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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE PHILLIPS COLON HEALTH
PROBIOTIC SALES PRACTICES
LITIGATION

Civil Action No.:11-3017(ES)(JAD)

**FIRST CONSOLIDATED AMENDED
CLASS ACTION COMPLAINT AND
DEMAND FOR JURY TRIAL**

Plaintiffs Troy Yuncker and Dino Rikos (“Plaintiffs”), by and through their attorneys, bring this action on behalf of himself, all others similarly situated and the general public against defendant Bayer HealthCare, LLC (“defendant” or “Bayer”). Plaintiffs allege, on information and belief, except for information based on personal knowledge, as follows:

NATURE OF THE ACTION

1. This is a consumer protection class action addressing Bayer’s advertisements regarding its over-the-counter “OVERALL DIGESTIVE HEALTH” products called Phillips’ Colon Health Probiotic + Fiber, and Phillips Colon Health Probiotic Caps (collectively, “Phillips’ Colon Health”).

2. Through its advertising and labeling, Bayer claims that Phillips’ Colon Health provides “OVERALL DIGESTIVE HEALTH” and “helps defend against” “constipation, diarrhea, [and] gas and bloating” because they contain “3 strains of good bacteria.” Bayer claims in its advertising and labeling that “scientific evidence” proves that these digestive and immune

health benefits result from taking Phillips' Colon Health and that Phillips' Colon Health "contains the most common and most studied bacteria for digestive health." According to Bayer, Phillips' Colon Health "replenishes the good bacteria when diet and stress cause constipation and upset your natural balance." Bayer's representations are false, misleading and reasonably likely to deceive the public.

3. In October 2008 and June 2009, Bayer began marketing Phillips' Colon Health Probiotic Caps and Phillips' Colon Health Probiotic + Fiber, respectively. Prominently placed on its label and throughout its other advertisements, Bayer stated and continues to state that Phillips' Colon Health contains "3 strains of good bacteria to promote overall digestive health," and "help[] defendant against occasional: constipation, diarrhea, [and] gas and bloating." It advertised and continues to advertise that with "scientific evidence" supporting the health benefits of its "probiotic" bacteria, Phillips' Colon Health supports your "digestive system" and "immune system."

4. In truth, the ingredient matrix found in Phillips' Colon Health does not provide the advertised digestive health and immune system benefit claims, and Bayer has no basis to make these claims.

5. Bayer conveyed and continues to convey its deceptive claims about Phillips' Colon Health on the Phillips' Colon Health's packages and labels, and through a variety of media, including the Internet, television advertising, in-store sampling, and point-of-sale displays. These representations appear prominently and conspicuously on every Phillips' Colon Health container.

6. Through this extensive advertising campaign, Bayer has conveyed one message: Phillips' Colon Health, with its probiotic bacteria cultures, is scientifically proven to provide all consumers with digestive and immune system health benefits.

7. Bayer's deceptive advertising and marketing campaign is designed to cause and has caused consumers to buy Phillips' Colon Health. Bayer's deception has been very successful. In an April 2009 article, Hammacher Resource Group, Inc., a retailing strategy group, singled out Phillips' Colon Health as a new probiotic supplement product showing high rankings in the digestive health category of products. Phillips' Colon Health is sold nationwide in the digestive health sections of drug, grocery, and mass retailers.

8. Plaintiffs bring this action on behalf of themselves and other similarly situated consumers to halt the dissemination of this false and misleading advertising message, correct the false and misleading perception it has created in the minds of consumers, and obtain redress for those who have purchased Phillips' Colon Health. Plaintiffs allege violations of the New Jersey Consumer Fraud Act, California's Consumers Legal Remedies Act, California's Unfair Competition Law, Illinois' Consumer Fraud Act, breach of implied warranty of merchantability, and unjust enrichment.

JURISDICTION AND VENUE

9. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$5,000,000 and is a class action in which members of the Class are citizens of states different from Bayer. Further, greater than two-thirds of the Class members reside in states other than the state in which Bayer is a citizen.

10. Venue is proper in this Court pursuant to 28 U.S.C. §1391 in that many of the acts and transactions giving rise to this action occurred in this district and because defendant:

(a) is authorized to conduct business in this district and has intentionally availed itself of the laws and markets within this district through the promotion, marketing, distribution and sale of its products in this district;

- (b) does substantial business in this district;
- (c) maintains its global headquarters in this district; and
- (d) is subject to personal jurisdiction in this district.

PARTIES

11. Plaintiff Troy Yuncker is citizen of the State of Illinois. In May 2011, at the Walgreen's store located at 200 West Adams Street, Chicago, Illinois 60606, Plaintiff Yuncker was exposed to and saw Bayer's claims by reading the product label, purchased Phillips' Colon Health Probiotic Caps at the aforementioned Walgreen's for the retail price in the amount of approximately \$15 in reliance on these claims, and suffered injury in fact and lost money as a result of the unfair competition described herein by purchasing Phillips' Colon Health but not receiving what was promised. Mr. Yuncker purchased Phillips' Colon Health Probiotic Caps believing it would provide the advertised digestive health benefits. As a result of his purchase, Plaintiff suffered injury in fact and lost money. Had Plaintiff known the truth about Bayer's misrepresentations and omissions, he would not have purchased the Phillips' Colon Health Probiotic Caps product. Plaintiff Yuncker is not claiming physical harm or seeking the recovery of personal injury damages.

12. Plaintiff Dino Rikos is citizen of the State of Illinois. At various times beginning in 2010, and in California and Illinois, Plaintiff Rikos was exposed to and saw Bayer's claims by reading the product label, purchased Phillips' Colon Health Probiotic Caps for the retail price in the amount of approximately \$15 on separate occasions in Del Mar, California and Naperville, Illinois at drugstore chains, including Walgreens, in reliance on these claims, and suffered injury in fact and lost money as a result of the unfair competition described herein by purchasing Phillips' Colon Health but not receiving what was promised. On each occasion, Mr. Rikos purchased the Phillips' Colon Health Probiotic Caps product believing it would provide the

advertised digestive health benefits. As a result of his purchase, Plaintiff suffered injury in fact and lost money. Had Plaintiff known the truth about Bayer's misrepresentations and omissions, he would not have purchased the Phillips' Colon Health Probiotic Caps product. Plaintiff Rikos is not claiming physical harm or seeking the recovery of personal injury damages.

13. Bayer Consumer Care, is a wholly owned division of defendant Bayer HealthCare, LLC, and maintains its global headquarters in Morristown, New Jersey. Bayer HealthCare, LLC is a subsidiary of Bayer AG. Bayer Consumer Care, which was established as an independent business group in 1994, and is now a division, has businesses in non-prescription medicines and dietary supplements, including Aspirin®, Aleve®, Alka-Seltzer®, and Phillips' Colon Health. From its New Jersey headquarters, Bayer Healthcare, LLC, through its Bayer Consumer Care division, promotes, markets, distributes and sells Phillips' Colon Health to tens of thousands of consumers throughout the United States.

FACTUAL ALLEGATIONS

14. Since the 2008 nationwide launch, Bayer has consistently and uniformly conveyed the message to consumers throughout the United States that Phillips' Colon Health, with its three strains of probiotic bacteria, delivers digestive and immune system benefits backed by scientific evidence of the "most studied bacteria for digestive health." These claims are factually baseless and deceptive.

15. The use of bacteria for "probiotic" purposes is in its scientific infancy. In fact, scientists have yet to settle on a precise definition of "probiotic." The World Health Organization and the Food and Agriculture Organization of the United Nations define "probiotics" as "[l]ive microorganisms, which, when administered in adequate amounts, confer a health benefit on the host." The National Center for Complementary and Alternative Medicine ("NCCAM"), one of the institutes of the National Institutes of Health, notes that the "rapid

growth in marketing and consumer interest and use has outpaced scientific research on the safety and efficacy of probiotics for specific health applications.” The U.S. Food and Drug Administration has not approved any health claims for probiotics.

16. In its advertising Bayer defines probiotics: “Probiotics are live microorganisms that are similar to the good bacteria already inside our bodies. Available to use mainly through dietary supplements and foods, these probiotics can restore intestinal balance by boosting the number of those bacteria that are helpful to us.”

17. Scientists have not yet mapped the tens of thousands of bacteria strains in the human body’s intestinal flora, and do not know whether increasing one type of bacteria provides health benefits. Scientists do not yet know when increasing one type of bacteria becomes harmful. The European Food Safety Authority (“EFSA”), established by the European Union to promote food safety and evaluate food claims, reports that “The numbers/proportions of bacterial groups that would constitute a ‘balanced/healthy’ intestinal flora have not been established. Increasing the number of any groups of bacteria is not in itself considered as beneficial.” EFSA states that:

The gastrointestinal tract is populated with a large number of microorganisms and it normally acts as an effective barrier against generalized systemic infections. It is not possible to provide the exact number of bacterial groups that would constitute a beneficial microbiota.

18. There is almost no scientific support for the notion that healthy people, such as those targeted by Bayer, benefit from bacterial supplements. If these bacteria are probiotic, they must survive the digestive tract in sufficient quantities to achieve the possible benefit. However, there is no consensus on the quantities of probiotics people might need to ingest, or for how long, in order to achieve a probiotic effect, if probiotics have any such effect in healthy people. In

fact, healthy people do not need bacterial supplements because their gut is already in a state of homeostasis.

19. Using the term as a marketing tool, and without regard to whether it actually delivers any probiotic benefits, Bayer stamps “PROBIOTIC” on the label of Phillips’ Colon Health. In fact, Bayer has no legitimate basis to claim that the bacteria it laces Phillips’ Colon Health with has any beneficial effects when people consume it, that it helps or replaces bacteria naturally found in the human body, that it reduces the growth of “harmful” bacteria, promotes healthy digestion or supports the immune system.

BAYER’S CLAIMS ABOUT PHILLIPS’ COLON HEALTH

20. Bayer’s marketing materials state that Phillips’ Colon Health promotes “OVERALL DIGESTIVE HEALTH” and “Defend[s] Against Occasional: CONSTIPATION, DIARRHEA, [AND] GAS AND BLOATING.” According to Bayer, these digestive and immune system benefits are the result of Phillips’ Colon Health’s “proprietary blend” of three of the “most studied” bacteria for digestive health.

21. On the Phillips’ Colon Health packaging and website, Bayer claims that the bacteria cultures in Phillips’ Colon Health are the “most studied bacteria for digestive health” and that there is “scientific evidence that [the bacteria in the product] help relieve gas, diarrhea, constipation and other GI discomforts.” Phillips’ Colon Health “also supports a health immune system.” The Phillips’ Colon Health advertising statements – conspicuously stated on the product label – include:

- 3 strains of good bacteria to promote

OVERALL DIGESTIVE HEALTH

- *Helps Defend Against Occasional:*

CONSTIPATION

DIARRHEA

GAS AND BLOATING

These statements are false and misleading and reasonably likely to deceive the average consumer.

22. Phillips' Colon Health is described in a medical manner as coming in a "capsule" form to be consumed "one capsule daily."

23. The front label on each package of Phillips' Colon Health substantially appears as follows:



24. The side and back panels of the packaging and labeling for Phillips' Colon Health, as well as the labeling on the bottle inside the packaging repeat and reinforce the same misleading digestive and immune system health benefits claim. For example, the back panel of Phillips Colon Health Probiotic Caps states:

This once-daily capsule contains probiotics to help with occasional

- **CONSIPATION**
- **DIARRHEA**
- **GAS AND BLOATING**

WHEN SHOULD YOU TAKE PROBIOTICS?

- **Everyday** to support overall digestive health
- When **traveling**
- Can be taken with laxative products

WHY TAKE PHILLIPS' COLON HEALTH?

- To support a **Healthy** colon, one of the most important parts of your **digestive system**.
- To replenish the good bacteria when **diet and stress** cause constipation and upset your natural balance causing bloating, gas and diarrhea.
- To support a **healthy immune system**.

HOW DOES PHILLIPS' COLON HEALTH WORK?

- Contains the most common and most studied bacteria for digestive health (Lactobacillus and Bifidobacterium), which closely resemble your body's **natural** good bacteria.
- There is scientific evidence that Lactobacillus and Bifidobacterium help relieve gas, diarrhea, constipation and other GI discomforts.

25. Despite evidence, which demonstrates that the statement is false and deceptive, Bayer claims that all persons suffering from “irregularity” should take Phillips’ Colon Health: “Phillips’ Colon Health is right for anyone who suffers from irregularity symptoms and currently treats with an over the counter remedy.”

26. Bayer’s Phillips’ Colon Health television commercials convey the same message conveyed by Bayer in other media. A typical Phillips’ Colon Health television commercial claims:

Woman 1: You're the colon lady.

Woman 2: Diarrhea, constipation, gas, bloating...that's me.

Woman 1: Can I tell you what a difference Phillips' Colon Health has made.

Woman 2: It's the probiotics. The good bacteria that get your colon back in balance
[hands Woman 1 package of Phillips' Colon Health].

Woman 1: I'm good to go.

Announcer: Phillips' Colon Health [Tag states: "Be good to your colon, and it will be
good to you."]

27. Bayer repeats its false and deceptive statements on its publicly available webpage, www.phillipsrelief.com. Bayer also lists this website on the packaging of Phillips' Colon Health. Despite being false and deceptive, Bayer makes the following similar claims on its website:

What is Phillips' Colon Health Probiotic Caps?

Phillips' Colon Health Probiotic Caps is a probiotic supplement that helps replenish the good bacteria in your colon. When taken daily, it helps support a healthy immune system and it supports your overall digestive health and helps defend against occasional constipation, diarrhea, gas and bloating.

What is Phillips' Colon Health Probiotic + Fiber?

Phillips' Colon Health Probiotic + Fiber helps promote the health of your colon in 2 ways. Its advanced digestive health formula contains a unique proprietary blend of 3 strains of good bacteria that help promote the colon's natural balance, plus is a good source of soluble prebiotic fiber, inulin, that give the probiotics a boost.

What is Phillips Colon Health?

Phillips' Colon Health is a probiotic supplement that replenishes the good bacteria when diet and stress cause constipation and upset your natural balance causing bloating, gas and diarrhea.

Why take Phillips' Colon Health?

Phillips' Colon Health supports a healthy colon, one of the most important parts of your digestive system. It replenishes the good bacteria when diet and stress cause constipation and upset your natural balance causing bloating, gas and diarrhea. It also supports a healthy immune system.

How does Phillips' Colon Health work?

Phillips' Colon Health contains the most common and most studied bacteria for digestive health (Lactobacillus and Bifidobacterium), which closely resemble your body's natural good bacteria. There is scientific evidence that Lactobacillus and Bifidobacterium help relieve gas, diarrhea, constipation and other GI discomforts.

When should I take Phillips' Colon Health?

When stressed, traveling or using antibiotics, Phillips' Colon Health can help balance your digestive system.

**SCIENTIFIC EVIDENCE PROVES THAT BAYER'S CLAIMS
ARE FALSE AND DECEPTIVE**

28. On its packaging, labeling, and product website, Bayer deceptively conveys the deceptive marketing message that Phillips' Colon Health's efficacy "Contains the most common and most studied bacteria for digestive health (Lactobacillus and Bifidobacterium)," which is substantiated by "scientific evidence."

29. Phillips' Colon Health digestive health and immune system claims are false and deceptive. Numerous studies have confirmed that the bacteria and inulin fiber in Phillips' Colon Health, in isolation or in combination, do not provide the advertised digestive health and immune system benefits.

30. Widespread consensus exists within the legitimate scientific community about the proper research and testing needed to substantiate a claim made for a given effect ascribed to a probiotic bacteria. As the American Society for Microbiology concluded in a symposium focusing on purported probiotic bacteria used in food:

There is a pronounced need for large, carefully designed (randomized, placebo controlled) clinical trials of probiotics that undertake broad sampling of host

microbiota, have clear end points, and have well informed participants who consent to treatment. Investigations like these are needed to overcome the placebo effect [of probiotic treatments] and other barriers to the thorough investigation of probiotic products.¹

31. In 2002, a joint working group of scientists for the Food and Agriculture Organization of the United Nations and the World Health Organization generated guidelines for the evaluation of probiotics in food, and defined the data necessary to substantiate probiotic health claims. The Joint FAO/WHO Working Group Report stated that data generated by *in vitro* tests are “not fully adequate to predict the functionality of probiotic microorganisms in the human body,” and that “*in vitro* data for particular [bacteria] strains are not sufficient for describing them as probiotics.” The report is clear: “[p]robiotics for human use will require substantiation of efficacy with human trials.” The report also emphasized that the human study must utilize appropriate sample sizes, and “[s]tatistically significant differences [between the placebo and test products] must apply to biologically relevant outcomes.” The report recommended that at least a second, independent double-blinded, randomized, placebo-controlled human trials (“DBPC”) test confirm the test results.²

32. Likewise, the World Gastroenterology Organization Global Guidelines published in October 2011 for Probiotics and Prebiotics recommended that all benefit claims must “be substantiated by consistent results from well-designed, double-blind, placebo-controlled human

¹ R. Walker & M. Buckley, “Probiotic Microbes: The Scientific Basis,” at 19 (colloquium convened before the American Society of Microbiology, Nov. 5-7, 2005).

² M. Araya, *et al.*, “Guidelines for the Evaluation of Probiotics in Food” (Food and Agriculture Organization of the United Nations and World Health Organization, Report of a Joint Working Group, April 30 and May 1, 2002), http://www.who.int/foodsafety/fs_management/en/probiotic_guidelines.pdf.

studies,” and in vitro and animal studies “are not considered sufficient to document such claims.”³

33. The Food and Agriculture Organization of the United Nations has also established “minimum” guidelines for the evaluation of prebiotics, such as the inulin fiber in Phillips’ Colon Health Probiotic + Fiber. As with probiotic products, a sufficiently powered randomized trial is “required,” and “[s]ubstantiation of a claim should be based on studies with the final product type, tested in the target host.”⁴

34. Thus, a properly conducted clinical or scientific trial – *e.g.*, one capable of providing substantiation for Bayer’s claims – is the well-designed, randomized controlled trial (“RCT”).⁵ In RCTs, human study subjects similar to each other are randomly assigned to receive either the test substance or a placebo. Double-blind RCTs, where neither the patient nor the administering researcher knows which intervention is placebo, is preferred and considered more accurate than a single-blind RCT.

35. According to a leading group of international scientists and researchers, there also should be a proven correlation in human trials when claiming probiotic health benefits in food products:

The principle outcome of efficacy studies on probiotics should be proven benefits in human trials, such as statistically and biologically significant improvement in condition, symptoms, signs, well-being or quality of life; reduced risk of disease

³ See World Gastroenterology Organisation Global Guidelines: Probiotics and Prebiotics (October 2011), <http://www.worldgastroenterology.org/probiotics-prebiotics.html>.

⁴ See M. Pinero, *et al.* “FAO Technical Meeting on Prebiotics,” *Clin Gastroenterol*, Vol. 42, Supp. 3, Part 2 (Sept. 2008) (No. 11-2793 Docket Entry 97-12) .

⁵ *Id.*

or longer time to next occurrence; or faster recovery from illness. Each should have a proven correlation with the probiotic tested.⁶

36. The three strains of bacteria infused in Phillips' Colon Health are *Lactobacillus gasseri*, *Bifidobacterium bifidum*, and *Bifidobacterium longum*. On its packaging and website, Bayer describes each of these purportedly probiotic bacteria strains:

- **Lactobacillus gasseri** – To support nutrient absorption and lactose digestion
- **Bifidobacterium bifidum** – To help guard against occasional intestinal disturbances
- **Bifidobacterium longum** – To support digestive and immune health. These bacteria help naturally defend against occasional digestive upsets

37. In July 2009, EFSA reviewed the scientific proof in relation to *Lactobacillus gasseri* and *Lactobacillus coryniformis* and decreasing potentially pathogenic intestinal microorganisms and improvement of intestinal transit. EFSA concluded that the human intervention studies did not show an effect on decreasing potentially pathogenic intestinal microorganisms. EFSA also concluded that the data available do not demonstrate a cause and effect relationship between consuming the bacteria and improvement of intestinal transit within the normal range.⁷

38. EFSA also analyzed and reviewed the studies regarding the two other strains in Phillips' Colon Health: *Bifidobacterium bifidum*, and *Bifidobacterium longum*. In a December 2009 scientific opinion, EFSA found that a cause and effect relationship has not been established

⁶ *Id.*

⁷ See EFSA Panel on Dietetic Production, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to “Lactobacillus gasseri CECT5714 and Lactobacillus coryniformis CECT5711” and decreasing potentially pathogenic intestinal microorganisms and improvement of intestinal transit (ID 937) pursuant to Article 13 of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal 2009; 7(9) 1238. Available at www.efsa.europa.eu (last visited October 1, 2010).

between the consumption of the combination of *Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium infantis*, *Bifidobacterium longum*, and decreasing potentially pathogenic intestinal microorganisms in infants and children aged between 0 and 36 months.⁸

39. EFSA also reviewed scientific studies for a claim that consuming a bacterial powder containing *Bifidobacterium longum* and two other strains “improve[s] the general immunity by maintaining the microbiological balance.” EFSA found that the one unpublished *in vitro* study it was provided did not establish the claimed immune system improvement. According to EFSA, “*In vitro* studies are not sufficient to predict *in vivo* efficacy in humans.”⁹

40. EFSA also reviewed studies for a claim that consuming a bacterial powder containing *Bifidobacterium longum* and two other strains brings back the normal functioning of your digestive system during microflora disturbances. EFSA found that the two clinical studies provided did not constitute substantiation. In one study, those consuming the product containing *Bifidobacterium longum* did not see an improvement in the incidence of diarrhea and only saw a modest reduction in the frequency of daily stools. Likewise, the second study did not provide proof because isolating strain-specific benefits was not possible. EFSA again rejected the use of

⁸ See EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to combination of bifidobacteria (*Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium infantis*, *Bifidobacterium longum*) and decreasing pathogenic intestinal microorganisms pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2009; 7(12):1420. Available at www.efsa.europa.eu (last visited October 1, 2010).

⁹ See Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from the Institute of Biotechnology, Sera and Vaccines BIOMEN S.A. on the scientific substantiation of a health claim related to LACTORAL and improvement of the general immunity. EFSA Journal 2008: 860, 1-8. Available at www.efsa.europa.eu (last visited October 1, 2010).

in vitro studies to predict *in vivo* efficacy in humans.¹⁰ Based upon this same evidence, EFSA also rejected a claim that the same powder product containing *Bifidobacterium longum* helps protect the digestive system from infectious bacteria.¹¹

41. In 2012, EFSA also published a scientific opinion based on a review of purported proof for claims that consumption of the combination of the same three bacteria strains in Phillips Colon Health provides defenses against unhealthy bacteria in the general adult population. EFSA concluded that no cause and effect relationship has been demonstrated for the consumption of the three bacteria in Phillips Colon Health and the maintenance of defenses against pathogenic bacteria.¹²

42. Similarly, inulin fiber does not provide the digestive health benefits marketed by Bayer for its Phillips' Colon Health. For example, in a study published in August 2010, analyzing the impact of inulin fiber and/or a probiotic combination on gastrointestinal and immune system endpoints, the authors concluded that "for numerous parameters, inulin and

¹⁰ See Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from the Institute of Biotechnology, Sera and Vaccines BIOMEN S.A. on the scientific substantiation of a health claim related to LACTORAL and normal functioning of the alimentary tract. EFSA Journal 2008: 861, 1-9. Available at www.efsa.europa.eu (last visited October 1, 2010).

¹¹ See Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from the Institute of Biotechnology, Sera and Vaccines BIOMEN S.A. on the scientific substantiation of a health claim related to LACTORAL and building of the natural intestinal barrier. EFSA Journal 2008: 859, 1-9. Available at www.efsa.europa.eu (last visited October 1, 2010).

¹² See Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from the European Commission on the scientific substantiation of health claims related to a combination of *Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* M 20/5 and *Bifidobacterium longum* SP 07/03 and maintenance of upper respiratory tract defence against pathogens. EFSA Journal 2012; 10(6): 2718. Available at www.efsa.europa.eu (last visited March 24, 2014).

probiotics led to no synergistic but antagonistic interactions.”¹³ Likewise, the authors of a randomized, double-blind study published in 2011 examining the effects of daily inulin consumption by healthy males concluded that inulin fiber does not provide digestive health benefits as measured by any of the tested endpoints (which related to constipation, diarrhea and bloating): stool weight, intestinal transit, stool frequency or stool consistency.¹⁴

43. Despite studies which demonstrate the false and misleading nature of the claims, and inadequate and inapposite testing, Bayer continues unequivocally to claim that with its proprietary blend of three of the most studied bacteria for digestive health, Phillips’ Colon Health is proven to deliver digestive and immune benefits, balancing your digestive system and relieving gas, diarrhea, constipation and other GI discomforts.

44. Although it is just a tiny “capsule” of natural bacteria, Phillips’ Colon Health Probiotic Supplement retails for approximately \$15 for a 30-count package.¹⁵ And Phillips’ Colon Health Probiotic + Fiber Supplement Power retails for approximately \$26 for a 30-dose package.¹⁶ The only reason consumers spend money to purchase Phillips’ Colon Health is for the advertised digestive health and immune system benefits claims; claims which are false and deceptive.

¹³ See C. Mair, C. Plitzner, *et al.*, Inulin and probiotics in newly weaned piglets: effects on intestinal morphology, mRNA expression levels of inflammatory marker genes and haematology, *Arch Anim. Nutr.* 2010 Aug; 64(4):304-21.

¹⁴ See J. Slavin and J. Feirtag, Chicory inulin does not increase stool weight or speed up intestinal transit time in health male subjects, *Food Func.*, 2011, 2, 72.

¹⁵ See www.amazon.com (\$14.95 on April 14, 2011); www.walgreens.com (\$15.99 on April 14, 2011); www.gnc.com (\$21.99 on April 14, 2011), www.cvs.com (\$17.99 on April 14, 2011), www.walgreens.com (\$16.99 on March 24, 2014), www.walmart.com (\$13.24 on March 24, 2014).

¹⁶ See www.drugstore.com (\$26.49 on April 14, 2011).

CLASS ACTION ALLEGATIONS

45. Plaintiffs bring this lawsuit on behalf of themselves and the proposed Class members under Rule 23(b)(2) and (3) of the Federal Rules of Civil Procedure. The proposed Class consists of:

All persons who purchased Phillips' Colon Health until the date notice is disseminated. Excluded from the Class are defendant's officers, directors and employees and those who purchased Phillips' Colon Health for the purpose of resale.

46. Plaintiffs also propose a California subclass (on behalf of Plaintiff Rikos) and an Illinois Subclass (on behalf of Plaintiffs Rikos and Yuncker) consisting of, respectively,:

All persons who purchased Phillips' Colon Health within the State of California until the date notice is disseminated. Excluded from the Class are defendant's officers, directors and employees and those who purchased Phillips' Colon Health for the purpose of resale.

and

All persons who purchased Phillips' Colon Health within the State of Illinois until the date notice is disseminated. Excluded from the Class are defendant's officers, directors and employees and those who purchased Phillips' Colon Health for the purpose of resale.

47. **Numerosity.** The members of the Class are so numerous that their individual joinder is impracticable. Plaintiffs are informed and believe, and on that basis allege, that the proposed Class contains many thousands of members. The precise number of Class members is unknown to Plaintiffs.

48. **Existence and Predominance of Common Questions of Law and Fact.** Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether Bayer had competent scientific evidence to support each of the claims that it made about Phillips Colon Health;

(b) whether the claims discussed above are true, or are misleading, or reasonably likely to deceive;

(c) whether Bayer's alleged conduct violates public policy;

(d) whether the alleged conduct constitutes violations of the laws asserted herein;

(e) whether Bayer engaged in false or misleading advertising;

(f) whether Plaintiffs and Class members have sustained monetary loss and the proper measure of that loss;

(g) whether Plaintiffs and Class members are entitled to an award of disgorgement of Bayer's profits;

(h) whether Plaintiffs and Class members are entitled to an award of punitive damages; and

(i) whether Plaintiffs and Class members are entitled to declaratory and injunctive relief.

49. **Typicality.** Plaintiffs' claims are typical of the claims of the members of the Class in that Plaintiffs assert the same claims.

50. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the members of the Class. Plaintiffs have retained counsel highly experienced in complex consumer class action litigation, and Plaintiffs intend to prosecute this action vigorously. Plaintiffs have no adverse or antagonistic interests to those of the Class.

51. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by

individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against the defendant. It would thus be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs done to them. Further, this action presents no unusual management difficulties under the circumstances here.

52. Adequate notice can be given to Class members directly using information maintained in defendant's records or through notice by publication.

53. Damages may be calculated, in part, from the sales information maintained in defendant's records, so that the cost of administering a recovery for the Class can be minimized. However, the precise amount of damages available to Plaintiffs and the other members of the Class is not a barrier to class certification.

54. Plaintiffs seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent defendant from engaging in the acts described, and requiring defendant to provide full restitution to Plaintiffs and Class members.

55. Unless a class is certified, defendant will retain monies received as a result of its conduct that was taken from Plaintiffs and proposed Class members. Unless a classwide injunction is issued, defendant will continue to commit the violations alleged, and the members of the Class and the general public will continue to be misled.

56. Bayer has acted and refused to act on grounds generally applicable to the Class, making appropriate final injunctive relief with respect to the Class as a whole.

COUNT I

**(For Violations of the New Jersey Consumer Fraud Act – N.J.S.A. §56:8-1, *et seq.*
On Behalf of Plaintiffs Rikos and Yuncker and all Class Members)**

57. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

58. This Count arises under the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*, and is brought on behalf of Plaintiffs and Class members pursuant to sections 56:8-19 and 56:8-2.12 of the Act.

59. Section 56:8-2 provides, in relevant part:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice

60. Plaintiffs and Class members are consumers who purchased “merchandise” – Phillips’ Colon Health – pursuant to a consumer transaction for personal use and are, therefore, subject to protection under the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*

61. Bayer conducted trade or commerce within the meaning of the New Jersey Consumer Fraud Act.

62. The acts, practices, misrepresentations, concealments, and omissions by Bayer were made in connection with the sale and advertisement of its Phillips’ Colon Health and with the intent that others rely upon such concealment, suppression and omission, constitute unlawful, deceptive and unconscionable commercial practices within the meaning of the New Jersey Consumer Fraud Act.

63. As a result of the use and employment by Bayer of the unlawful acts, Plaintiffs and other Class members have suffered ascertainable losses equal to the difference between the amount they paid for the product and the true value of the product. As is alleged above, the products provide no health benefits to the user and, thus, are worthless.

64. Under N.J.S.A. 56:8-2.11, 56:8-2.12 and 56:8-19, Plaintiffs and other Class members are entitled to a refund of all moneys acquired by Bayer by means of the unlawful practices alleged above, as well as compensatory damages, including treble damages and attorneys' fees.

COUNT II

(For Violations of the Consumers Legal Remedies Act – Civil Code §1750, *et seq.* n Behalf of Plaintiff Rikos and California Subclass)

65. Plaintiff Rikos repeats the allegations contained in the paragraphs above as if fully set forth herein.

66. This cause of action is brought pursuant to the Consumers Legal Remedies Act, Civil Code §1750, *et seq.* (the "CLRA"). Plaintiff Rikos is a consumer as defined by Civil Code §1761(d). The Phillips' Colon Health products are goods within the meaning of the CLRA.

67. Bayer violated and continues to violate the CLRA by engaging in the following practices proscribed by §1770(a) of the CLRA in transactions with Plaintiff Rikos and the Class which were intended to result in, and did result in, the sale of the Phillips' Colon Health Phillips' Colon Health:

- (a) Representing that [Phillips' Colon Health has] . . . characteristics, . . . uses [or] benefits . . . which they do not have
- (b) Representing that [Phillips' Colon Health is] of a particular standard, quality or grade . . . if they are of another.
- (c) Advertising goods . . . with intent not to sell them as advertised.

- (d) Representing that [Phillips' Colon Health has] been supplied in accordance with a previous representation when [they have] not.

68. Bayer violated and continue to violate the CLRA by representing and failing to disclose through its advertisements the Phillips' Colon Health as described above when it knew, or should have known, that the representations and advertisements were unsubstantiated, false and misleading.

69. Pursuant to §1782(d) of the CLRA, Plaintiff Rikos and the Class seek a Court order enjoining the above-described wrongful acts and practices of Bayer and for restitution and disgorgement.

70. Pursuant to §1782 of the CLRA, by letter dated May 24, 2011, Plaintiff Rikos notified Bayer in writing by certified mail of the particular violations of §1770 of the CLRA and demanded that Bayer rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act. A true and correct copy of this letter was attached as Exhibit A to the *Rikos* Complaint. *See* No. 11-3017, Docket Entry 1-1.

71. Bayer has failed to rectify or agree to rectify the problems associated with the actions detailed above or give notice to all affected consumers within 30 days of the date of written notice pursuant to §1782 of the CLRA. Therefore, Plaintiff Rikos further seeks claims for actual, punitive and statutory damages, as appropriate.

72. Bayer's conduct is malicious, fraudulent and wanton, and provides misleading information that can lead to the delayed treatment of serious and life-threatening illness and diseases.

73. Pursuant to §1780(d) of the CLRA, attached as Exhibit B to the *Rikos* Complaint was the affidavit showing that this action has been commenced in the proper forum. *See* No. 11-3017, Docket Entry 1-2.

COUNT III
**(Unlawful Business Acts and Practices in Violation of California
Business & Professions Code Section 17200, *et seq.*
On Behalf of Plaintiff Rikos, and California Subclass)**

74. Plaintiff Rikos repeats the allegations contained in the paragraphs above, as if fully set forth herein.

75. Business & Professions Code §17200 prohibits any “unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising.” For the reasons discussed above, Bayer has violated each of these provisions of Business & Professions Code §17200.

76. Bayer has violated §17200's prohibition against engaging in unlawful acts and practices by, inter alia, making the representations and omissions of material facts, as set forth more fully herein, and violating California's fraud and deceit statutes, Civil Code §§1572, 1573, 1709, 1710, 1711, the CLRA, Civil Code §§1770(a)(5), (a)(7), (a)(9) and (a)(16), Business & Professions Code §17200 et seq., Health & Safety Code §11333, 21 U.S.C. §321, by misbranding Phillips' Colon Health in violation of federal law, and by violating the common law, including breach of implied warranty.

77. Plaintiff Rikos and the Class reserve the right to allege other violations of law which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

78. Bayer's acts, omissions, misrepresentations, practices and non-disclosures as alleged herein also constitute “unfair” business acts and practices within the meaning of Business & Professions Code §17200 *et seq.* in that its conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous as the gravity of the conduct outweighs any alleged benefits attributable to such conduct.

79. As stated in this Complaint, Plaintiff alleges violations of consumer protection, unfair competition and truth in advertising laws in California and other states resulting in harm to consumers. Plaintiff Rikos asserts violations of the public policy of engaging in false and misleading advertising, unfair competition and deceptive conduct towards consumers. This conduct constitutes violations of the unfair prong of Business & Professions Code §17200 *et seq.*

80. There were reasonably available alternatives to further Bayer's legitimate business interests, other than the conduct described herein.

81. Bayer's claims, nondisclosures and misleading statements, as more fully set forth above, were also false, misleading and/or likely to deceive the consuming public within the meaning of Business & Professions Code §17200.

82. Bayer's advertising, including its labeling, as described herein, also constitutes unfair, deceptive, untrue and misleading advertising.

83. Bayer's conduct caused and continues to cause substantial injury to Plaintiff Rikos and the other Class members. Plaintiff Rikos has suffered injury in fact and has lost money as a result of Bayer's unfair conduct.

84. Bayer has thus engaged in unlawful, unfair and fraudulent business acts and practices and false advertising, entitling Plaintiff Rikos to judgment and equitable relief against defendant, as set forth in the Prayer for Relief.

85. Additionally, pursuant to Business & Professions Code §17203, Plaintiff Rikos seeks an order requiring Bayer to immediately cease such acts of unlawful, unfair and fraudulent business practices and requiring Bayer to engage in a corrective advertising campaign.

COUNT IV
**(Violation of Illinois' Consumer Fraud Act, 815 ILCS 505/1, et seq.
On Behalf of Plaintiffs, and Illinois Subclass)**

86. Plaintiffs Rikos and Yuncker repeat the allegations contained in the paragraphs above as if fully set forth herein.

87. Plaintiffs and Class members are consumers within the meaning of the Illinois Consumer Fraud and Deceptive Business Practices Act.

88. The Illinois Consumer Fraud Act prohibits:

Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with the intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act," approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby.

815 ILCS 505/2.

89. As a result of the deceptive and misleading promises and affirmations of fact made by Bayer on its Phillips' Colon Health product labels and through its marketing campaign, as described above, Bayer has deceived and continues to deceive Plaintiffs and Class members.

90. Bayer has intentionally engaged in these unfair and deceptive acts and made false or misleading representations, intending that Plaintiffs and Class members rely on the deception.

91. Bayer's deceptive conduct occurred in the course of engaging in trade or commerce.

92. Plaintiffs and the Class have purchased Phillips' Colon Health and suffered actual damages, proximately caused by Bayer's unfair and deceptive acts and practices.

COUNT V
**(Breach of Implied Warranty of Merchantability
On Behalf of Plaintiffs and all Class Members)**

93. Plaintiffs Rikos and Yuncker repeat the allegations contained in the paragraphs above as if fully set forth herein.

94. At all times relevant hereto, there was a duty imposed by law which requires that a manufacturer or seller's product be reasonably fit for the purposes for which such products are used, that product be acceptable in trade for the product description, and that the product conform to label descriptions.

95. Notwithstanding the aforementioned duty, at the time of purchase, Bayer's Phillips' Colon Health products sold to Plaintiffs and the Class were not merchantable because the products do not conform with the label descriptions of health benefits provided by the products.

96. As the scientific proof for the efficacy of probiotics products demonstrates that probiotic products provide no health benefits, Bayer was notified that the Phillips' Colon Health products were not merchantable.

97. As a result of the non-merchantability of the Phillips' Colon Health products, Plaintiffs and the members of the Class sustained a loss or damages.

COUNT VI
**(Unjust Enrichment
On Behalf of Plaintiffs and all Class Members)**

98. Plaintiffs Rikos and Yuncker repeat the allegations contained in the paragraphs above as if fully set forth herein.

99. By its unlawful conduct alleged herein, Bayer unjustly received a benefit at the expense of Plaintiffs and the other members of the Class.

100. Plaintiffs and Class members conferred a benefit on Bayer by purchasing Phillips Colon Health, notwithstanding the fact that Plaintiffs and Class members purchased the products from intermediate retailers.

101. Bayer appreciated and/or realized the benefits in the amounts of the profits they earned from sales of Phillips Colon Health to Plaintiffs and Class members.

102. It is unjust to allow Bayer to retain the profits from its unlawful conduct alleged herein without providing compensation to Plaintiffs and the other members of the Class.

103. Bayer acted with conscious disregard for the rights of Plaintiffs and the other members of the Class.

104. Plaintiffs and the members of the Class are entitled to restitution of, disgorgement of, and/or the imposition of a constructive trust upon, all profits, benefits, and other compensation obtained by Bayer from its deceptive, misleading, bad faith, and unlawful conduct.

WHEREFORE, Plaintiffs demand judgment as follows:

- A. Certifying the Class as requested herein;
- B. Awarding Plaintiffs and the proposed Class members damages;
- C. Awarding restitution and disgorgement of Bayer's revenues to Plaintiffs and the proposed Class members;
- D. Awarding declaratory and injunctive relief as permitted by law or equity, including: enjoining defendant from continuing the unlawful practices as set forth herein, and directing defendant to identify, with Court supervision, victims of its conduct and pay them restitution and disgorgement of all monies acquired by defendant by means of any act or practice declared by this Court to be wrongful;
- E. Awarding Plaintiffs and the Class punitive damages;
- F. Ordering Bayer to engage in a corrective advertising campaign;

- G. Awarding attorneys' fees and costs; and
- H. Providing such further relief as may be just and proper.

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Dated: March 31, 2014

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JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

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