] ensure that [there is] competent and reliable scientific evidence." Tr. 2.39:9-15.

According to the record, the Bayer medical group determines "the strength of the evidence" by looking to the "totality of evidence." Tr. 2.44:16-18, 2.45:11-18; see also Tr. 2.38:16–2.39:8. The medical team "review[s] the literature in the public domain" and "look[s] at all the studies," including those "related to the mechanism of action" "animal studies" and "human data that may include randomized control[led] studies." Tr. 2.44:18-19, 2.45:2-18. The medical group "continu[ally] review[s] public domain data" on an ongoing basis, reviewing new studies around the time of their publication. Tr. 2.45:19 – 2.46:11, 2.9:4-10. They "keep abreast of the literature" by performing searches on scientific and medical databases (*e.g.*, PubMed) and

look at hundreds of articles per year. Tr. 2.45:19-23, 2.48:13-17. They do not "document or make note of or copy and paste every study" reviewed because it would not be "feasible" and because these studies are in their possession through access to the databases. Tr. 1.64:7-17, 2.49:2-12, 2.9:4-10, 2.52:8-13. The medical representative determines whether the claims are substantiated based on available evidence. Tr. 2.36:15-2.37:4.

LMR "starts at idea generation" and approval is required before a product is launched. Tr. 2.42:22-25. As part of the LMR process for a new product, the medical team creates a "medical POV." Tr. 2.43:1-9. The medical POV is based upon the "studies and literature from public domains, such as PubMed, Embase, Medline" as well as "proprietary data from suppliers." Tr. 2.43:2-9. If there is "not much evidence" supporting a new product, then Bayer does not create a medical POV but produces a "one-page document [] summarizing the top line results of the data available." Tr. 2.44:16-24. If there is a "vast amount of evidence" and sufficient substantiation to move forward the medical team creates a "full blown medical point of view" file. Tr. 2.44: 16-24. The medical POV file describes the "strength of the evidence, the abundance of evidence and studies" that allows the company to move forward with the product. Tr. 2.43:2-9.

G. SCIENTIFIC SUBSTANTIATION FOR PCH

Bayer followed its LMR review process for PCH. Dr. Pana Beke explained that her predecessor Dr. Sefali Patel conducted a public literature search for probiotics and drafted a medical POV memo before launching PCH. PX-68 (Bayer HealthCare Consumer Care Division Point of View Memo: Probiotics for Gut and Immune Health, June 16, 2006 ("2006 POV Memo")); *see also* Tr. 1.52:18-20. This POV memo documented Bayer's first public literature search and review. PX-68. In a section entitled "literature review," Dr. Patel explained that the

"[l]iterature search resulted in an abundant number of matches for probiotic research in gut . . . health." PX-68 at 3. Dr. Patel uncovered such a "vast number of research material" that her "review was limited to encompass the last 6 years." *Id.* The memo proceeded to discuss over one dozen studies on gut/digestive health, that analyzed endpoints such as "constipation," "gas," "flatulence" "defecation frequency," "colonic transit," "irritable bowel syndrome," "ulcerative colitis," and "production of short chain fatty acids." PX-68 at 3-5. The memo was not an exhaustive list of all the studies Dr. Patel reviewed, but rather "reflect[ed] a sample of the studies that are" in the public domain. Tr. 2.53:19-21. The POV memo concluded that "[t]here is sufficient substantiation for the use of probiotics for gut or immune health." PX-068 (2006 POV Memo) at 1. After the POV Memo was drafted, the medical group continued to do public literature searches and to review data on a regular basis to determine that PCH's claims were substantiated. Tr. 2.9:4-10 ("[W]e reviewed public domain data at the time [of launch in 2008]. We continue to review public domain data as we go on. That is what we do every single day.").

Upon taking over the medical responsibility for PCH in 2009, Dr. Beke went "through the diligence of understanding the background for [PCH], understanding the probiotics, understanding the evidence . . . which included looking at all of the literature in the public domain . . . as well as the additional data that was shared . . . by . . . Wakunaga." Tr. 1.53:8-16. Additionally, Dr. Beke further educated herself about probiotics by "talking to experts," "talking to scientific people at [trade associations]," "really looking at the totality of evidence . . . to make sure that the claims for the product were adequately substantiated." Tr. 1.53:8-24. After she gained "a good understanding" of "the data, the evidence behind [PCH]," "the claims behind [PCH]," and "the medical POV," Dr. Beke signed the medical POV affirming that in her medical opinion, the claims were substantiated. Tr. 1.116:15-25.

Dr. Beke did continuous reviews of the literature to stay up to date on the substantiation for PCH. Dr. Beke explained that she conducts a "weekly search" in multiple scientific databases including PubMed, Embase and Medline. Tr. 2.18:2-15; Tr. 2.52:1-13. The search parameters included "the individual species with the benefit" of constipation, diarrhea, gas and bloating. Tr. 1.120:11-17; Tr. 1.71:20-25. These searches returned "hundreds of studies." *Id.* Dr. Beke explained that this search process ensures that Bayer reviews and relies upon the published studies "at the time [they are] published." Tr. 2.45:25. Therefore if a "study was published in . . . [she] would take a look at it around that time" of publication. Tr. 2.45:25-2.46:2. Since Dr. Beke took over responsibility for PCH, the scientific and medical evidence substantiating the claims for PCH "has strengthened." Tr. 2.53:23-25.

Dr. Beke did not print out or make a separate record of the studies she reviewed and relied upon. Such a task would be impractical given that her group reviews over 60,000 studies each year. Tr. 1.121:1-5; *see also* Tr. 2.96:22-2.97:13 (Government witness stating that obligation to maintain documents does not require printing or filing documents). Instead, Bayer's medical group reviews all of the scientific literature online and maintains access to the databases where that literature is published. In that way, Dr. Beke and her colleagues possess the necessary substantiation and can locate, pull, and use the medical and scientific studies as needed. Tr. 1.68:18-1.69:3; *see also* Tr. 2.46:14-25.

PCH is primarily substantiated through studies done on the species of bacteria found in PCH. Tr. 2.54:18-23. Bayer produced nearly 100 of these studies to the FTC during the Government's investigation. *See* Tr. 3.39:7-17. All of the species level studies discussed by Dr. Beke and Bayer's experts at trial were part of the public domain studies that Dr. Beke reviewed and relied upon. Tr. 1.117:14-1.118:5. Contrary to assertions in the Government's closing

argument, all but one of the studies discussed at trial was produced by Bayer to the FTC during the Government's investigation. DX-25, DX-30, DX-31, DX-32, DX-36, DX-167. The final study was produced during this litigation. These species-specific randomized controlled trials included:

• Pitkala, et al. published "*Fermented Cereal with Specific Bifidobacteria Normalizes Bowel Movements in Elderly Nursing Home Residents: A Randomized, Controlled Trial*." DX-36. This study demonstrated that the PCH species *Bifidobacterium longum* "had a significant effect in normalizing . . . bowel movements." DX-36; Tr. 6.100:9 – 6.101:16.

• Margreiter, et al. published "*Therapeutic value of a Lactobacillus gasseri and Bifidobacterium longum fixed bacterium combination in acute diarrhea: a randomized, double-blind, controlled clinical trial*." DX-32. This study was a "double-blind[ ] active control clinical trial [that was also] randomized." Tr. 6.102:24-6.103:1. The study showed that a combination of two species in PCH (*Lactobacillus gasseri* and *Bifidobacterium longum*) "shorten[] the duration and decreases the severity of . . . diarrhea in adults." DX-32; Tr. 6.101:23–6.102:16.

• Guglielmetti, et al., published "*Randomised clinical trial: Bifidobacterium bifidum MIMBb75 significantly alleviates irritable bowel syndrome and improves quality of life – a double-blind, placebo-controlled study*." DX-26. This study was a "prospective, multi-centre, randomized, double-blind, placebo-controlled, two-arm nutritional study." DX-26. The study showed that one of the species in PCH (*Bifidobacterium bifidum*) "significantly alleviates irritable bowel syndrome and improves quality of life." DX-26; Tr. 6.103:15–6.104:25.

• Guerra et al., published "*Pediatric functional constipation treatment with Bifidobacterium-containing yogurt: A crossover, double-blind, controlled trial*." DX-25. This was a crossover, double-blind controlled trial. The study showed that one of the PCH species (*Bifidobacterium longum*) significantly improved constipation and abdominal pain. DX-25; Tr. 5.56:3–5.57:21.

• Madden, et al., published "*Effect of probiotics on preventing disruption of the intestinal microflora following antibiotics therapy: A double-blind, placebo-controlled pilot study*." DX-031. This study was a double blind placebo controlled clinical trial. The study showed an improvement in gut microflora and a better response to antibiotic therapy, often a cause of gastrointestinal issues. DX-31; Tr. 5.62:21–5.65:17.

There were also two strain-specific studies conducted by Wakunaga. The first, known as the Florida Study, showed "a positive impact in [its] primary outcome." Tr. 6.108:16-21. The PCH product was proven to be beneficial for "maintenance" of gut homeostasis, which Dr. Fennerty described as digestive health and the absence of symptoms like constipation, diarrhea,

gas and bloating. Tr. 5.74:1-5. The second strain-specific study, known as the Canadian study, was "primarily a neutral study" but showed results that "trend[ed] positive" for digestive health benefits. Tr. 6.106:4-19. The study population was just over 100 people, and Dr. Fennerty explained that "[t]he study was underpowered" meaning there were "not enough people" to show a statistically significant benefit. Tr. 5.71:14-25. The study does not undercut Bayer's substantiation of PCH because many successful products, including FDA-approved drugs, have neutral studies. *Id.* Dr. Beke also possessed and relied upon proprietary data from Wakunaga (Bayer's supplier for PCH). Tr. 1.53:8-24, 1.77:18 – 1.78:11; *see also*, *e.g.*, PX-69 (Scientific Dossier of Probiotics Prepared Exclusively for Bayer Healthcare).

H. GOVERNMENT'S EVIDENCE

In its contempt motion, the Government for the first time disclosed the expert opinion of Dr. Loren Laine, who opined that competent and reliable scientific evidence for the PCH claims at issue requires a randomized controlled trial ("Laine-Level RCT") meeting 8 specific requirements: (1) randomized; (2) placebo-controlled; (3) double-blind; (4) human clinical trial; (5) done in the target population; (6) with the specific product at issue; (7) using appropriate statistical methods; and (8) designed with the desired outcome as the primary endpoint. Gov't Mot. for Contempt at 15-30.

Dr. Laine testified that only the "highest quality evidence," Tr. 4.41:9-12, "level one evidence," Tr. 4.40:23-4.41:1, or an "excellent" study of his design, Tr. 4.41:14-16, would satisfy the "competent and reliable scientific evidence standard." Dr. Laine admitted, however, that he had: (1) "never written any articles, books, or clinical guideline on probiotics," Tr. 4.65:12-14; (2) "never conducted a study of any kind on probiotics," Tr. 4.65:18-20; and (3) is "not an expert in probiotics," Tr. 4.66:1-3. Additionally, Dr. Laine does not "hold [himself] out

as an expert on dietary supplements." Tr. 4.67:16-18. Dr. Laine does not "know of any probiotic product that has a study meeting [his] design." Tr. 4.36:15-16. In fact, he indicated that he does not "know of any dietary supplement at all" that has a study meeting his design. Tr. 4.36:20-22.

Dr. Laine testified that his study design did not distinguish between drugs or supplements. Dr. Laine explained that his study design would apply equally to "drugs," "educational brochures," "surgical interventions," "supplements" and even "food." Tr. 4.31:8-18; *see also* Tr. 4.31:19-23. Similarly, Dr. Laine testified that his study design was not specific to probiotics or dietary supplements. He stated: "this clinical trial design[], is basically appropriate for any situation in which you want to obtain reliable results." Tr. 4.31:19-23. His required clinical study design is "not unique to GIs" but also would apply to other areas of medicine, including "ophthalmology" and "rheumatology." Tr. 4.35:4-4.36:13.

The FTC did not provide Dr. Laine with a copy of the FTC Guidance for Industry regarding the substantiation necessary for dietary supplement claims. Therefore, Dr. Laine testified that he "did not rely on [the FTC Guidance] or look at it when [he] made [his] original report." Tr. 4.16:4-5. Dr. Laine also was not familiar with DSHEA, which regulates dietary supplements and categorizes supplements differently from drugs. Tr. 4.21:1-4. Dr. Laine "had not heard of the statute" at "the time that [he] provided [his] report." Tr. 4.21:1-4. Dr. Laine also "did not review [ ] or consider . . . FDA regulations in any way" in formulating his expert opinion. Tr. 4.23:13-16. Nor was Dr. Laine informed of the regulatory distinction between "structure function" claims and disease claims. Tr. 4.24:1-11.

Although Dr. Laine did "know in a general sense there has been a different interpretation [between the substantiation standards for dietary supplements and drugs]" he was

"not up on the legal and regulatory issues as an expert." Tr. 4.26:9-14. Dr. Laine admitted he was "not paying attention to the law or regulations about the difference between dietary supplements and drugs." Tr. 4.26:16-20.

The Government presented no evidence of any law, regulation or guidance that would have provided notice to Bayer that Laine-Level RCTs are required for the PCH claims at issue. Tr. 2.59:4-8. Nor did the Government present evidence that it had ever applied the Laine-Level RCT standard to any other probiotic or dietary supplement.

I. BAYER'S EXPERTS

Bayer presented testimony from Dr. Daniel J. Merenstein. Dr. Merenstein is a professor of medicine and director of research programs at Georgetown University Medical Center, where he teaches classes on probiotics and clinical research. Tr. 6.8:14–6.9:5; DX-5-B (Dr. Daniel J. Merenstein CV) at 2. Dr. Merenstein is a leading expert on probiotics and has been a lead investigator on eight probiotic clinical trials, published multiple articles on probiotics, and has given national and international lectures to physicians and consumers about probiotics. Tr. 6.12:19–6.13:4; DX5-B (Merenstein CV) at 17-20.

Dr. Merenstein was part of the expert panel on probiotics convened by the International Scientific Association of Probiotics and Prebiotics ("ISAPP") that issued a report in 2014 titled, "*The consensus statement on the scope and appropriate use of the term probiotic*." Tr. 6.13:5-21; DX-29 ("ISAPP Expert Consensus Report"). As a physician, Dr. Merenstein "see[s] patients in a primary care setting," where "[g]astrointestinal health issues" are "one of the primary things" he addresses. Tr. 6.9:11-21. Because probiotics are "one of the number one things we use for gastrointestinal issues," they are used "quite often" and are "a regular part of primary care." Tr. 6.10:3-7, 22-23. Dr. Merenstein has recommended various probiotic supplements,

including PCH, "thousands of times" throughout his career. Tr. 6.10:16-23. The Government presented no expert in probiotics, and Dr. Merenstein testified without contradiction regarding the expert consensus opinion on the benefits of probiotics for digestive health. Tr. 4.66:1-3, 4.67:16-18.

Dr. M. Brian Fennerty is a professor of medicine at the Oregon Health & Science University and a clinical researcher in the field of gastroenterology. Tr. 5.5:15-18; Tr. 5.10:5-10; DX-4-B (Dr. M. Brian Fennerty CV) at 1. He has "many hundreds of publications in th[e] field" of gastroenterology. Tr. 5.9:18-21. His clinical research has been published in *The New England Journal of Medicine, The Journal of the American Medical Association, The Annals of Internal Medicine, and Gastroenterology* - "some of the best scientific medical journals in the world." Tr. 5.9:18–5.10:4. He has "been involved in the design and implementation and interpretation and conduct of many hundreds of clinical trials and studies." Tr. 5.10:5-10. Dr. Fennerty has done research on probiotics and the gut microbiome and has reviewed "[m]any hundreds, if not thousands" of studies on probiotics in his career. Tr. 5.8:24 – 5.9:7. In his clinical practice as a gastroenterologist, Dr. Fennerty has recommended probiotics, including PCH, to his patients "[m]any hundreds, if not thousands of times." Tr. 5.8:2-4. More specifically, he has "recommend[ed] probiotics that contain [L]actobacillus and [B]ifidobacter[ium], similar to the probiotics that are found in PCH," to "help" his patients "maintain . . . digestive health." Tr. 5.8:5-23.

Dr. Fennerty and Dr. Merenstein both testified that Dr. Laine is incorrect in suggesting that experts in the field would require Laine-Level RCTs to substantiate the PCH claims at issue. Tr. 5.108:3-4 (Dr. Fennerty testified that "a great, great majority, vast majority of my colleagues would disagree with Dr. Laine" that a Laine-Level RCT is required to substantiate the PCH

claims), Tr. 5.27:16-21 (the view that a Laine-Level RCT is required for competent and reliable scientific evidence for the PCH claims is "very inconsistent with what the expectation is within the field of expertise [of] gastroenterology or . . . probiotics."), Tr. 6.38:19 – 6.39:1 ("There is no question in [Dr. Merenstein's] view and in the expert's view in the field . . . , both probiotic and primary care experts," that "the species-level RCTs" on "gasseri, bifidum, and longum . . . provide [substantiation for PCH claims] on their own" without the need for a Laine-Level RCT).

II. CONCLUSIONS OF LAW

A. LEGAL STANDARD

Courts possess inherent authority to enforce compliance with their orders through civil contempt. *Shillitani v. United States*, 384 U.S. 364, 370 (1966). "[C]ivil contempt may be employed to coerce the defendant into compliance with the court's order and to compensate for losses sustained by the disobedience." *McDonald's Corp. v. Victory Invs.*, 727 F.2d 82, 87 (3d Cir. 1984). For a party to be held in contempt, the moving party must demonstrate "'(1) that a valid order of the court existed; (2) that the defendant[] had knowledge of the order; and (3) that the defendant[] disobeyed the order.'" *FTC v. Lane Labs- USA, Inc.*, 624 F.3d 575, 582 (3d Cir. 2010) (quoting *Marshak v. Treadwell*, 595 F.3d 478, 485 (3d Cir. 2009)). The party seeking civil contempt must prove it by clear and convincing evidence, *Lane Labs-USA*, 624 F.3d at 582, which is proof greater than a preponderance of the evidence but less than proof beyond a reasonable doubt, *Araujo v. N.J. Transit Rail Operations, Inc.*, 708 F.3d 152, 159 (3d Cir. 2013); *see also Colorado v. New Mexico*, 467 U.S. 310, 316 (1984) (when "the truth of [the] factual contentions are 'highly probable'"). The Government therefore must prove by clear and convincing evidence that Defendant violated a "clear and unambiguous provision of the consent decree." *Harris v. City of Phila.*, 47 F.3d 1342, 1348 (3d Cir. 1995). Specificity in the terms of

consent decrees is a predicate to a finding of contempt, because [a defendant] will not be held in contempt . . . unless the order has given [it] fair warning." Id. at 1349 (internal citation and quotation marks omitted). If the purported legal requirement cannot be "'discern[ed]'" from the "'four corners'" of the consent decree, the contempt action fails. *United States v. New Jersey*, 194 F.3d 426, 430 (3d Cir. 1999).

To "be placed at risk of contempt," a defendant must be "given specific notice of the norm to which [it] must pattern [its] conduct." *New Jersey*, 47 F.3d at 1349 (citing *Int'l Longshoremen's Ass'n v. Phila. Marine Trade Ass'n*, 389 U.S. 64, 76 (1967)). Any "ambiguities and omissions in orders redound to the benefit of the person charged with the contempt." *Ford v. Kammerer*, 450 F.2d 279, 280 (3d Cir. 1971) (per curiam).

The Court interprets the consent decree "with reference to traditional principles of contract interpretation" and, therefore, discern[s] the scope of a consent decree by examining the language within its four corners." *New Jersey*, 194 F.3d at 430. "In so doing, [the court] must not strain the decree's precise terms or impose other terms in an attempt to reconcile the decree with [the court's] own conception of its purpose." *Id.* (quoting *Harris v. City of Phila.*, 137 F.3d 209, 212 (3rd Cir. 1998)).

An advertisement's meaning is a question of fact. *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th 73 Cir. 2009); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957–58 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008). "When assessing the meaning and representations conveyed by an advertisement, the court must look to the advertisement's overall, net impression rather than the literal truth or falsity of the words in the advertisement." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1189; *cf. In re Nat'l*

Credit Mgmt. Grp., LLC, 21 F. Supp. 2d 424, 441 (D.N.J. 1998) ("[A] court is not limited to express claims, but may also look to the overall net impression conveyed by the advertising and promotional statements of a defendant."). Where implied claims are conspicuous and "reasonably clear from the face of the advertisement[]," extrinsic evidence is not required to establish the existence of implied claims. *Kraft, Inc. v. FTC*, 970 F.2d 311, 320 (7th Cir. 1992); *cf. FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 386 (1965) (finding a certain claim "rest[ed] on an inference that could reasonably be drawn from the commercials themselves").

Injunctions, including consent decrees, must comply with Federal Rule of Civil Procedure 65(d), which requires that an injunction "state its terms specifically" and "describe in reasonable detail . . . the act or acts restrained or required." Fed. R. Civ. P. 65(d). A party will not be held in contempt of a court order if that order is so vague or indefinite that the party subject to the order lacked certainty as to what the order prohibited or directed. *Harris v. City of Philadelphia*, 47 F.3d 1342, 1349–50 (3d Cir. 1995).

B. BAYER MADE STRUCTURE-FUNCTION CLAIMS, NOT DISEASE CLAIMS

According to the FDA's final rule on structure-function claims, Bayer's claims for PCH are appropriate dietary supplement claims, called "structure-function claims," not disease claims. *See* 65 Fed. Reg. 1000, 1006 (Jan. 6, 2000) ("a claim that a product 'helps promote digestion' would be a structure-function claim because it does not refer explicitly or implicitly to an effect on a disease state"); *id.* at 1026 ("for relief of 'occasional constipation' should not be considered [a] disease claim[]"); *id.* at 1031 (stating that "'[a]lleviates the symptoms referred to as gas'" and "'alleviates bloating'" are structure-function claims "because the symptoms . . . are not sufficiently characteristic of specific diseases"); *see also id.* at 1033 ("'helps maintain regularity' is an acceptable structure/function claim"); *see also id.* at 1015, 1029.

The Government never asserted or presented any evidence that Bayer made disease claims under DSHEA and the Food Drug and Cosmetic Act. *See* 21 U.S.C. § 343(r)(6) (a claim that a product can "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases" is a disease claim). Every package of PCH and every advertisement contains a disclaimer that that PCH is "not intended to diagnose, treat, cure or prevent any disease." *See*, *e.g.*, PX-2; Tr. 2.91:15-17.

The claims made for PCH are ubiquitous in the industry. *See*, *e.g.*, DX-243 (**Align** probiotic package) ("defense" and "defend against," "ongoing protection from episodic: constipation, diarrhea, urgency, and gas and bloating," "clinically proven to naturally defend against [constipation, diarrhea, urgency, and gas and bloating]"); DX-244 (**Culturelle** probiotic package) ("promotes better digestive health," "helps your digestive system work better," "helps reduce your digestive upset," "helps with occasional diarrhea," "helps with gas and bloating,"); DX-254 (**Nature's Bounty** probiotic package) ("gas and bloating formula," "patented strain to alleviate occasional gas and bloating" that has been "studied by gastroenterologists," "advanced support for: gas and bloating" and "abdominal comfort"); DX-246 (**PureLife** probiotic package and bottle) ("gas and bloating prevention," "helps digest," "helps prevent occasional gas and bloating," "relieves occasional abdominal discomfort"); DX-247 (**Activia** probiotic advertisement) ("helping to regulate your digestive system," "may help reduce the frequency of minor digestive issues like bloating, gas, discomfort and rumbling").

The Government has not pointed to any instance when it has asserted that these claims are disease claims. If these claims were disease claims, then many of the most popular probiotic supplements on the market would be in violation of the law, and subject to seizure by the FDA.

Accordingly, the Court finds that the Government has failed to prove by clear and convincing evidence that Bayer made any express disease claims for PCH.

The Government also has argued that Bayer made implied claims that PCH will prevent, treat, or cure constipation, diarrhea, gas and bloating. The Government has failed to prove by clear and convincing evidence that Bayer made such an implied claim.

The Government presented no evidence that Bayer made any implied disease claims. The Government offered no consumer survey data, no consumer testimony, no expert opinion on consumer understanding of the PCH ads, no marketing data, and no copy tests of any PCH advertisement. The FTC also made no factual findings regarding Bayer's claims, unlike cases cited by the Government, *see Kraft, Inc. v. FTC*, 970 F.2d 311, 320 (7th Cir. 1992); *cf. FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 386 (1965), where the FTC did make factual findings. Without evidence or an agency finding, the Court cannot conclude by clear and convincing evidence that Bayer made any implied disease claims.

Even if Bayer made implied claims regarding prevention, treatment, or cure, they are not disease claims. Although the words "prevent, treat, and cure" often signal a disease claim, the Government has not proven that Bayer advertised PCH to prevent, treat, or cure any disease. Instead, the Government asserts that Bayer advertised PCH to prevent, treat, or cure constipation diarrhea, gas and bloating. These are not diseases, but rather variations of the normal state of health. *See* Tr. 5.16:23 – 5.17:6.

The Government has pointed to only one advertisement, a store display, that includes the phrase "prevention of occasional digestive upsets." PX-120. Although the display uses the word "prevention," it is not a disease claim. The use of the term "occasional" as well as the described symptom, "digestive upsets," do not indicate a disease state; rather, this is a structure-function

claim. *See* 65 Fed. Reg. 1000, 1006 (promotes digestion "does not refer explicitly or implicitly to an effect on a disease state").

Further, every one of Bayer's labels and advertisements contain the FDA disclaimer that PCH is "not intended to diagnose, treat, cure or prevent any disease," and a Government witness conceded that, with this disclaimer, Bayer "disclaim[ed]" any disease claim. Tr. 2.91:24. The context of Bayer's ads confirms that there are no implied disease claims. *See* 65 Fed. Reg. at 1011 (in evaluating claim, must look at the overall "context in which the claim is presented"); *id.* at 1022, 1024-25, 1028, 1032 (same). Far from showing anyone "suffering from [a] disease," *id.* at 1012, Bayer's advertisements display active healthy people playing golf, riding a tour bus, going on a safari, or getting on an airplane. *See*, *e.g.*, PX-157, -158 (ad showing PCH spokeswomen speaking to active and healthy individuals on a safari); PX-34, -41 (ad showing PCH spokeswomen speaking to active and healthy individuals on an airplane); PX-23, -25 (ad showing PCH spokeswomen speaking to active and healthy individuals at a book reading). And the ads do not involve a doctor or nurse, but the PCH spokesperson, referred to as the "Colon Lady," who is giving humorous wedding speeches about bloating, performing dramatic readings in book stores, and preaching about gas on street corners. Tr. 2.98:10-20 (Government witness affirming that the advertisements "made [her] laugh"). As a Government witness testified, "[n]one of [PCH's] advertisements show sick people." Tr. 2.98:4-5. "None of those advertisements show[] anyone suffering from a disease," Tr. 2.98:7-9, let alone "clearly and conspicuously," *FTC v. National Urological Group, Inc.*, 645 F. Supp.2d 1167, 1189 (2008). For the foregoing reasons, the Court is unable to find that the Government has met its burden of showing by clear and convincing evidence that Bayer made an implied disease claim.

C. BAYER WAS NOT PROVIDED WITH ANY NOTICE THAT THE CONSENT DECREE REQUIRES A LAINE-LEVEL RCT

To prove contempt, the Government must show by clear and convincing evidence that Bayer violated a "clear and unambiguous provision of the consent decree." *Harris*, 47 F.3d at 1348. If there is ambiguity or doubt, there can be no contempt. *Ford*, 450 F.2d at 280. If the purported legal requirement cannot be "discern[ed]" from the "four corners" of the consent decree, the contempt action fails. *Harris v. City of Phila.*, 137 F.3d 209, 212 (3d Cir. 1998) (citing *United States v. Armour & Co.*, 402 U.S. 673, 681-82 (1971). The Government does not meet this standard.

As two other courts have held, competent and reliable scientific evidence does not require drug-level clinical trials, and the Government cannot try to reinvent this standard through expert testimony. *FTC v. Garden of Life Inc.*, 845 F. Supp. 2d 1328, 1334-35 (S.D. Fla. 2012) (When a consent decree speaks only of "competent and reliable scientific evidence," the Government cannot redefine it through expert testimony and "require [the] court to read additional requirements into the Consent Decree."), *aff'd in part and vacated in part*, 516 F. App'x 852 (11th Cir. 2013); *Basic Research, LLC v. FTC*, No. 2:09-cv-0779 at 26-27 (D. Utah Nov. 25, 2014) (By demanding "gold standard" clinical trials, which "exceed[] the requirements of the [consent decree]," the Government failed the "expectation of reasonableness.").

The Government's position that Laine-Level RCTs are required is found nowhere within the four corners of the consent decree, but only within the expert report that was filed with the Government's motion for contempt. The Consent Decree that Bayer agreed to in January of 2007 speaks only of "competent and reliable scientific evidence." DX-1. The Consent Decree does not mention randomized controlled clinical trials of any kind, let alone say they are required. *Id.* In the seven years after entering the Consent Decree, the Government never told Bayer or anyone else in the industry that drug-level clinical trials or Laine-Level RCTs were

required. Indeed, counsel for the Government conceded in closing argument that "you have to go outside of the four corners of the consent decree" in order to find support for the Government's standard. Tr. 7.61:3-4.

Because the definition of "competent and reliable scientific evidence" looks to the view of experts in the relevant field, it is appropriate for the Court to consider the testimony of experts in the field. *See*, *e.g. FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575, 582 (3d Cir. 2010). (A consent decree does not need to delineate the specific scientific substantiation necessary for every conceivable claim.) But, for there to be contempt, the legal standard must be "clear and unambiguous." *Harris*, 47 F.3d at 1348. The Government cannot seek contempt on the basis of a lone expert who proposes a standard that was not disclosed to industry until the day the government filed its contempt motion.

This is especially true where, as here, that testimony is inconsistent with the agency's own guidance. The FTC has issued Guidance which provides scientific and medical advice regarding the meaning of competent and reliable scientific evidence. That Guidance specifically refutes the standard the Government is seeking to impose. According to the FTC Guidance: "There is no fixed formula for the number or type of studies required . . ." FTC Guidance PX-1 at 9. Moreover, "[t]here is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine." *Id.* at 12. In fact, "[t]he FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science." *Id.* at 8

The Government has entered into consent decrees with other companies in which it required "two adequate and well-controlled human clinical studies," that "shall be randomized . . . double-blind and placebo-controlled." DX-239 (2010 Dannon Co., Inc., Consent Decree),

Definitions ¶ 3, § II; DX-240 (2010 Nestle HealthCare Nutrition, Inc., Consent Decree), Definitions ¶ 3, § II; DX-241 (2010 Iovate Health Sciences USA, Inc., Consent Decree), Definitions ¶ 4, § II; DX-242 (2012 Jason Pharms., Inc., Consent Decree), Definitions ¶ 1, § II.

Likewise, in *POM Wonderful LLC*, 777 F.3d 478, 497 (D.C. Cir. 2015), the consent decree provision at issue explicitly required "randomized and controlled human clinical trials." *Id.* The D.C. Circuit expressly distinguished that provision, which pertained to "disease-related" claims, from another provision, which pertained to "more general claims about health benefits." *Id.* (emphasis omitted). This other provision required only "competent and reliable scientific evidence," not "randomized, controlled, human clinical trials support." *Id.*; *see also id.* at 501 ("In short, Part III's baseline requirement for all health claims does not require RCT substantiation, whereas the specific requirements in Part I for disease-related claims not only contemplate RCT substantiation, but call for — as a categorical matter—two RCTs"); *id.* at 504 ("[S]everal orders over the past decade require only 'competent and reliable scientific evidence'—not necessarily RCTs, let alone two RCTs—to substantiate disease claims akin to those made by petitioners.") These examples show that when the Government wants to require RCTs, it knows how to do so. The Government cannot enter into a consent decree using the general competent and reliable scientific evidence standard and then subsequently require RCTs through the expert testimony it produces in a contempt action.

The Government identifies only one case in which any court has held that RCTs are required under the competent and reliable scientific evidence standard. *See* Dkt. No. 186 at 75 (citing *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957–58 (N.D. Ill. 2006)). However, this holding by a magistrate judge was expressly rejected on appeal by the United States Court of Appeals for the Seventh Circuit. Although the Seventh Circuit affirmed the judgment, the panel made clear

that "[p]lacebo-controlled, double-blind testing is not a legal requirement for consumer products." *Id.* at 861; *see also id.* ("Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies."). Although "[a] placebo-controlled, double-blind study is the best test; something less may do." *Id.* at 862. The Seventh Circuit affirmed the judgment solely because the defendant's tests were "bunk," not because the defendant failed to have a placebo controlled clinical trial. *Id.*

Therefore, the Court concludes that the plain language of the 2007 Consent Decree does not give Bayer any notice that Laine-Level RCTs are required for its probiotic claims or any dietary supplement claims. To interpret the plain language to include the additional requirement of an 8-part Laine-Level RCT—which the government did not disclose until it sought contempt—would improperly "strain the decree's precise terms or impose other terms." *United States v. New Jersey*, 194 F.3d at 430 (quotation marks omitted).

D. DR. LAINE'S TESTIMONY DOES NOT SATISFY THE GOVERNMENT'S BURDEN

Even assuming Bayer had been placed on proper notice, the Government has not met its burden to show that Bayer is in contempt. The Government argues that the Consent Decree looks to what experts in the field require for substantiation, that Dr. Laine is an expert in the field, and that Dr. Laine requires Laine-Level RCTs. But, Dr. Laine's testimony does not meet the Government's burden.

First, Dr. Laine lacks the expertise necessary to prove what experts in the field would require. Dr. Laine admitted he is "not an expert in probiotics" and has limited experience in probiotics. A gastroenterologist who is not an expert in probiotics and does not regularly use them in his practice is not in a position to testify as what type of evidence experts in the relevant area require. DX-1 at 2. Second, Dr. Laine's opinion cannot be reconciled with the legal and

regulatory standards that govern the substantiation of dietary supplement claims. Dr. Laine had no familiarity with DSHEA, the statute that regulates dietary supplements and treats supplements differently from drugs. Tr. 4.21:1-4

Dr. Laine "did not review or consider FDA regulations in any way" in formulating his expert opinion. Tr. 4.23:13-16. Dr. Laine was not aware of the distinction between "structure function" claims for dietary supplements and disease claims for drugs. Tr. 4.24:1-11. Dr. Laine admitted he was "not paying attention to the law or regulations about the difference between dietary supplements and drugs" in formulating his opinion. Tr. 4.26:16-20.

Dr. Laine testified that his opinion makes no distinction between "drugs" and "supplements" (or even "educational brochure[s]," "surgical intervention[s]," and "food.") Tr. 4.31:8-18; *see also* Tr. 4.31:19-23 (agreeing that his "clinical trial design[] is basically appropriate for any situation in which you want to obtain reliable results . . . for those . . . symptoms.") This is directly contrary to DSHEA, in which Congress expressly recognized "the benefits of dietary supplements to health," eliminated the pre-approval requirement that applies to drugs, and lowered the substantiation requirement for dietary supplements. *See* 21 U.S.C. § 343(r)(6).

The Government did not provide Dr. Laine with the FTC Guidance that defines what substantiation is necessary for dietary supplement claims. Dr. Laine "did not rely on [the FTC Guidance] or look at it when [he] made [his] original report." Tr. 4.16:4-5. Dr. Laine's opinion is contrary to the FTC Guidance. For example, Dr. Laine "testified . . . that there is a specific study design or protocol that . . . should be followed to substantiate [PCH]." Laine Tr. 4 27:10-15. The FTC Guidance, by contrast, provides that there is "no fixed formula" and "no set protocol." FTC Guidance PX-1 at 12. Similarly, Dr. Laine opined that any study relied upon by

Bayer must be done on the exact three-strain product and in the exact population that the product is marketed to. Tr. 4.13:6-21. The FTC Guidance, however, permits companies to use tests done on a "similar formulation" and permits companies to "extrapolate" between populations. FTC Guidance at 15-16.

Additionally, contrary to the assertion of Government counsel, Dr. Laine's testimony does not reflect the opinion of experts in the field. The opinion Dr. Laine offered was a personal opinion that he did not share with any other expert or physician. Tr. 4.64:18-22. The Government presented no evidence that any other expert agreed with Dr. Laine's opinion. Dr. Fennerty testified that few, if any, relevant experts would agree with Dr. Laine:

> I respect Dr. Laine's declaration, and I read it carefully, and I gave it a lot of consideration. But not only myself, I think a great, great majority, vast majority of my colleagues would disagree with Dr. Laine here . . . . I just don't agree with him, and I don't see where other experts in the field would agree with him."

Tr. 5.108:1-8.

Moreover, Dr. Laine's standard conflicts with the longstanding understanding of substantiation requirements in the industry. Although the claims Bayer makes for PCH are the same exact claims made by many other probiotics on the market today, none has a study that meets Dr. Laine's standard. Tr. 4.36:15-19; Tr. 5.26:1-7; Tr. 6.115:9-13.

In addition, Bayer presented evidence from Dr. Merenstein and Dr. Fennerty showing that experts in the relevant fields do not require Laine-Level RCTs to substantiate probiotic supplement claims. Both Dr. Merenstein and Dr. Fennerty understood and relied upon the FTC Guidance and the distinction it draws between supplements and drugs in formulating their expert opinions. Tr. 6.12:14-18; Tr. 5.16:16-20; Tr: 6.16:23-25; Tr. 5.13:13-17. Dr. Merenstein, the only expert in probiotics that testified in the case, stated: "Dr. Laine's RCTs are clearly . . . not a

requirement for a supplement," and "[i]t's clear they are not required" to demonstrate the efficacy of probiotics. Tr. 6.23:1-3, 6.31:13-18. Dr. Fennerty also testified that as an expert gastroenterologist and clinical researcher: Dr. Laine's RCT "is a superb study design, but I disagree that it is necessary for substantiation in this case." Tr. 5.26:1-8, 5.25:9-11.

Neither Dr. Fennerty nor Dr. Merenstein could identify, after research, a single probiotic or a single dietary supplement on the market that possessed a study design meeting Dr. Laine's criteria. Tr. 6.115:9-10 ("[No] product currently on the market [] has a study that meets Dr. Laine's design."). Dr. Laine could not identify one either. Tr. 4.36:15-17; Tr. 4.36:20-24. Dr. Merenstein has done RCTs but none that would meet Dr. Laine's test. Tr. 6.70:5-6 ("They had some similarities, but they are not Laine-Level RCTs").

Futhermore, Dr. Laine's testimony is contradicted by the Expert Consensus Report by ISAPP, on which he relied. Far from requiring Laine-Level RCTs, the Expert Consensus Report concluded that RCTs were not required for probiotic claims concerning digestive health. Tr. 6.65:19-6.66:2 ("To determine whether an association exists between a substance (such as a probiotic) and a desired outcome (such as maintain a healthy digestive system), it is important to examine the following criteria: temporal relationship . . . biological plausibility . . . dose response . . . replication of findings" and other non-RCT data). The report stated that probiotics should be subject to the same standard applied to other dietary supplements, such as vitamins C and calcium, neither of which is supported by a RCT on a healthy population. Tr. 6.66:12-14 ("probiotic foods or supplements should not be held to a high[er] standard of evidence than other foods or supplements"); Tr. 6.66:19-20 ("no robust RCTs in healthy individuals supporting these benefits" on vitamin and calcium).

The Expert Consensus Report further concluded that the "panel [was] convinced that sufficient evidence has accumulated to support the concept of 'core' [i.e., gastrointestinal health] benefits of certain probiotics," including the species in PCH. ISAPP Report at 3; *see also* Tr. 6.56:9-15, 6.84:18-22 (panel's conclusion that the species of *Lactobacillus gasseri*, *Bifidobacterium bifidum*, and *Bifidobacterium longum* provide a core benefit for digestive health issues including constipation, diarrhea, gas and bloating was "unanimous").

Finally, some of the factual and scientific underpinnings of Dr. Laine's opinion are inaccurate. For example, Dr. Laine testified that species of bacteria combined in one product "could be antagonistic." Tr. 3.63:21-22. Dr. Fennerty explained that the idea that probiotics could be antagonistic "is contrary to what I think most experts in the field would state, including myself;" there is no "biological plausibility" and no "evidence" for Dr. Laine's suggestion. Tr. 5.80:15-23. Dr. Merenstein explained that he "wholeheartedly disagree[s]" with Dr. Laine's statement that probiotics could be antagonistic. Tr. 6.74:21. He said: "[Dr. Laine] cites nothing for that . . . because there's no references. There is no possibility. There's no one that believes that they are antagonistic. It makes no sense." Tr. 6.75:8-11.

Dr. Laine also mischaracterized the extent to which existing probiotic studies are "positive" for digestive health benefits. In response to the Court's question whether "there [were] any positive studies," Dr. Laine responded "there were some [but] [i]t was the minority." Tr. 3.71:7-20. Although it is unclear whether Dr. Laine was referring to the studies Bayer produced to the Government or the studies in the public domain, it is clear that Dr. Laine's statement was wrong. No study (produced to the Government or in the public domain) is negative. Tr. 5.50:8-15. Dr. Merenstein testified that this assertion by Dr. Laine was "entirely incorrect" and that the "mass majority [are] positive." Tr. 6.35:12-16; Tr. 6.35:25. Dr. Fennerty

corroborated that "the majority of them are positive studies." Tr. 5.51:6-7. Although some studies are null (meaning they show no statistically significant benefit), none shows negative results. *See id.*; *see also* Tr. 7.74:20-7.75:5.

Accordingly, the Court finds that the Government has not met its burden of demonstrating by clear and convincing evidence that Bayer is in contempt of the 2007 Order simply because it relied on one expert who seems to require a higher-level RCT.

E. BAYER POSSESSED AND RELIED UPON EVIDENCE FROM THE PUBLIC DOMAIN, AS WELL AS PROPRIETARY DATA

Bayer presented testimony and documents demonstrating the scientific studies it possessed and relied upon to support its claims for PCH. The Government asserts that the Court should infer that Bayer did not possess or rely upon any such studies because Bayer did not print out, copy, or otherwise record all of those studies. But, the Consent Decree does not require Bayer to make records or copy studies. Bayer's only obligation was to possess and rely upon competent and reliable scientific evidence. To possess and rely upon a scientific study, Bayer need not copy it from an electronic database that Bayer already possesses and put it in a filing cabinet.

The parties to consent decrees are bound by words' "objective definition[s]." *United States v. New Jersey*, 194 F.3d at 430 (quoting *In re Unisys Corp. Long-Term Disability Plan ERISA Litigation*, 97 F.3d 710, 715 (3d Cir. 1996)); *see also Unisys*, 97 F.3d at 715 ("[C]ommon words of accepted usage . . . should be interpreted in accord[ance] with [that] usage unless such an interpretation would produce irrational results.") (quotation omitted). In ordinary usage, Bayer can "possess" scientific evidence for its claims without creating an electronic or paper copy of each study.

The dictionary definition of "possess" extends to knowledge or mastery of intangible information. To possess is "to have knowledge of," *Random House Webster's Unabridged Dictionary* 1509 (2d ed. 2001), "to have knowledge or skill in," *Webster's Third New International Dictionary* 1770 (1993), "[t]o acquire command of or have knowledge of," *The American Heritage College Dictionary* 1087 (4th ed. 2004), or "to have mastery or knowledge of: . . . possess valuable information," *The American Heritage Dictionary* (5th ed. 2011).

Courts frequently describe an actor who knows legally relevant facts as "possessing" evidence, information, or knowledge, regardless of whether those facts are memorialized in tangible form. *See Whiteley v. Warden*, 401 U.S. 560, 566–67 (1971) (noting that the arresting officer "possessed" information and knowledge from a bulletin heard on the radio, from personal observation of the suspect's vehicle, and from his partner's knowledge of the suspect's name); *Merkle v. Upper Dublin Sch. Dist.*, 211 F.3d 782, 790 (3d Cir. 2000); *California v. Trombetta*, 467 U.S. 479, 485 (1984) ("[The government] may be required to disclose the identity of undercover informants who possess evidence critical to the defense."); *United States v. Valenzuela-Bernal*, 458 U.S. 858, 861 (1982) (describing the government's decision to deport aliens after "conclud[ing] that the passengers possessed no evidence material to the prosecution or defense of respondent").

Dr. Pana Beke, the current medical lead for PCH testified that Bayer reviewed and relied upon the scientific studies in the public domain. Bayer first obtained studies in the public domain before launching the product when the medical lead at the time, Dr. Sefali Patel, drafted a medical POV file for PCH. PX-068. Dr. Beke also testified that Bayer possessed and relied upon proprietary studies from Wakunaga. Tr. 1.53:8-24, 1.77:18–1.78:11.

Even after Dr. Patel finalized the 2006 POV Memo, the medical group reviewed data in the public domain on an ongoing basis to evaluate substantiation. Upon taking over as the medical lead when Dr. Patel left Bayer for a position at another company, Tr. 2.40:3-9; Tr. 2.43:17-20, Dr. Beke continued to conduct public literature reviews to obtain scientific studies related to the claims for PCH. Tr. 2.9:4-10. This search process ensured that Bayer reviewed and relied upon the published studies "at the time [they were] published." Tr. 2.45:25.

There is no basis to conclude that the absence of electronic or physical records should give rise to an inference that Bayer did not possess and rely upon competent and reliable scientific evidence. Any such inference is contrary to the uncontradicted testimony of Dr. Beke that Bayer did in fact possess and rely upon the scientific studies in the public domain. Dr. Beke's testimony was corroborated by the POV memo and by the testimony of Drs. Merenstein and Fennerty about what information is in the public domain. Additionally, no inference should be drawn from the lack of physical records, because the recordkeeping provision of the Consent Decree did not require Bayer to print out documents in the public domain. The recordkeeping provision required Bayer to "maintain" documents, and as the Government's witness testified, the obligation to "maintain" documents "does not mean create." Tr. 2.96:22-2.97:4. It does not require a company "to print out stuff that [it] see[s] on the internet." Tr. 2.97:5-13. Finally, the Government never told Bayer in the seven years since entering into the Consent Decree that it was required to copy or print out the studies it reviewed on public databases. Tr. 1.121:1-5. The Government did not even raise this issue in its contempt motion or any other brief prior to its trial brief. Dkt. No. 158. The Court therefore finds that for purposes of compliance with the terms of the Consent Decree, it was sufficient that Bayer relied upon studies it accessed on medical and scientific databases that were in its possession.

III. CONCLUSION

For the reasons stated above, the Court concludes that the Government failed to establish, by clear and convincing evidence, that Bayer violated the 2007 Order issued by this Court. The United States did not carry its burden of proving that Bayer failed to possess and rely upon competent and reliable scientific evidence to substantiate its specific claims about PCH's efficacy for constipation, diarrhea, and gas and bloating. Therefore, this Court declines to find that Bayer is in contempt of the 2007 Order.

This Court's Opinion will be filed under temporary seal. The Opinion will be unsealed on October 8, 2015 unless an appropriate motion to seal same (pursuant to Local Civil Rule 5.3(c)) is filed by either side or non-party Wakunaga of America Co., Ltd. by October 5, 2015.

An appropriate Order accompanies this Opinion.

DATED: September 24, 2015

s/ Jose L. Linares
JOSE L. LINARES
U.S. DISTRICT JUDGE