IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. BAYER CORPORATION Defendant.	Case No. 2:07-cv-00001 (Hon. Jose L. Linares) *Document Filed Electronically*

DEFENDANT'S BRIEF IN OPPOSITION TO THE GOVERNMENT'S MOTION FOR AN ORDER TO SHOW CAUSE

Mark D. Hopson, Esq. (pro hac application pending)
Jonathan F. Cohn, Esq. (pro hac application pending)
Stephen Blank, Esq. (pro hac application pending)
Cara Viglucci Lopez, Esq. (pro hac application pending)
Benjamin Mundel, Esq. (pro hac application pending)
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
Ph.: (202) 736-8000

Timothy I. Duffy, Esq.
Mark K. Silver, Esq.
COUGHLIN DUFFY LLP
350 Mount Kemble Avenue
P.O. Box 1917
Morristown, New Jersey 07962-1917
Ph.: (973) 267-0058
Fax: (973) 267-6442
Attorneys for Defendant Bayer Corporation

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INTRODUCTION

The government's entire motion is premised on a novel and erroneous legal standard that was unveiled for first time in the contempt motion. According to the government, Bayer lacks scientific substantiation for Phillips' Colon Health ("PCH") because the company has not conducted "randomized, placebo-controlled, and double-blind" "human clinical trials" on the "specific product," using the precise "population[s]" and "methods" chosen by the government. Dkt No. 4 Attachment 1 at 16. *This is not and has never been the standard for dietary supplement claims such as those at issue.* It is a brand new multi-part test the government invented for this litigation—relying on a single physician who was not even disclosed until the government moved for contempt.

No government entity has asserted this test before. It is not embodied in Bayer's consent decree, which speaks only of "competent and reliable scientific evidence." Dkt. No. 2 at 2. Nor is it embodied in the Federal Trade Commission's guidance, which makes clear that "competent and reliable scientific evidence" does *not* require such clinical trials, but rather allows for other evidence, including animal testing, *in vitro* testing, and extrapolation from other research. *See* FTC, *Dietary Supplements: An Advertising Guide for Industry* at 3 (Apr. 2001), *available at* http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry/ ("FTC Guidance") (Certification of Jonathan F. Cohn, Exh. 1). Nor is it

embodied in any statute, regulation, or anything else. The test was born on September 12, 2014, when the government filed its contempt motion.

Because the government's novel multi-part test conflicts with the consent decree, agency guidance, and the underlying statute, it is invalid. But, even if it were legally defensible, the Court should still deny the government's motion. Contempt requires a violation of a "*clear and unambiguous* provision of the consent decree." *Harris v. City of Phila.,* 47 F.3d 1342, 1350 (3d Cir. 1995) (emphasis added). Where, as here, the government's motion depends on a legal test found nowhere in the consent decree and announced for the first time in a contempt motion, there can be no contempt. Bayer and the entire dietary supplement industry relied on the FTC's guidance. Any purported violation by Bayer was excusable, inadvertent, and no different from the rest of the industry. The Court should deny the government's motion.[1]

BACKGROUND

I. Dietary Supplement Health & Education Act

Recognizing the health benefits of dietary supplements, Congress enacted the Dietary Supplement Health & Education Act of 1994

[1] If the Court issues an order to show cause, Bayer requests an evidentiary hearing to provide evidence, including expert testimony, showing (among other things) that (1) experts in the relevant field do not require randomized, controlled clinical trials, let alone clinical trials that meet the government's novel multi-part test; (2) PCH's claims are substantiated by competent and reliable scientific evidence; and (3) Bayer acted in good faith and substantially complied with the consent decree.

(DSHEA), Pub. L. No. 103-417, sec. 8, § 413(c) (codified at 21 U.S.C. § 350(b)), ensuring that supplements can be marketed and sold without following the stringent requirements imposed on *drugs*. Whereas new drugs must be pre-approved by the Food and Drug Administration, *see id.*. § 331(d); *id.* § 355(a), and traditionally must be supported by randomized, placebo-controlled, double-blind clinical trials, *see* 21 C.F.R. 5, § 314.126,[2] dietary supplements need not.

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

II. Agency Guidance

DSHEA does not specify what substantiation is necessary to render a claim "truthful and not misleading." Accordingly, in April 2001, the Federal Trade Commission provided guidance, stating that the relevant standard is "competent and reliable scientific evidence." FTC Guidance at 3. The FTC defines this phrase to

[2] *See also* FDA, *FDA's Drug Review Process*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm#qualit (last updated Apr. 25, 2014).

mean: "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.* at 9.

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

Further, studies on the precise formula used in the advertised product are not required. Rather, it can be "appropriate to extrapolate from the research to the claimed effect," even if there "are significant discrepancies between the research conditions and the real life use being promoted." *Id.* at 16. The Food and Drug Administration (FDA) agrees in its guidance, recognizing that randomized, controlled clinical trials for dietary supplements may not be "possible, practical, or ethical." *See*

FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act* (Dec. 2008) ("FDA Guidance").

III. Consent Decree

In 2007, Bayer entered into a consent decree, which provides for the identical standard as the agency guidance. Seeking to avoid litigation, and without admitting any wrongdoing, Bayer agreed it must possess "competent and reliable scientific evidence" for its dietary supplement claims. Dkt. No. 2 § 3(B). The decree defines this term the same way the guidance documents do: "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." Dkt. No. 2 at 2.

Nowhere in the decree is there any provision requiring randomized, controlled clinical trials. *Other* consent decrees that the FTC has entered into with *other* companies for *other* types of products require clinical trials for *other* claims. *See e.g., FTC v. Iovate Health Sci USA*, Consent Decree at 7, No. 10-CV-587 (W.D.N.Y. July 29, 2010) ("competent and reliable scientific evidence [under this section] shall consist of at least two adequate and well controlled human clinical studies"); *United States v. Jason Pharm., Inc.,* Consent Decree at 3, 6, No. 12-CV-01476 (D.D.C. Sept. 17, 2012) ("competent and reliable scientific evidence shall consist of at least one adequate and well-controlled human clinical study" which is defined as a study of certain size and

length where participants are "randomly assigned to a treatment and a control group"). But Bayer's decree does not.

IV. Phillips Colon Health

Among the dietary supplements Bayer sells is PCH, a probiotic supplement. Probiotics are microorganisms that provide health benefits, such as supporting a healthy digestive system. The benefits of probiotics have been well-recognized for over 100 years, and there is no dispute that probiotics are safe. *See* Dkt. No. 4 Attachment 1 at 9 n.4 ("government is not challenging the safety of [PCH]"); David R. Snydman, *The Safety Of Probiotics,* 46 Clinical Infectious Diseases S104 (Supp. 2008) (explaining that "epidemiologic evidence suggests no population increase in risk" and "[t]here have been many controlled clinical trials on the use of probiotics that demonstrate safe use"); *id.* ("millions of people around the world consume probiotics daily for perceived health benefits"). Indeed, many of us consume probiotics on a regular basis. Probiotics occur naturally in yogurt, milk, and other dairy products, and they can be purchased in granola bars, juices, chocolate, and scores of supplements.

The science supporting the efficacy of probiotics and PCH in particular is substantial. The science supporting Bayer's claims includes, among other studies and research:

- Numerous randomized, controlled, clinical trials on the species of bacteria in PCH;[3]

[3]Probiotics, like all bacteria, are formally categorized into taxonomic groups of class, order, family, and genus. Species within a particular genus are further defined by a

- *In vitro* and animal studies on the strains in the product;
- Genomic tests confirming that the strains of bacteria in PCH help defend against constipation, diarrhea, gas and bloating.

In addition, a recent consensus report from probiotics experts concluded that **"certain effects can be ascribed to probiotics as a general class," and among these effects are digestive benefits**. Colin Hill *et al.*, *The International Scientific Association for Probiotics and Prebiotics Consensus Statement on the Scope and Appropriate Use of the Term Probiotic*, 11 Nature Reviews Gastroenterology & Hepatology 506, 607 (20014) ("ISAPP Report") (emphasis added). The consensus report further concluded that **"nonstrain-specific claims" may be made about the three species of bacteria in PCH (Bifidobacterium bifidum, Bifidobacterium longum, and Lactobacillus gasseri), including claims about "a healthy digestive tract."** *Id.* at 507-08 (emphasis added) (noting "body of available research, including high-quality meta-analysis, on a diversity of clinical end points (such as infectious diarrhea, antibiotic-associated diarrhea, gut transit, IBS, abdominal pain and bloating, uncreative colitis and necrotizing enterocolitis)"); *id.* at 511 ("The panel also believes that probiotic foods or supplements should not be held to a higher standard of evidence than other foods or supplements," and "[m]any other supplements are also

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distinct combination of traits, meaning strains within one species share this combination. *See generally*, Erko Stackebrandt, *et al.*, *Report Of The Ad Hoc Committee For The Re-Evaluation of The Species Definition in Bacteriology*, Int'l. Journal of Systematic and Evolutionary Microbiology at 1044 (2012).

recommended by doctors for uses not supported by RCTs"). Likewise, doctors have strongly recommended entire *genera* and *species* of a bacteria used in PCH for digestive issues. *See, e.g.,* Blake Rodgers *et al.*, *Prescribing an antibiotic? Pair it with probiotics*, 62 J Fam. Prac., 148 (2013) (giving an "A" recommendation, urging physicians to recommend probiotics including the two genera in PCH, lactobacillus and bifidobacteria).

V. FTC's Investigation

Bayer has been marketing PCH since 2008 and notified FDA of each of its label claims. Three years later, in August 2011, the FTC began to investigate whether Bayer possessed adequate substantiation for PCH. At no time, did the FTC assert the multi-part test the government is now espousing.

A year and a half later, in March 2013, the FTC referred the case to the Department of Justice for enforcement. On September 12, 2014, the government filed its motion, announcing for the first time its new substantiation test.

STANDARD OF REVIEW

The government bears a "heavy burden to show . . . civil contempt," *Fox Capital Co.*, 96 F.2d 684, 686 (3d Cir. 1938), and must prove by clear and convincing evidence that the defendant violated a "clear and unambiguous provision of the consent decree." *Harris v. City of Phila.,* 47 F.3d 1342, 1350 (3d Cir. 1995).[4] To be

[4] The government must also show that a valid court order existed and that the defendant had knowledge of the order. These items are not in dispute.

"placed at risk of contempt," a defendant must be "given specific notice of the norm to which [it] must pattern [its] conduct." *Id.* at 1349 (citing *Int'l Longshoremen's Ass'n v. Phila. Marine Trade Ass'n*, 389 U.S. 64, 76 (1967)). Any "ambiguities and omissions in orders redound to the benefit of the person charged with the contempt," *Ford v. Kammerer*, 450 F.2d 279, 280 (3d Cir. 1971) (per curiam). A court "must not strain the decree's precise terms or impose other terms" not embodied in the agreement. *Harris v. City of Phila.*, 137 F.3d 209, 212 (3d Cir. 1998) (citing *United States v. Armour & Co.*, 402 U.S. 673, 681-82 (1971). If the purported legal requirement cannot be "discern[ed]" from the "four corners" of the consent decree, the contempt action fails. *Id.*

ARGUMENT

The government does not—and cannot—dispute that Bayer satisfies the "flexible" standard of "competent and reliable scientific evidence" that has existed for over 13 years. This standard allows companies to rely on many types of evidence, including animal and *in vitro* studies, and to extrapolate from other research. Not only does Bayer have such support for its claims, but it also has numerous randomized clinical trials on the very species of bacteria in PCH, and sophisticated genomic research confirming its strains help defend against occasional constipation, diarrhea, gas and bloating. None of this is at issue.

Instead, the government's motion is premised on its novel multi-part legal test, which was never before articulated to Bayer or anyone else in the dietary supplement

industry, and is found nowhere within the "four corners" of the consent decree. According to the government, Bayer is required to have "human clinical trials that (1) are randomized, placebo-controlled, and double-blind; (2) use the specific product for which the claims are made; (3) are performed in the population at which the claims are directed; and (4) use validated methods and appropriate statistical methods to assess 'outcomes.'" Dkt. No. 4 Attachment 1 at 16. It is this novel standard, and *only* this novel standard, that the government argues Bayer violated.

For two reasons, the Court should deny the government's motion. First, the government's newly asserted standard is erroneous, because it is inconsistent with the plain terms of the consent decree, the FTC's guidance, DSHEA, and the First Amendment. Second, even if the standard were valid, Bayer cannot be held in contempt for allegedly violating a novel standard that did not previously exist and that the government now seeks to apply retroactively.

I. The Government Is Applying An Erroneous And Unjustifiable Legal Standard.

The government's novel standard is unlawful for four separate reasons.

A. The Consent Decree Does Not Require Randomized, Controlled Clinical Trials.

First, the consent decree does not require randomized, controlled clinical trials for dietary supplement claims. The FTC has signed *other* decrees with *other* companies that require such trials for *other* product claims (though never with all of the prongs of

the government's new multi-part test). *See supra* at 5. But no such provision is in the Bayer decree.

Confronted with similar facts, another district court rejected the FTC's attempt "to read additional requirements into the Consent Decree." *FTC v. Garden of Life*, 845 F. Supp. 2d 1328, 1335 (S.D. Fla. 2012) *aff'd in part and vacated in part,* 516 F. App'x. 852 (11th Cir. 2013); *see also id.* at 1337 ("Again, the Consent Decree does not require [defendant] to only make representations that are supported by uncontroverted evidence; rather, the Consent Decree merely requires [defendant] to possess competent and reliable evidence that substantiates its claims."). When a consent decree speaks only of "competent and reliable scientific evidence," the government cannot redefine it through expert testimony or otherwise. *See id.* at 1335-37. The decree speaks for itself, and when Bayer signed its decree in 2007, it did not agree to the requirements now being demanded retroactively by the government seven years later.

B. Agency Guidance Expressly States That Randomized, Controlled Clinical Trials Are Not Required.

Second, the government's position conflicts with the FTC's own guidance, which expressly provides that "competent and reliable scientific evidence" does *not* require randomized, controlled clinical trials. Instead, the guidance makes clear that the standard is "flexible," and "[t]here is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration."

FTC Guidance at 8-9. "[R]esults obtained in animal and *in vitro* studies *will also be examined*," *id.* at 10 (emphasis added), and "epidemiologic evidence may be an acceptable substitute for clinical data." *Id.* It can also be "appropriate to extrapolate from the research to the claimed effect" even if there "are significant discrepancies between the research conditions and the real life use being promoted." *Id.* at 16; *see also* FDA Guidance (recognizing that randomized, controlled clinical trials may not be "possible, practical, or ethical" for dietary supplements); *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008) (holding that "[n]othing in the Federal Trade Commission Act . . . requires placebo-controlled, double-blind studies" and that "[p]lacebo-controlled double-blind testing is not a legal requirement for consumer products").

The conflict between the government's new standard and the FTC's guidance is stark:

Government's Motion	FTC's Guidance
Must be "human clinical trials." at 16. • "Non-clinical studies, such as those done in animals, are not sufficient." at 16.	"[A]nimal and in vitro studies will also be considered." at 10.
"Randomized, placebo-controlled, and double blind[ing]. . . . is mandatory." at 16-17.	"[N]o fixed formula for the . . . type of studies required." at 9. "[N]o set protocol." at 12. "[S]ufficiently flexible to ensure that consumers have access to information about emerging areas of science." at 8.
Must be exactly the same "product." at 18. "[O]ne cannot 'extrapolate.'" at 18.	"[C]onsider all relevant research." at 14. Can "extrapolate." at 16.
Must be "performed in the population at which the claims are directed." at 16. "[O]ne cannot 'extrapolate.'" at 18.	Can use different populations if "scientifically sound to make such extrapolations." at 17. Can "extrapolate." at 16.

The new standard is erroneous because it conflicts with the FTC's own published guidance, on which Bayer and the industry have relied.

Moreover, the government's new requirement that "one cannot 'extrapolate'" and that the research must specifically be conducted on "[PCH] or a product comprised of the *same combination of the same strains of bacteria*," Dkt. No. 4 Attachment 1 at 18, also conflicts with recent scientific literature. *See* ISAPP Report at 507-08, 511 (rejecting strain-specificity argument); *see also* supra at 7. The government cites older articles, *see* Dkt. No. 4 Attachment 1 at 18-21, but these articles never represented a consensus, and they expressly addressed disease research. *See e.g.,* World Gastroenterology Org., *Probiotics and Prebiotics* 4 (2008) (recognizing there is "no universally established and/or enforced standards"); Food & Agric. Org. U.N. & World Health Org., *Report of Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics*, 1 (2001) (WHO Report) ("no international consensus on the methodology to assess the efficacy and the safety of [probiotics], at present").

Indeed, the ISAPP Report, which included three of the five outside authors of the WHO Report (Reid, Morelli, and Sanders), expressly "revisit[ed]" the WHO Report and rejected its strain-specificity hypothesis. ISAPP Report at 507. The ISAPP Report concluded that, because of "the rapidity of scientific breakthroughs, the research regarding the mechanisms and health effects of probiotics extend much

beyond what was included in [the WHO report]." *Id.* at 510. Thus, the government relies on an outdated and erroneous report.

C. The Government's Standard Conflicts With DSHEA.

Third, the government's novel standard conflicts with DSHEA, which Congress enacted to promote the sale of dietary supplements and "to clarify that dietary supplements are not drugs." S. Rep. No. 103-410, at 2 (1994). Recognizing "the benefits of dietary supplements to health," and seeking to "empower[] [consumers] to make choices about preventive health care programs based on data from scientific studies," DSHEA Pub. L. No. 103-417 § 2(2), (8), 108 Stat. at 4352-261, Congress eliminated the pre-approval requirement that applies to drugs, and lowered the substantiation requirement for dietary supplements, 21 U.S.C. § 343(r)(6).

Under DSHEA, dietary supplement statements like those at issue here need only be "truthful and not misleading." *Id.* § 343(r)(6)(B). They are not subject to the stringent clinical-trial standard applicable to drugs, FDA's Drug Review Process; *see also id.* § 343(r)(6)(A) (including on the list of appropriate dietary supplement statements those which "describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function"); *see also supra* at 2-3.

There is an exception for when dietary supplements are marketed like drugs—with claims that they will "diagnose, mitigate, treat, cure, or prevent a *specific disease or*

class of diseases." *Id.* § 343(r)(6)(c) (emphasis added). But the government acknowledges that Bayer does *not* claim PCH will "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." The government and its expert, Dr. Loren Laine, "took as true" that Bayer's advertisements are "directed toward *healthy* consumers *and do not make disease claims*." Dkt. No. 4 Attachment 1 at 21-22 (second emphasis added). Indeed, the government and Laine affirmatively argue that "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.* at 22 (emphasis added).

The FDA's final rule confirms that Bayer made appropriate dietary supplement claims, called "structure-function claims," and not disease claims. *See* 65 Fed. Reg. 1000, 1006 (Jan. 6, 2000) ("a claim that a product 'helps promote digestion' would be a structure-function claim because it does not refer explicitly or implicitly to an effect on a disease state"); *id.* at 1026 ("for relief of 'occasional constipation' should not be considered [a] disease claim[]"); *id.* at 1031 (stating that "'[a]lleviates the symptoms referred to as gas'" and "'alleviates bloating'" are structure-function claims "because the symptoms . . . are not sufficiently characteristic of specific diseases"); *see also id.* at 1033 ("'helps maintain regularity' is an acceptable structure/function claim"); *see also id.* at 1015, 1029. Never before have such claims ever required randomized, controlled clinical trials on the product.

Bayer's advertisements likewise do not make disease claims. Far from showing anyone "suffering from [a] disease," *id.* at 1012, Bayer's advertisements display active healthy people playing golf, riding a tour bus, or getting on an airplane. And they are not talking to a doctor, but the cheeky "Colon Lady," who is giving humorous wedding speeches about bloating, performing dramatic readings in book stores, and preaching about gas on street corners. *See, e.g.,* Dkt. No. 4. Attachment 4, Exh. 3, 10, 14-16.; *see also* 65 Fed. Reg. at 1011 (in evaluating claim, must look at the overall "context in which the claim is presented"); 1022, 1025, 1028, 1032 (same). To avoid any doubt, these advertisements expressly state that the product is not intended to diagnose, treat, cure or prevent any disease. (This disclaimer goes beyond DSHEA's requirement, which applies only to labeling, *see* 21 U.S.C. § 343(r)(6)(C).) [5]

D. The Government's Novel Standard Violates The First Amendment.

Fourth, the government's restrictive standard violates the First Amendment. Restrictions on commercial speech are subject to heightened scrutiny unless the speech is actually false or inherently misleading. *See Va. State Bd. of Pharmacy v. Va.*

[5]In a paragraph that seems to contradict the rest of the motion, the government suggests that by marketing PCH along with Phillips' over-the-counter drugs, Bayer is somehow marketing PCH as a drug. *See* Dkt. No. 4 Attachment 1 at 14-15. But this assertion is unprecedented. The government never raised it before—at any time during or preceding its lengthy investigation. And a stroll through one's neighborhood drugstore reveals that many dietary supplements are sold alongside over-the-counter drugs. Regardless, the government cannot have it both ways: It cannot simultaneously contend that Bayer is marketing PCH as a drug designed to treat "disease," *id.* at 14, while also arguing that Bayer cannot rely on any study that involves "participants who have *diseases*," *id.* at 22. That is a Catch 22.

Citizens Consumer Council, Inc., 425 U.S. 748 (1976). To satisfy this heightened scrutiny, (1) "the asserted governmental interest [must be] substantial"; (2) "the regulation [must] directly advance[] the governmental interest asserted"; and (3) "it [must] not [be] more extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n.*, 447 U.S. 557, 566 (1980).

Bayer's statements regarding PCH are not false or misleading. There is no dispute that the claims are, in fact, substantiated under the well-established "flexible" standard for dietary supplements, which looks to animal studies, *in vitro* studies, and other research. The government's only argument is that the claims are not also supported by randomized, controlled clinical trials meeting the government's newly announced requirements. But the flexible standard already "ensure[s] that consumers have access to truthful, well-qualified information about emerging areas of science." FTC Staff Comments, *In re Request for Comment on First Amendment Issues* at 18 (2002), *available at* http://www.ftc.gov/os/2002/09/fdatextversion.pdf ("FTC Comments"). The government said so itself. *See id.* Thus, *Central Hudson* applies.

The government cannot satisfy this constitutional test. Indeed, it fails at the outset. There is no "substantial" government interest in imposing a requirement of randomized, controlled clinical trials. To the contrary, in enacting DSHEA, Congress deliberately distinguished dietary supplements from drugs, *see* S. Rep. No. 103-410, at 2 ("The purpose of this legislation . . . is also to clarify that dietary supplements are not drugs . . . ."), and established a different test for dietary supplements, which

promoted "the dissemination of *more* truthful and non-misleading information," 65 Fed. Reg. at 1003 (emphasis added); *see also* FTC Comments at 22; 13 Cong. Rec. S 16610 (daily ed. Oct. 24, 1990) (Statement of Sen. Hatch) Nutrition Labeling and Education Act of 1990, ("a more lenient standard for dietary supplements is envisioned").

Congress did so because, among other reasons, it found that dietary supplements provide health benefits and that consumers should be "empowered" to make their own choices from available information. *See* DSHEA Pub. L. No. 103-417 § 2(8), 108 Stat. at 4326. These interests are all the more significant where, as here, there is *no* safety issue, as the government concedes. Dkt. No. 4 Attachment 1 at 9 n.4*; see also* DSHEA Pub. L. 103-417 § 2(14) ("dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare"); FTC Comments at 22 ("The benefits of a flexible approach are especially significant when the information relates to consumer health."). The government has no substantial interest in adopting a novel standard that undercuts the congressionally recognized benefits of dietary supplements and consumer choice. The government's new standard violates the First Amendment.

II. Even If The Government's New Standard Were Legally Defensible, Bayer Still Cannot Be Held In Contempt.

Even if the Government's newly announced multi-part test were legally defensible, Bayer cannot be held in contempt for three reasons. First, contempt

requires clear and convincing evidence of a violation of a "clear and unambiguous" provision in a court order, *Harris,* 47 F.3d at 1348, and there is no such clarity here. Second, Bayer has "substantially complied" with the consent decree by faithfully following the existing standard stated in the FTC's guidance, and under Third Circuit precedent, a party who "substantially complies" with a court order cannot be held in contempt, *FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575, 591 (3d Cir. 2010). Third, principles of equity prohibit the government from singling out Bayer with a contempt action while the rest of the industry is allowed to follow the standard that has existed for over 13 years.

A. There Is No Clear And Convincing Evidence Of A Violation Of A Clear And Unambiguous Court Order.

To prove contempt, the government must show by clear and convincing evidence that Bayer violated a "clear and unambiguous provision of the consent decree." *Harris,* 47 F.3d at 1348 (3d Cir. 1995). If there is ambiguity or doubt, there can be no contempt. *Ford*, 450 F.2d at 280. A court "must not strain the decree's precise terms or impose other terms" not embodied in the agreement. *Harris v. City of Phila.*, 137 F.3d 209, 212 (3d Cir. 1998) (citing *United States v. Armour & Co.*, 402 U.S. 673, 681-82 (1971). If the purported legal requirement cannot be "discern[ed]" from the "four corners" of the consent decree, the contempt action fails. *Id.*

The government does not even attempt to satisfy this standard. Its requirement of randomized, controlled clinical trials is found nowhere in the "four

corners" of the consent decree, but only within the four corners of an expert report that was filed along with the government's motion. A brand new standard invented for litigation cannot be the premise of a contempt action. *See also FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2318 (2012) (holding that Federal Communications Commission had violated due process by changing its "fleeting expletives" policy and finding, without fair notice, that two television networks had violated the new policy).

B. Bayer Has Substantially Complied With The Consent Decree, So It Cannot Be Held In Contempt.

Under Third Circuit precedent, a party cannot be held in contempt when it "substantially complies" with a court order. *Lane Labs*, 624 F.3d at 591 (3d Cir. 2010). "A party substantially complies when it takes all reasonable steps to do so, but nonetheless contravenes the court order by good faith mistake or excusable oversight." *Id.* at 590. "In order to avail oneself of the defense, a party must show that it (1) has taken all reasonable steps to comply with the valid court order, and (2) has violated the order in a manner that is merely 'technical' or 'inadvertent.'" *Id.* 591.

There is no question that Bayer substantially complied. First, it fully complied with the published guidance. The only "standard" it failed to meet was the multi-part test that was announced for the first time on September 12, 2014. Bayer did not comply with the new standard because it was not articulated during—or at any time preceding—the government's "prolonged delay in initiating contempt proceedings."

Id. at 591 n.19. *See also FTC v. Lane Labs-USA*, 2011 WL 5828518, at *16 (D.N.J. Nov. 18, 2011) ("This extensive delay understandably led Defendants to believe that they were in compliance with the Final Order, and for the FTC to bring its motion after six years seems to the Court to be fundamentally unfair."); *Precious Metals Assocs. Inc. v. Commodity Futures Trading Comm'n.*, 620 F.2d 900, 909 (1st Cir. 1980) (noting that courts have applied laches "where unreasonable agency delay has caused hardship.").

Second, any violation was "inadvertent." Bayer did all it could and simply did not know the standard, which did not yet exist. Indeed, Bayer filed multiple notification letters with the FDA, beginning on July 8, 2008, disclosing its dietary supplement claims to the government. Yet, for years, the government never objected to these claims, and never even issued a warning letter, which would have put Bayer on notice of the purported violation. Nor has the government issued warning letters in response to over 100 other notifications by other companies making similar claims. *See, e.g.*, Notification Letter from Jeffrey Bram, Garden of Life to FDA (Jan. 4, 2013) ("helps relieve the occasional symptoms of gas, bloating, constipation and diarrhea"); Notification Letter from Brian Spurling, Good Herbs to FDA (Nov. 24, 2010 ("for relief from occasional constipation"). Instead, it jumped headlong into a contempt action, wielding a new standard and seeking "hundreds of millions" of dollars in contempt damages, Dkt No. 4 Attachment 1 at 29; *see United States v. Atl. Refining Co.*, 360 U.S. 19, 23 (1959) (rejecting government's attempt to change interpretation of

consent decree when "the language . . . in its normal meaning supports [a different] interpretation" that the "government accepted . . . without challenge" for years).

Finally, any violation was "technical" (although it need not be for application of "substantial compliance," which is phrased in the disjunctive: "inadvertent *or* technical"). According to the government, the standard turns on a single gastroenterologist's opinion on a matter of emerging science regarding the balance of trillions of microorganisms in the gut. It is hard to imagine what could be more "technical."

C. Principles Of Equity Prohibit A Finding Of Contempt.

A "civil contempt" case is a "proceeding in equity." *Gompers v. Buck's Stove & Range Co.*, 221 U.S. 418, 451 (1911). It is from the court's "broad equitable power" that a court may "enforce a consent decree in response to a party's non-compliance." *Holland v. N.J. Dep't of Corr.*, 246 F.3d 267, 270, 282-83 (3d Cir. 2001). Equitable principles prohibit a finding of contempt.

It is beyond dispute that the government's action targets only Bayer. The rest of the industry gets to proceed with business as usual—even though *no one* in the industry meets the government's novel standard.[6] To be sure, the *in terrorem* effect of the government's action may well be industry-wide, potentially clearing probiotics and

[6] The government baldly asserts that its motion "promotes market fairness" because Bayer is "luring consumers away from available alternatives." Dkt. No. 4 Attachment 1 at 30, n.14. But the government has identified no available alternatives, and under the government's novel multi-part test, there appear to be no alternatives. Thus, damages would be zero.

other dietary supplements from drugstore shelves. But Bayer should not be singled out for idiosyncratic treatment, let alone the threat of contempt and a demand for "hundreds of millions" of dollars, when it has simply followed the same standard and same guidance that the rest of the industry has followed.

The FTC is acting arbitrarily. Indeed, it recently settled with Dannon and Nestle for *$0.00*, even though (unlike Bayer) both companies made unsubstantiated *disease* claims for their probiotic products. *See In the Matter of The Dannon Company*, No. C-4313 (F.T.C. Jan 31, 2011) Complaint at 5, (claims that "DanActive reduces the likelihood of getting a cold or the flu"); *In the Matter of Nestle Healthcare Nutrition, Inc.*, No. C-4312 (F.T.C. Jan. 12, 2011) Complaint at 7 (claims that BoostKid "Reduces the general incidence of illness in children, including upper respiratory tract infections"). The government is thus doing precisely what it said it should not do in setting the boundaries for dietary supplement claims: straying from "uniform industry-wide requirements" and creating an "'[un]level playing field' for all members of the dietary supplement industry." 65 Fed. Reg. at 1008.

CONCLUSION

The Court should deny the government's motion.

COUGHLIN DUFFY LLP
Attorneys for Defendant Bayer Corporation

By: */s/ Timothy I. Duffy*
Timothy I. Duffy

Dated: October 3, 2014

Of Counsel:

Mark D. Hopson, Esq. (pro hac application pending)
Jonathan F. Cohn, Esq. (pro hac application pending)
Cara Viglucci Lopez, Esq. (pro hac application pending)
Stephen Blank, Esq. (pro hac application pending)
Benjamin Mundel, Esq. (pro hac application pending)

SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005