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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,

Plaintiff,

v.

BAYER CORPORATION,

Defendant.

Civ. Action No. 07-00001

BRIEF IN SUPPORT OF MOTION
FOR ORDER TO SHOW CAUSE
WHY DEFENDANT SHOULD
NOT BE HELD IN CONTEMPT

RETURN DATE: OCTOBER 6,
2014

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INTRODUCTION

Today, the United States is compelled — again — to take action against Bayer Corporation (“Bayer”) due to its unsubstantiated claims for one of its products. In 2007, this Court entered a negotiated permanent injunction (“2007 Order”) against Bayer to resolve the United States’ complaint alleging that Bayer marketed its WeightSmart line of One-A-Day vitamins using unsubstantiated claims. The 2007 Order requires Bayer to have competent and reliable scientific evidence to substantiate any representation it makes about the benefits, performance, or efficacy of any dietary supplement it markets or sells. Docket No. 2 § III, at 4–5.

Despite the 2007 Order, Bayer now markets a product, Phillips’ Colon Health, by telling consumers that its “proprietary blend” of three specific strains of bacteria is effective for constipation, diarrhea, and gas and bloating — claims for which Bayer fails to possess *any* competent and reliable scientific evidence. The United States estimates consumers have spent hundreds of millions of dollars for this product. Because of Bayer’s widespread, unsubstantiated efficacy claims in violation of this Court’s 2007 Order, consumers should be compensated for their loss. Accordingly, the United States brings this motion for an order to show cause why Bayer should not be held in contempt for violation of this Court’s 2007 Order.

BACKGROUND

I. Procedural History

On January 3, 2007, the United States filed a complaint against Bayer alleging, among other things, that Bayer made advertising claims that its One-A-Day WeightSmart vitamin could help users control their weight and that Bayer did not possess competent and reliable scientific evidence to substantiate its claims. Docket No. 1. The complaint further alleged that these unsubstantiated claims violated a 1991 Federal Trade Commission (“FTC”) administrative order against Miles Inc., to which Bayer is a successor, requiring Miles to substantiate benefit claims for One-A-Day brand vitamins. *Id.*

To resolve the complaint, Bayer agreed to pay a \$3,200,000 civil penalty and to have this Court permanently enjoin Bayer from making any representation, express or implied, about the benefits, performance, or efficacy of any dietary supplement it markets or sells unless Bayer “possesses and relies upon competent and reliable scientific evidence that substantiates the representation” at the time it makes the representation. Docket No. 2 §§ I, III, at 3–5. The 2007 Order expressly defines “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. This court entered the consent decree as its final order in the matter on January 3, 2007. *Id.* at 10.

The FTC began a non-public investigation of Bayer’s advertising for Phillips’ Colon Health in 2011, pursuant to section VII.B of the 2007 Order. In that investigation, the FTC focused on Bayer’s constipation, diarrhea, and gas and bloating claims; Bayer’s purported substantiation for these claims; and product sales. In 2011 and 2012, in response to the FTC’s investigation, Bayer produced to the FTC approximately 100 papers and several cover letters as purported evidence for advertising claims relating to constipation, diarrhea, and gas and bloating. Bayer also provided revenue information through 2012.

II. The Product and Claims at Issue

A. The Product: Phillips’ Colon Health

In 2008, Bayer began nationally advertising a new product, Phillips’ Colon Health. *See* Tab A, Declaration of Crystal Ostrum ¶ 9. The product typically is sold in capsule form, with each capsule purportedly containing 1.5 billion cells of a special, three-bacteria-strain formula. *See* Tab A, Ex.1, at 1–2. A bottle of 30 capsules retails for approximately \$18, Tab A, Ex. 1, at 3, Ex. 2, at 3, and the product is shelved “nationwide in drug, grocery and mass retailers with other gastrointestinal products.” Tab A, Ex. 9, at FTC_PCH0014059.

Bayer asserts that Phillips’ Colon Health is a “probiotic supplement”

containing a “proprietary blend” of three specific strains of bacteria: *Lactobacillus gasseri* KS-13; *Bifidobacterium bifidum* G9-1; and *Bifidobacterium longum* MM-2. Tab A, Ex. 1, at 1. In bacteria taxonomy, *Lactobacillus* and *Bifidobacterium* are genera; *gasseri*, *bifidum*, and *longum* are species within a particular genus; and the alpha-numeric characters are strains within a species. *See* Tab A, Ex. 33, at 3. Applying this taxonomy to cars, one could have a Volkswagen (genus) Golf (species) 1.4D (strain), which differs from a Volkswagen (genus) Golf (species) 2.0i turbo (strain). *Id.*

B. Bayer’s Prominent Claims about Constipation, Diarrhea, and Gas and Bloating

In an expensive, multi-media, nationwide advertising campaign spanning 2008 to the present, Bayer expressly and impliedly makes benefits, performance, or efficacy claims for Phillips’ Colon Health relating to constipation, diarrhea, and gas and bloating.¹ For example, on the packaging for Phillips’ Colon Health,

¹ Bayer has spent more than \$100 million to air television commercials nationwide that prominently tout Phillips’ Colon Health as a defender against, or as a prevention, cure, or treatment for, constipation, diarrhea, and gas and bloating. *See, e.g.*, Tab A, Exs. 16, 19, 26 (including the first and last pages of dissemination reports for commercials [REDACTED], [REDACTED], and PHILPM-0110); *see also* additional television commercials discussed further below (dissemination information included as part of exhibits). For those dissemination reports where only the first and last pages appear in the interest in minimizing lengthy attachments, the complete report is on file with the government and is available for review at the Court’s request. In addition, a CD containing videos of the television

Bayer expressly claims that the product is effective against occasional constipation, diarrhea, and gas and bloating. Tab A, Ex. 1, at 1–2. The front of a 30-count package of Phillips’ Colon Health prominently states that the product “helps defend against” these symptoms, as follows:

3 strains of good bacteria to promote
OVERALL DIGESTIVE HEALTH*

Helps Defend Against Occasional:*

- *CONSTIPATION*
- *DIARRHEA*
- *GAS AND BLOATING*

Id. at 1.² At the bottom of a side panel, not proximate to the related claim and printed in small type, is text with an asterisk: “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.” *Id.* at 2.³ Similarly, prominent

commercials referenced in this brief will be provided to the Court and to the defendant. *See* Tab A ¶ 33 & Ex. 27.

² Bayer has continued to use a nearly identical package for Phillips’ Colon Health. *See* Tab A ¶ 8 & Ex. 2 (package purchased in September 2014).

³ Presumably, Bayer added this language in an attempt to be compliant with the Dietary Supplement Health and Education Act of 1994 (“DSHEA”), which requires this statement, if used, to be “prominently displayed and in boldface type.” Pub. L. No. 103-147, § 6, 108 Stat. 4325, 4329 (1994) (codified at 21 U.S.C. § 343(r)(6)). However, Bayer’s compliance with DSHEA is not at issue in this case — Bayer’s compliance with this Court’s 2007 Order is. Bayer made a promise to the Court that it would substantiate dietary supplement claims with

wording on the back of that same packaging makes the following express claims:

*This once-daily capsule contains
probiotics to help with occasional**

- **CONSTIPATION**
- **DIARRHEA**
- **GAS AND BLOATING**

Id. Bayer makes similar, prominent express claims regarding occasional constipation, diarrhea, and gas and bloating efficacy in its national television and print advertising. *See, e.g.*, Tab A, Exs. 11, 12, 16, 22, 26.

In addition to those express claims, Bayer routinely makes claims implying that Phillips' Colon Health prevents, cures, or treats constipation, diarrhea, and gas and bloating. For example, one of Bayer's television commercials for Phillips' Colon Health features a spokesperson (the "Colon Lady") emphasizing "diarrhea, constipation, gas, bloating," and then a consumer praising "what a difference Phillips' Colon Health has made." Tab A, Ex. 10. As discussed further below, other television commercials for Phillips' Colon Health make similar implied claims. Likewise, Bayer's print advertisements make claims implying that Phillips' Colon Health prevents, treats, or cures constipation, diarrhea, and gas and bloating. *See, e.g.*, Tab A, Ex. 8 (depicting a large SOS-distress signal with the

competent and reliable scientific evidence, and it has failed to do so for Phillips' Colon Health.

repeated words “constipation,” “diarrhea,” “gas,” and “bloating,” and stating “[m]aybe your colon is trying to tell you something,” which implies Phillips’ Colon Health can treat or cure active symptoms); Tab A, Ex. 6, at FTC_PCH0009743 (asserting that a person should take Phillips’ Colon Health “when your system is under distress from [o]ccasional diarrhea or constipation,” which also implies Phillips’ Colon Health can treat or cure active symptoms).

ARGUMENT

III. Legal Standard

The standard for civil contempt is well established under Supreme Court and Third Circuit authority. 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).

The party seeking civil contempt must prove it by “clear and convincing evidence.” *FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575, 582 (3d Cir. 2010); *Roe v. Operation Rescue*, 54 F.3d 133, 137 (3d Cir. 1995). Clear and convincing evidence means proof that is 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) (describing clear and convincing evidence as occurring when “the truth of [the] factual contentions are ‘highly probable’”).

In order for a party to be held in contempt, the moving party must show ““(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*, 624 F.3d at 582 (quoting *Marshak v. Treadwell*, 595 F.3d 478, 485 (3d Cir. 2009)). While courts should hesitate to find a party in contempt when ““there is ground to doubt the wrongfulness of the conduct,”” willfulness is not an element of contempt. *Id.* (quoting *Robin Woods Inc. v. Woods*, 28 F.3d 396, 399 (3d Cir. 1994)).

IV. Bayer Is in Contempt of the 2007 Order

The first two requirements for contempt are easily met: there is no question that the order entered by this Court on January 3, 2007, is a valid court order, nor is there any doubt that Bayer has knowledge of the order, inasmuch as it consented to the order. *See* Docket No. 2.

The clear and convincing evidence demonstrates that the third requirement for contempt is met as well. Bayer is in violation of the 2007 Order, and has been since the inception of its advertising campaign for Phillips’ Colon Health in 2008. The 2007 Order prohibits Bayer from making any representation, express or implied, about the benefits, performance, or efficacy of any dietary supplement it

markets or sells unless Bayer possesses competent and reliable scientific evidence that substantiates the representation at the time it makes the representation. Docket No. 2 §§ I, III, at 3–5. As discussed further below, the representations that Bayer makes regarding the benefits, performance, or efficacy of Phillips’ Colon Health for constipation, diarrhea, and gas and bloating are covered by the 2007 Order, but Bayer does not possess the competent and reliable scientific evidence required to substantiate those representations.

A. Bayer’s Phillips’ Colon Health Claims Are Subject to the 2007 Order

The 2007 Order applies to “any representation,” express or implied, “[a]bout the benefits, performance, efficacy, safety or side effects”⁴ of a dietary supplement. Docket No. 2 §§ III, III.B, at 4–5. Bayer designates Phillips’ Colon Health as a “probiotic supplement,” Tab A, Ex. 1, and thus, its claims are within the purview of the 2007 Order.

1. Express Claims

First, the evidence is clear that from 2008 to the present, Bayer has widely disseminated prominent express claims concerning Phillips’ Colon Health that fall within the scope of the 2007 Order. As noted above, Bayer expressly claims on

⁴ In this matter, the government is not challenging the safety of Phillips’ Colon Health or any of its potential side effects.

packaging and in some television and print advertisements that Phillips' Colon Health, a "probiotic supplement," "helps defend against" occasional constipation, diarrhea, and gas and bloating.⁵ Asserting that Phillips' Colon Health helps defend against such specific symptoms is, at a minimum, a representation about the product's benefits, performance, or efficacy, which brings the claims within the scope of the 2007 Order. *See* Docket No. 2 § III.B, at 5.

2. *Implied Claims*

Second, Bayer's television and print advertisements also make clear that Bayer impliedly claims that Phillips' Colon Health prevents, cures, or treats constipation, diarrhea, and gas and bloating. 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 Cir. 2009); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957–58 (N.D. Ill. 2006). "When assessing the meaning and representations conveyed by an advertisement, the court must look to the

⁵ As noted previously, Bayer also expressly claims that Phillips' Colon Health "help[s] with" occasional constipation, diarrhea, and gas and bloating (in addition to its express claims that the product "helps defend against" such specific symptoms). A common definition of "help" is "[t]o remedy, obviate, prevent, cause to be otherwise." Oxford University Press, *OED Online* (June 2014), <http://www.oed.com/view/Entry/85740> (definition 11.a.). This definition is synonymous with preventing, curing, and treating. Accordingly, Bayer also makes express claims that Phillips' Colon Health can prevent, cure, or treat occasional constipation, diarrhea, and gas and bloating.

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) (when considering a preliminary injunction concerning deceptive advertising, noting “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. *Kraft, Inc. v. FTC*, 970 F.2d 311, 320 (7th Cir. 1992); *cf. FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 386 (1965) (sustaining an FTC administrative conclusion that a certain claim was made because it was “a matter of fact resting on an inference that could reasonably be drawn from the commercials themselves”).

In Bayer’s \$100-million television campaign, the clear implication of many commercials is that Phillips’ Colon Health does more than just “help defend against” or “help with” occasional constipation, diarrhea, and gas and bloating: Bayer implies that Phillips’ Colon Health can prevent, cure, or treat these specific symptoms, regardless of frequency.

- One of Bayer’s Colon Lady television commercials lauds “what a difference Phillips’ Colon Health has made” in relation to “diarrhea, constipation, gas, [and] bloating.” Tab A, Ex. 10.

- Another commercial announces that the “three good probiotics in Phillips’ Colon Health defended against the bad gas, diarrhea, and constipation,” without limitation as to those symptoms’ frequency. Tab A, Ex. 14.
- A separate commercial reveals how a consumer “felt lost” concerning “bad gas, diarrhea, and constipation” until she used Phillips’ Colon Health. Tab A, Ex. 15.
- In a similar commercial, Bayer emphasizes constipation, gas, bloating, and diarrhea, and how “when your colon’s out of whack, it can make you extremely uncomfortable.” Tab A, Ex. 3. Bayer then proclaims that with Phillips’ Colon Health, “you can avoid those very unpleasant symptoms.” *Id.*
- Bayer’s prevent, cure, or treat theme continues in two other commercials that again underscore those same specific symptoms, followed by the inquiry, “is your colon sending you a message?” Tab A, Exs. 4, 7. Bayer then repeats its claim that with Phillips’ Colon Health, “you can avoid those very unpleasant symptoms.” Tab A, Exs. 4, 7.

All of these illustrative advertisements imply that Phillips’ Colon Health prevents, cures, and treats constipation, diarrhea, and gas and bloating (without regard to

whether such conditions are occasional).

Many of Bayer's print advertisements for Phillips' Colon Health continue the central theme that the product can prevent, cure, or treat constipation, diarrhea, and gas and bloating.

- One advertisement depicts a large "SOS" (the international distress signal) formed from the repeated words "constipation," "diarrhea," "gas," and "bloating," and beneath that, a picture of the Phillips' Colon Health package paired with the message: "[m]aybe your colon is trying to tell you something." Tab A, Ex. 8. By linking the widely recognized symbol of distress with its product, Bayer clearly implies that Phillips' Colon Health is appropriate to treat or cure active constipation, diarrhea, and gas and bloating.
- Another print advertisement claims that Phillips' Colon Health "can help you feel better every day" and again, that taking Phillips' Colon Health every day "can be especially helpful when your system is under distress" from "occasional diarrhea or constipation," "stress," "poor diet," or "travel." Tab A, Ex. 6, at FTC_PCH0009742–43.
- That same advertisement even goes on to say that "*Good* Bacteria protect you from disease," and then makes sure to mention that Phillips' Colon Health contains "three *beneficial* strains of bacteria,"

Id. (emphasis added) — while several other Bayer advertisements further connect the dots that Phillips’ Colon Health can protect a consumer from far more than “occasional” symptoms by trumpeting that Phillips’ Colon Health contains “*good* bacteria,” *see, e.g.*, Tab A, Exs. 5, 20, 23 (emphasis added).

- Bayer also used a press release to imply Phillips’ Colon Health was appropriate “to address digestive symptoms like constipation, diarrhea, gas and bloating,” and even “traveler’s diarrhea.” *See* Tab A, Ex. 9, at FTC_PCH0014057–58.

Still more, although Bayer designates Phillips’ Colon Health as a probiotic supplement, Bayer repeatedly advertises Phillips’ Colon Health along with Phillips’ Milk of Magnesia, a laxative, and Phillips’ Stool Softener, both of which are familiar over-the-counter *drugs*. *See, e.g.*, Tab A, Exs. 5, 6, 13, 16, 19, 22–26. Bayer makes sure to point out to consumers that Phillips’ Colon Health is “on the shelf near your other trusted Phillips’ products,” Tab A, Ex. 5, and is available in stores’ laxative aisles, Tab A, Ex. 17. The obvious implication of such advertisements is that a consumer should think of Phillips’ Colon Health as being in the same category as two of Bayer’s gastrointestinal over-the-counter *drugs*, which, as drugs, *are* indicated to prevent, cure, or treat disease. Bayer advertised Phillips’ Colon Health in this manner even though it was well aware that “[t]he

majority of Americans do not know how probiotics work or think that probiotics work the same as laxatives or antacids.” Tab A, Ex. 18, at 2.

Thus, the clear, implied messages from Bayer’s expensive advertising campaign — communicated to consumers nationwide via television and print — are that people who actively *have* symptoms of constipation, diarrhea, and gas and bloating should use Phillips’ Colon Health to make these symptoms go away and to prevent those symptoms from occurring again, even when those symptoms are more than “occasional.” Such claims are, at a minimum, representations about Phillips’ Colon Health’s benefits, performance, and efficacy — and as a result, are claims within the scope of the 2007 Order. *See* Docket No. 2 § III.B, at 5.

B. Requirements for Competent and Reliable Scientific Evidence for Bayer’s Phillips’ Colon Health Claims

The 2007 Order prevents Bayer from making any representation about the benefits, performance, or efficacy of a dietary supplement unless, “at the time the representation is made,” Bayer “possesses and relies upon competent and reliable scientific evidence that substantiates the representation.” *Id.* § III, at 4–5. The 2007 Order further 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 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.

As discussed, the relevant express and implied advertising claims refer to constipation, diarrhea, and gas and bloating. Because those specific discomforts are digestive symptoms, gastroenterology is the directly relevant area of expertise to assess whether Bayer possesses competent and reliable scientific evidence to substantiate its claims. *See* Declaration of Loren Laine, M.D., Tab B, at 4–5. Therefore, Dr. Laine, a board-certified gastroenterologist, Professor at Yale University School of Medicine, and immediate past Chair of the American Gastroenterological Association, Tab B, at 2–3 & App. 1, is a professional with expertise in the relevant area as required by the 2007 Order.

Dr. Laine explains that competent and reliable scientific evidence for Bayer’s Phillips’ Colon Health claims requires 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” (here, constipation, diarrhea, or gas and bloating). Tab B, at 5. Non-clinical studies, such as those done in animals, are not sufficient. *See id.* The requirement for this type of clinical study design is “well-established and uniformly accepted by gastroenterologists and researchers,” *id.*, and thus is in accord with the 2007 Order’s mandate that competent and reliable scientific

evidence must “us[e] procedures generally accepted in the profession to yield accurate and reliable results,” Docket No. 2, at 2. Each requirement is summarized below.

1. Randomization, Blinding, and Placebo Control

Placebo control — comparing the active product to a placebo during a clinical trial — is mandatory for patient-reported symptoms like constipation, diarrhea, and gas and bloating to separate out what merely is a “placebo effect” from a product’s apparent beneficial effect. Tab B, at 8. Randomization — the process by which clinical trial participants are randomly assigned to take either the product or a placebo — also is important to ensure that differences in the outcomes studied can be attributed to the product being studied. *Id.* at 6–7. In addition, double blinding — where both the investigators and participants in a clinical trial do not know which patients are taking the product and which are taking the placebo — is mandatory for studies assessing subjective symptoms like constipation, diarrhea, and gas and bloating to prevent bias. *Id.* at 7. Otherwise, a patient’s knowledge of whether he is taking the active product or an inactive placebo can “dramatically influence” how that person rates his symptoms, and an investigator’s knowledge of the same can not only affect her rating and recording of study outcomes, but also can result in her signaling to the patient whether he’s taking the product or placebo. *Id.* at 7–8.

2. *Specific Product To Be Studied*

Moreover, “[a] basic tenet of clinical research is that the product for which a claim of efficacy is being assessed is the one used in the clinical trial.” *Id.* at 8. It is also common sense. That is, competent and reliable scientific evidence to substantiate Bayer’s Phillips’ Colon Health claims must be based on clinical trials of Phillips’ Colon Health or a product comprised of *the same combination of the same strains* of bacteria. *See id.* at 8–10, 17. Studies done using products containing a different combination of bacterial strains than Phillips’ Colon Health do not qualify as substantiation for Bayer’s claims, because different combinations of ingredients can have different effects. *See* Tab B, at 8–10, 17. Furthermore, one cannot “extrapolate” (or generalize) the health effects of one bacterial strain to another strain of the same species of bacteria in the absence of a separate clinical study assessing whether that other strain has the same effect. *Id.* at 9–10.

These principles are not only the expert conclusion of Dr. Laine, but also the position of many scientific organizations. For example, in 2001, a scientific panel of the Food and Agriculture Organization of the United Nations and the World Health Organization concluded: “[R]andomized double blind, placebo controlled human trials should be undertaken to establish the efficacy of [a] probiotic⁶

⁶ As noted previously, Bayer advertises Phillips’ Colon Health as a

product. . . . [D]ata obtained with one specific probiotic food cannot be extrapolated to other foods containing that particular probiotic strain or *to other probiotic microorganisms.*” Food and Agric. Org. of the United Nations & World Health Org., *Report of a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Acid Bacteria* 15–16 (2001) (emphasis added), Tab A, Ex. 28. Other expert organizations have reached the same conclusion. *See, e.g.,* U.S. Pharmacopeial Convention, *Appendix XV: Microbial Food Cultures Including Probiotics*, in *Food Chemicals Codex 8, First Supplement* 1710 (2012) (“Because of genetic, biochemical, and physiological differences among strains of the same species, health benefits of probiotics are considered to be specific to the strain (and intake levels) tested. Any health benefits believed to be associated with one strain of a probiotic (as a result of research trials) cannot be used to substantiate benefits of other strains of the same species or genus without separate trials.”), *available at* http://www.usp.org/sites/default/files/usp_pdf/EN/fcc/appendix_xv-_microbial_food_cultures.pdf, Tab A, Ex. 31; World Gastroenterology Organisation, *Practice Guideline: Probiotics and prebiotics* 4 (2008) (“Probiotic research suggests a range of potential health benefits. However, the effects described can

“probiotic supplement.”

only be attributed to the strain or strains tested, and not to the species”),
available at http://www.worldgastroenterology.org/assets/downloads/en/pdf/guidelines/19_probiotics_prebiotics.pdf, Tab A, Ex. 30;⁷ Am. Academy of Microbiology, *Probiotic Microbes: The Scientific Basis* 19 (2006) (“Each claim made for a given effect ascribed to a probiotic needs to be substantiated for each probiotic strain. Effects observed for one strain of a species should not be extrapolated to another strain of this species.”), *available at* <http://academy.asm.org/index.php/clinical-medical-public-health-microbiology/453-probiotic-microbes-the-scientific-basis>, Tab A, Ex. 29.

Even the International Probiotics Association (“IPA”), a trade group of which Bayer is a member, Tab A, Ex. 32, warns that “[i]t is important to note that the effects [of probiotics] are strain specific and cannot be regarded as general for the various probiotics,” Tab A, Ex. 33, at 1. IPA repeats this warning when it explains that “[p]robiotic bacteria are very strain dependent, not species dependent,” and as a result, “claims on health effects of a certain probiotic are only

⁷ Bayer presumably is aware of the content of this report, given that Bayer cited to it several times in support of a 2011 press release concerning Phillips’ Colon Health. *See Ruining the Mood? One in Four Americans Report Avoiding Intimacy Due to Digestive Disturbances*, PR Newswire (Nov. 1, 2011), <http://www.prnewswire.com/news-releases/ruining-the-mood-one-in-four-americans-report-avoiding-intimacy-due-to-digestive-disturbances-132993518.html>, Tab A, Ex. 18, at 3–4.

valid for that specific strain, not species.” *Id.* at 3.⁸ Indeed, Bayer has not provided, nor has the government found, any published authority asserting that efficacy specifically concerning constipation, diarrhea, or gas and bloating can be presumed for an untested strain or combination of strains based on results from a different strain(s) in the same genus or species.

3. *Study Population — Exclusion and Inclusion Criteria*

Yet “[a]nother basic tenet of clinical research” is that the people enrolled in a clinical trial must be representative of the population that will use the product for the effect(s) the trial is assessing. Tab B, at 10. In evaluating the design of any possibly relevant study for Bayer’s advertising claims about constipation, diarrhea, and gas and bloating, Dr. Laine took as true Bayer’s proposition, contained in a

⁸ Indeed, Bayer frequently touts its three bacterial strains in advertisements, distinguishing Phillips’ Colon Health from other products. *See, e.g.*, Tab A, Ex. 17 (“The only leading probiotic with 3 clinically tested strains.”); Ex. 6, at FTC_PCH0009743 (“The combination of these three strains gives Phillips’ Colon Health more types of healthy bacteria than probiotic products that contain only one strain.”); Ex. 23 (“the only leading brand to contain three strains of good bacteria”); Ex. 20 (“contains a proprietary blend of 3 clinically tested strains of good bacteria – more strains than any other leading probiotic supplement,” and listing the specific alphanumeric designations of the product’s three strains); Ex. 21 (“only 1 probiotic has 3 clinically tested strains” and that three strains have “many benefits”); Exs. 16, 19, 25 (“with three strains of good bacteria”). However, as shown below, despite all of these strain-focused promises, Bayer has failed to conduct, rely on, or provide any clinical study that includes an analysis of the three strains in Phillips’ Colon Health for efficacy on constipation, diarrhea, or gas and bloating.

letter to the FTC dated August 3, 2012, that Phillips' Colon Health's

advertisements are [REDACTED]

[REDACTED]. *Id.* at 11. As a result of Bayer's statement that Phillips' Colon Health's

advertisements are [REDACTED]

[REDACTED], the appropriate study population to substantiate Bayer's claims first must exclude prospective participants who have *diseases or conditions* that might cause constipation, diarrhea, or gas and bloating, such as irritable bowel syndrome. *Id.*

After excluding persons with such diseases or conditions, participant enrollment in a clinical trial depends on the effect (i.e., advertising claim) being studied. For clinical trials specifically assessing (1) Bayer's express claims that Phillips' Colon Health *helps defend against* occasional constipation, occasional diarrhea, or occasional gas and bloating, or (2) Bayer's implicit claims that Phillips' Colon Health *prevents* constipation, diarrhea, or gas and bloating, *none* of the study participants would have the symptoms being assessed at the time of enrollment. *Id.* at 1, 12. These participants would be involved in a study assessing what Dr. Laine terms, for population purposes, "prevention claims." *Id.* at 1. Therefore, for "prevention claims," people without constipation, diarrhea, and/or gas and bloating would be studied to determine whether Phillips' Colon Health is effective, relative to placebo, in helping to defend against or in preventing those symptoms.

Conversely, for clinical trials specifically assessing Bayer's implicit claims that Phillips' Colon Health *cures* or *treats* constipation, diarrhea, or gas and bloating (what Dr. Laine terms "treatment claims"), *all* of the study participants would have the symptoms being assessed at the time of enrollment — though, as noted above, their symptoms would not be caused by diseases or conditions, such as irritable bowel syndrome. *Id.* at 1, 11–12. Accordingly, for "treatment claims," people with symptoms of constipation, diarrhea, and/or gas and bloating would be studied to determine whether Phillips' Colon Health is effective, relative to placebo, in curing or treating those symptoms.

4. Study Outcomes and Statistical Methods

Finally, it is important that a clinical study define the "primary outcome," which is used to measure the efficacy of a product, before the study begins, because that outcome is used to calculate how many people need to be enrolled in the study. Tab B, at 12–13. For subjective symptoms like constipation, diarrhea, and gas and bloating, outcomes are reported by the patients themselves, rather than by laboratory test, x-ray, or ultrasound. *Id.* at 12. To account for variety in subjective patient responses, it is important to use a validated questionnaire and scoring system to obtain accurate and reliable results. *Id.* Moreover, following the conclusion of a clinical trial, a product is not deemed to be efficacious unless appropriate statistical methods determine there is a statistically significant

difference between the product's results and the placebo's results. *Id.* at 14–17.

In other words, for a study to serve as competent and reliable scientific evidence to substantiate, for example, a claim that a product helps defend against a specific symptom such as occasional constipation, one must test that product in a population that does not have constipation at the time of enrollment (or a disease or condition that could cause constipation); compare the results against the use of a placebo in a comparable population; and then determine whether there is a statistically significant difference in defending against that specific symptom in the group that used the product as compared to the group that used a placebo.

Moreover, as will be discussed in the next section, none of Bayer's purported substantiation contains all of the required elements to be deemed competent and reliable scientific evidence for its Phillips' Colon Health claims.

C. No Competent and Reliable Scientific Evidence Exists to Substantiate Bayer's Phillips' Colon Health Claims Regarding Constipation, Diarrhea, and Gas and Bloating

Taking into consideration the requirements detailed above, Dr. Laine reviewed nearly 100 non-duplicate scientific papers and several cover letters that Bayer provided to the FTC to substantiate its Phillips' Colon Health claims. Tab B, at 4, 17–18 & App. 2. Dr. Laine further reviewed additional information the FTC provided to him and information that resulted from his independent, overly inclusive searches of scientific literature. *Id.* at 4, 18–19 & Apps. 2–4. Following

his review, Dr. Laine concluded that there is no competent and reliable scientific evidence to support claims that Phillips' Colon Health helps defend against occasional constipation, occasional diarrhea, or occasional gas and bloating, nor is there competent and reliable scientific evidence to support claims that Phillips' Colon Health prevents, cures, or treats constipation, diarrhea, or gas and bloating. *Id.* at 23–24.

1. Bayer's Own Papers Do Not Substantiate Its Claims

First and foremost, *none* of the nearly 100 documents that Bayer provided to the FTC and associated with Bayer's claims about constipation, diarrhea, and gas and bloating are clinical trials of Phillips' Colon Health or a product with the same three bacterial strains as Phillips' Colon Health. *Id.* at 17. For that reason alone, these documents are not competent and reliable scientific evidence to substantiate the claims Bayer makes for Phillips' Colon Health. *Id.* As stated above, to make a specific, gastrointestinal benefit, performance, or efficacy claim about Phillips' Colon Health under the 2007 Order, Bayer needs to have a clinical study of Phillips' Colon Health (or its equivalent) assessing that claim. Bayer has none.

In addition, even if the studies and other information Bayer associated with its claims about constipation, diarrhea, and gas and bloating were about the right combination of bacterial strains, they still would fail due to one or more additional deficiencies: they (a) are not human trials; (b) are not randomized, double-blinded,

or placebo-controlled trials; and/or (c) are studies in the wrong populations, such as (1) those made up of people with diseases or conditions that cause constipation, diarrhea, and gas and bloating (like irritable bowel syndrome); and (2) those made up of people who were not screened during the study's enrollment to make sure they *lacked* the assessed symptoms (for "prevention claims") or *had* the assessed symptoms (for "treatment claims").⁹ Tab B, at 17–18.

2. *No Other Published Papers Substantiate Bayer's Claims*

Beyond the documents provided by Bayer,¹⁰ Dr. Laine conducted an independent (and overly broad) search for other clinical studies and meta-analyses¹¹ that might substantiate Bayer's Phillips' Colon Health claims, but he

⁹ See prior discussion in Section IV.B.3 concerning study population requirements.

¹⁰ The 2007 Order requires Bayer to possess the competent and reliable scientific evidence upon which it is relying "at the time the representation is made." Docket No. 2, § III, at 4–5. Accordingly, anything *not* in Bayer's possession, during any period of its advertising campaign from 2008 to the present, by definition cannot meet the Order's substantiation requirements — nor may it retroactively bolster purported substantiation that was in Bayer's possession that yet failed to meet the requirements for competent and reliable scientific evidence.

¹¹ "Meta-analyses are formal reviews of a topic in which a search of the medical literature is performed, the studies relevant to the topic are identified and the data from the studies are recorded using a systematic approach, and the results are mathematically pooled together to provide a summary estimate of the results from the included studies." Tab B, App. 4, at 1.

was unable to find any that studied Phillips' Colon Health or a product with the same three bacterial strains, and he determined that many had additional fatal shortcomings. *Id.* at 18–20, apps 3–4.¹²

3. *Even Two Unpublished Studies of the Same Product Formula Do Not Substantiate Bayer's Claims*

Dr. Laine did review two potentially relevant, but not yet fully published, studies that used a product containing the same “proprietary blend” of three bacterial strains as Bayer asserts is in Phillips' Colon Health. *Id.* at 20. Both studies have scientific virtues: they are randomized, double-blind, placebo-controlled, human trials. *Id.* at 20, 23. These are the only studies, of which the government is aware, that might even begin an approach to substantiate Bayer's claims. Yet despite their attributes, neither study was done in the correct population to substantiate Bayer's claims. *Id.* at 23.

The first study, by the Canadian College of Naturopathic Medicine, was conducted in the wrong population to substantiate Bayer's Phillips' Colon Health claims because it used study participants who had irritable bowel syndrome, a

¹² Dr. Laine found one clinical study that used the same three bacterial *species* as found in Phillips' Colon Health, but not the same bacterial *strains*, and the study further is inapplicable to Bayer's Phillips' Colon Health claims about constipation, diarrhea, and gas and bloating because it assessed the product's impact on the common cold, rather than on gastrointestinal symptoms. *See* Tab B, at 18–19.

disease or condition that causes symptoms of constipation, diarrhea, and gas and bloating. *Id.* at 20. As noted above, a clinical trial potentially substantiates Bayer's Phillips' Colon Health claims only if its participants do not have such diseases or conditions. The second study, by the University of Florida, also was conducted in the wrong population to substantiate Bayer's Phillips' Colon Health claims because participants were not enrolled based on the presence or absence of symptoms of constipation, diarrhea, and gas and bloating. Tab B, at 21–22. As discussed previously, it is not enough for a study population to be free of diseases or conditions that cause constipation, diarrhea, and gas and bloating — the study population also must lack (for “prevention claims”) or have (for “treatment claims”) the *symptoms* being assessed.

Furthermore, neither study showed that the product had any beneficial effect on symptoms of constipation, diarrhea, and gas and bloating.¹³ *Id.* at 23.

Accordingly, even these studies do not constitute competent and reliable scientific

¹³ While the Canadian College of Naturopathic Medicine's study's primary outcome included assessments of abdominal pain, abdominal distension, and satisfaction with bowel habits, and a secondary outcome rated the severity *overall* of irritable bowel symptoms, none of the study's outcomes *directly* assessed the *symptoms* of constipation, diarrhea, or gas and bloating — and even then, the study showed no evidence of the product's beneficial effect. Tab B, at 20–21. The University of Florida study did not use gastrointestinal symptoms as its primary outcome, and while study participants reported on fifteen gastrointestinal symptoms, stool frequency, and stool consistency, the study failed to show [REDACTED]. *Id.* at 22–23.

evidence for Bayer's Phillips' Colon Health express or implied claims. *Id.* at 23–24.

Quite simply, as Dr. Laine's expert opinion reveals, the evidence clearly and convincingly demonstrates that Bayer does not possess and rely upon competent and reliable scientific evidence for its express claims that Phillips' Colon Health helps defend against occasional constipation, occasional diarrhea, and occasional gas and bloating, or for its implied claims that Phillips' Colon Health prevents, cures, or treats constipation, diarrhea, and gas and bloating.

V. Remedies Sought for Bayer's Contempt

Despite not possessing or relying upon competent and reliable scientific evidence for claims that Phillips' Colon Health defended against occasional constipation, diarrhea, and gas and bloating, or that Phillips' Colon Health prevents, cures, or treats those symptoms as required by the 2007 Order, Bayer continues to widely disseminate these claims to the public in promoting its product. In turn, consumers have spent hundreds of millions of dollars for a product marketed with pervasive, unsubstantiated claims. As a result of Bayer's behavior, consumers have experienced — and continue to experience — a significant, actual loss. This action seeks not only to put an end to Bayer's contempt, but also to

compensate consumers for their loss.¹⁴

Accordingly, the United States asks that this Court, after finding contempt, establish a fine of \$25,000 per day to coerce Bayer's compliance with this Court's 2007 Order and to halt consumers' continuing loss.

In addition, the United States asks this Court to allow expedited discovery and further briefing concerning the full measure of damages appropriate for Bayer's contempt.¹⁵ Following such discovery, the United States expects to ask this Court to award compensatory damages equal to the amount of consumers' loss resulting from Bayer's contempt, and to issue an order that further prohibits Bayer from making unsubstantiated claims for its products.

CONCLUSION

For the foregoing reasons, this Court should order Bayer to show cause why it should not be held in contempt of this Court's January 3, 2007, Order.

¹⁴ What is more, enforcing the Court's order here promotes market fairness. Bayer is making claims that it cannot support. In so doing, it is luring consumers away from available alternatives, thereby reducing the sales of those alternatives.

¹⁵ As part of the FTC's investigation, Bayer provided revenue information through 2012. The actual amount of sales for Phillips' Colon Health to date can be determined through discovery. In this brief, therefore, the United States addresses only Bayer's liability for contempt, and will brief the appropriate remedies in a future briefing, following discovery as this Court may allow.

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