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

UNITED STATES OF AMERICA, Plaintiff, v. BAYER CORPORATION, Defendant.	No. 2:07-cv-0001-JLL-JAD (Hon. Jose L. Linares) Motion Date: March 16, 2015

NOTICE OF MOTION FOR LEAVE TO APPEAR AS *AMICUS CURIAE*

Of Counsel:
Jeffrey S. Bucholtz
David M. Barnes
KING & SPALDING LLP
1700 Pennsylvania Ave., NW
Washington, DC 20006
Telephone: (202) 737-0500
Facsimile: (202) 626-3737
jbucholtz@kslaw.com
dbarnes@kslaw.com

Of Counsel:
Merritt E. McAlister
KING & SPALDING LLP
1180 Peachtree Street, NE
Atlanta, GA 30309
Telephone: (404) 572-4600
Facsimile: (404) 572-5100
mmcalister@kslaw.com

Austin A. Evans
Bar No. 04127-2005
KING & SPALDING LLP
1180 Peachtree Street, NE
Atlanta, GA 30309
Telephone: (404) 572-4600
Facsimile: (404) 572-5100
aevans@kslaw.com

Of Counsel:
Kathryn Comerford Todd
Steven P. Lehotsky
U.S. CHAMBER
LITIGATION CENTER, INC.
1615 H Street, NW
Washington, D.C. 20062
Telephone: (202) 463-5337
Facsimile: (202) 463-5346
KTodd@USChamber.com
SLehotsky@USChamber.com

Counsel for the Chamber of Commerce of the United States

NOTICE OF MOTION FOR LEAVE TO APPEAR AS *AMICUS CURIAE*

PLEASE TAKE NOTICE that on March 16, 2015, the undersigned counsel for the Chamber of Commerce of the United States shall move before the Honorable Jose L. Linares, U.S. District Judge, for entry of an Order granting the Chamber leave to file a brief as *amicus curiae* in support of Defendant Bayer Corporation; and

PLEASE TAKE FURTHER NOTICE that the proposed *amicus* brief is attached as an exhibit to this motion.

A proposed Order is also submitted herewith.

Dated: February 20, 2015

Respectfully submitted,

/s/ Austin A. Evans

Austin A. Evans
Bar No. 04127-2005
KING & SPALDING LLP
1180 Peachtree Street, NE
Atlanta, GA 30309
Telephone: (404) 572-4600
Facsimile: (404) 572-5100
aevans@kslaw.com

Of Counsel:
Kathryn Comerford Todd
Steven P. Lehotsky
U.S. CHAMBER
LITIGATION CENTER, INC.
1615 H Street, NW
Washington, D.C. 20062
Telephone: (202) 463-5337
Facsimile: (202) 463-5346
KTodd@USChamber.com
SLehotsky@USChamber.com

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David M. Barnes
KING & SPALDING LLP
1700 Pennsylvania Ave., NW
Washington, D.C. 20006
Telephone: (202) 737-0500
Facsimile: (202) 626-3737
jbucholtz@kslaw.com
dbarnes@kslaw.com

Of Counsel:
Merritt E. McAlister
KING & SPALDING LLP
1180 Peachtree Street, NE
Atlanta, GA 30309
Telephone: (404) 572-4600
Facsimile: (404) 572-5100
mmcalister@kslaw.com

CERTIFICATE OF SERVICE

I hereby certify that on February 20, 2015, a copy of the foregoing was electronically filed with the Clerk of the Court using CM/ECF system, which will send notification to all counsel of record.

/s/ Austin A. Evans
Austin A. Evans

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

UNITED STATES OF AMERICA, Plaintiff, v. BAYER CORPORATION, Defendant.	No. 2:07-cv-0001-JLL-JAD (Hon. Jose L. Linares)

BRIEF OF *AMICUS CURIAE* THE CHAMBER OF COMMERCE OF THE UNITED STATES

Of counsel:
Jeffrey S. Bucholtz
David M. Barnes
KING & SPALDING LLP
1700 Pennsylvania Ave., NW
Washington, D.C. 20006
Telephone: (202) 737-0500
Facsimile: (202) 626-3737
jbucholtz@kslaw.com
dbarnes@kslaw.com

Of Counsel:
Merritt E. McAlister
KING & SPALDING LLP
1180 Peachtree Street, NE
Atlanta, GA 30309
Telephone: (404) 572-4600
Facsimile: (404) 572-5100
mmcalister@kslaw.com

Austin A. Evans
Bar No. 04127-2005
KING & SPALDING LLP
1180 Peachtree Street, NE
Atlanta, GA 30309
Telephone: (404) 572-4600
Facsimile: (404) 572-5100
aevans@kslaw.com

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Kathryn Comerford Todd
Steven P. Lehotsky
U.S. CHAMBER
LITIGATION CENTER, INC.
1615 H Street, NW
Washington, D.C. 20062
Telephone: (202) 463-5337
Facsimile: (202) 463-5346
KTodd@USChamber.com
SLehotsky@USChamber.com

Counsel for the Chamber of Commerce of the United States

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

INTEREST OF *AMICUS CURIAE*

The Chamber of Commerce of the United States is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, from every geographic region of the country. A principal function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of concern to the nation's business community.

The Chamber submits this brief in support of Bayer Corporation because the business community is deeply concerned by the government's efforts to use unfounded threats of contempt to effectuate a sea change in the law—in this case, the long-established standards governing the dietary supplement industry. The substantiation standard under which the government is seeking to hold Bayer in contempt is not the law, and the Federal Trade Commission's campaign to impose this new standard through contempt actions raises serious free speech, due process, and administrative law concerns that implicate the interests of not only the dietary supplement industry but also of all businesses subject to regulation by the Commission.

INTRODUCTION

Recognizing the health benefits and low safety risks of dietary supplements, Congress enacted the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 ("DSHEA"), to enable companies like Bayer to market dietary supplements without subjecting those products to the extensive pre-market testing and approval requirements imposed on drugs under the Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 ("FDCA"). In keeping with DSHEA's text and purpose, the FTC has long made clear that a dietary supplement manufacturer can make claims regarding the health benefits of its products so long as the statements have reasonable scientific support—what the agency's Advertising Guide refers to as "competent and reliable scientific evidence." FTC, *Dietary Supplements: An Advertising Guide for Industry* at 9 (Apr. 2001).[1] This is a lower and more flexible standard than the FDCA's "substantial evidence" standard, which generally requires product-specific, well-controlled randomized clinical trials ("RCTs") to prove a drug's safety and efficacy. *See* 21 U.S.C. § 355(d); 21 C.F.R. § 314.126. As the FTC's Advertising Guide explains, unlike the rigid drug-approval standard, there is "no set protocol" for the type of studies required to substantiate a dietary supplement claim. *See* Advertising Guide at 12; *see also id.* at 10–11 (discussing the various types of

[1] *Available at* http://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf (last visited Feb. 19, 2015).

evidence that may suffice for any given claim).

Recently, however, the FTC has sought to go beyond the flexible substantiation standard enshrined in its Advertising Guide (and, apparently, to leave behind the balanced regulatory scheme that Congress established in DSHEA). The FTC has acknowledged—indeed, it has boasted—that it is seeking to impose a "more precise" substantiation standard through enforcement actions. Remarks by David C. Vladeck, Director, FTC Bureau of Consumer Protection, *Priorities for Dietary Supplement Advertising Enforcement* at 11 (Oct. 22, 2009).[2] To this end, in some recent enforcement actions, the FTC has taken the position that *all* dietary supplement claims—including basic health-benefit claims ("structure/function" claims in DSHEA's terminology)—must be supported with the *same* product-specific RCTs required to prove safety and efficacy in order to obtain FDA approval to market a drug. Indeed, even for those companies that have consent decrees or injunctions that predate the FTC's new campaign and adopt word-for-word the Advertising Guide's "flexible" standard (Advertising Guide at 8), the FTC has argued that that standard is not flexible at all but instead requires the same proof of efficacy through product-specific RCTs as required by the FDCA for drugs. *See Basic Research, LLC v. FTC*, No. 2:09-cv-0779,

[2] *Available at* http://www.ftc.gov/sites/default/files/documents/public_statements/priorities-dietary-supplement-advertising-enforcement/091022vladeckcrnspeech.pdf (last visited Feb. 19, 2015).

Memorandum and Order at 7 (D. Utah Nov. 25, 2014); *FTC v. Garden of Life, Inc.*, 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); *FTC v. Nat'l Urological Grp.*, No. 1:04-cv-03294, Doc. 332-1, Plaintiff's Memorandum In Support Of Its Motion For An Order To Show Cause at 3–4 (N.D. Ga. Nov. 11, 2011).

In this case, for example, the government contends that Bayer violated a 2007 consent decree by claiming that its probiotic supplement, Phillips' Colon Health, "help[s] with" and "helps defend against" "occasional constipation, diarrhea, gas, and bloating." FTC Brief in Support of Motion to Show Cause, Doc. 4-1, at 5–6, 9–10 (Sept. 12, 2014) ("FTC Brief"). Even though Bayer's consent decree mirrors the flexible substantiation standard in the FTC's Advertising Guide, and even though the claims at issue here are precisely the type of structure/function claims that Congress in enacting DSHEA sought to ensure would not be subjected to the FDCA's drug-approval standard, the government seeks to hold Bayer in contempt, arguing that Bayer was required to conduct the same type of RCTs to support these claims as would be required to obtain FDA approval of a drug.

The Court should reject the government's effort to use the Court's contempt power to erase Congress's distinction between dietary supplements and dietary supplement structure/function claims and drugs and drug claims. The substantiation standard under which the government seeks to hold Bayer in

contempt is not set forth in the consent decree. That by itself is dispositive of the government's contempt motion. *See* Defendant's Brief Showing Why It Should Not Be Held In Contempt, Doc. 73, at 32–34 (Dec. 12, 2014) ("Bayer Brief").

But the problems with the government's proposed substantiation standard, and its campaign to impose it through actions like this one, run far deeper. Requiring drug-like substantiation for dietary supplement structure/function claims is contrary to DSHEA as well as the FTC's own guidance—which, remarkably, the FTC has not withdrawn even as it seeks to leverage the threat of contempt to impose a different standard. The government's new approach also raises grave First Amendment concerns. And the government's effort to implement this unfounded legal standard through the back door of contempt actions deprives citizens of fair notice and violates basic principles of administrative law.

ARGUMENT

I. The Government's Proposed Substantiation Standard Is Contrary To Law.

The government's contempt motion is premised on the theory that Bayer must conduct the same kind of RCTs as would be required to obtain FDA approval of a drug before it may make health-benefit claims for a dietary supplement. *See* FTC Brief at 16. That position rewrites DSHEA.

A. The Government's Theory Is Incompatible With DSHEA.

The government's effort to impose a drug-like substantiation standard on

Bayer is wholly inconsistent with DSHEA. The very purpose of DSHEA was to eliminate what Congress found to be "unreasonable regulatory barriers" to the marketing of dietary supplements, which Congress found were "safe within a broad range of intake," by preventing the government from treating dietary supplements like drugs. DSHEA § 2(13), (14); *see also Dietary Supplements: Hearing before the H. Subcomm. on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Committee on Appropriations*, 103rd Cong. 27 (1993) (statement of Sen. Hatch) (substantiation standard for dietary supplement claims is a "lesser standard" than the requirement for drug claims). The government's effort to reinterpret "competent and reliable scientific evidence"—the relevant language of Bayer's consent decree—to mean "substantial evidence" as used in the FDCA's drug-approval provisions would undo exactly what Congress enacted DSHEA to accomplish.

Under the FDCA, any new drug and its label must be approved by FDA before the drug may be sold, 21 U.S.C. § 331(d); *id.* § 355(a), and any claims regarding the efficacy of a drug must be supported by "substantial evidence," *id.* § 355(d). The FDA has issued detailed regulations explaining that the FDCA's "substantial evidence" standard for "drugs" generally requires randomized, well-controlled, double-blind clinical trials supporting any drug-efficacy claim. 21 C.F.R. § 314.126.

In 1994, however, Congress amended the FDCA through DSHEA to ensure that dietary supplements would *not* be regulated like drugs. S. Rep. No. 103-410, at 33 (1994) ("dietary supplements are not drugs" and should not be regulated like drugs). Congress found dietary supplements to be generally safe and healthful, DSHEA § 2(2), (14), and enacted DSHEA to "narrow the reach of the FDA's preauthorization scheme" and its substantial evidence standard out of concern that "excessive regulation of dietary supplements" would prevent useful products from coming to market and "suppress . . . truthful information" in the process. *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 224 (2d Cir. 1998) (internal quotation marks omitted).

To prevent the government from treating dietary supplements as if they were drugs, DSHEA clarifies that dietary supplements will be regulated as foods, DSHEA § 3(a), and will thus be exempt from the FDCA's arduous preapproval requirements and the "substantial evidence" standard applicable to drugs. As long as the supplement is not marketed like a drug—*i.e.*, the manufacturer does not claim that the supplement can "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," 21 U.S.C. § 343(r)(6)—the supplement will not be regulated like a drug. Marketing a supplement with drug claims prohibited by section 343(r)(6) would transform the product, as a matter of law, from a food into a drug, subjecting it to the FDCA's regime applicable to drugs. *See also*

Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1038 (10th Cir. 2006) ("Congress enacted DSHEA to clarify that dietary supplements, absent declarations promoting the supplements as drugs, would be regulated in a manner similar to food products.").

DSHEA explicitly distinguishes "general well-being" claims and claims regarding how a product affects "the structure or function" of the human body from prohibited drug claims. 21 U.S.C. § 343(r)(6)(A). "Structure/function" claims are permitted so long as the manufacturer "has substantiation that [the claim] is truthful and not misleading." *Id*. § 343(r)(6)(B). So, for example, a calcium supplement manufacturer may state that its product "helps build strong bones," which is a basic "structure/function" claim, without having to meet the "substantial evidence" standard applicable to drugs under the FDCA, but it may not claim that its product "cures or prevents the disease osteoporosis." *See* FDA Guidance, *Label Claims for Conventional Foods and Dietary Supplements* (Dec. 2013).[3] The rationale underlying this distinction between permitted structure/function claims and forbidden drug claims is straightforward: "Unproven disease claims on a product marketed as a dietary supplement may induce consumers to treat themselves with the supplement instead of seeking treatments that are known to be effective." 65 Fed. Reg. 1000, 1006 (Jan. 6, 2000).

[3] *Available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm (last visited Feb. 19, 2015).

Bayer's claims for Phillips' Colon Health are not drug claims; instead, they are exactly the type of structure/function claims DSHEA intended to exempt from drug-level substantiation standards. The government appears to recognize as much with respect to Bayer's claim that Phillips' Colon Health "promote[s] overall digestive health." Dkt. No. 81, at 4–5. And (contrary to the government's unexplained suggestion, *id.*) Bayer's claims that Phillips' Colon Health helps "defend against occasional constipation, diarrhea, gas, and bloating" and "help[s] with occasional constipation, diarrhea, gas and bloating" are just as clearly structure/function claims permitted under DSHEA. An FDA final rule promulgated after DSHEA is directly on point: a claim that a product is designed "for relief of 'occasional constipation' should not be considered [a] disease claim[]" because it does not refer explicitly or implicitly to an effect on a disease state. *See* 65 Fed. Reg. 1000, 1026 (Jan. 6, 2000). Similarly, claims that a product "'[a]lleviates the symptoms referred to as gas'" or "'alleviates bloating'" are structure/function claims "because the symptoms . . . are not sufficiently characteristic of specific diseases." *Id.* at 1031.

This Court should reject the government's proposed substantiation standard. By seeking to impose RCTs for even basic structure/function claims for a probiotic supplement, the government is trying to do exactly what Congress sought to prevent in enacting DSHEA. As FDA has recognized, DSHEA's purpose was to

broaden the scope of the claims that may be made for dietary supplements "without subjecting them to regulation as drugs." 65 Fed. Reg. at 1000–01, 1008. DSHEA was enacted to remove "unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers." DSHEA § 2(13). The government has no license to reimpose the "unreasonable regulatory barriers" that Congress enacted DSHEA to eliminate.

B. The Government's Position Raises Serious First Amendment Issues.

Even if DSHEA could somehow be read to allow the government to require the same kind of substantiation—product-specific RCTs, and nothing less—for structure/function claims for a probiotic supplement as for drug claims for drugs, such a requirement would raise serious First Amendment concerns. The Court should therefore reject the government's proposed standard as a matter of constitutional avoidance.

Commercial speech is firmly protected by the First Amendment. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976). The free flow of commercial information serves societal interests by expanding consumer knowledge regarding the goods and services available in the marketplace. *See id.* "The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish . . . . [T]he general rule is that the speaker and the audience, not the government, [will]

assess the value of the information presented." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). The constitutional command that the channels of commercial speech generally should remain free from government interference has "great relevance" with respect to "the fields of medicine and public health." *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2664 (2011).

Yet under the government's proposed substantiation standard, scientific certainty would be required before a company like Bayer could lawfully speak about its products: Bayer would have to prove, through the same rigorous evidence required to demonstrate that a drug is safe and effective, that its advertising claims were true. That gets things exactly backwards under basic First Amendment principles, where prior restraints are forbidden and the speaker has the right to speak, with the burden on the government (or tort plaintiff) to prove that the speech is false or misleading. *Cf.* 15 U.S.C. § 45(a)(1) (FTC Act prohibition of "deceptive" practices). To be sure, certain speech that is "false" or "inherently misleading" can be banned. *Va. State Bd. of Pharmacy*, 425 U.S. at 771. But the government cannot redefine as "false" any speech that the speaker has not proved to be true with scientific certainty. As the D.C. Circuit held in *Pearson v. Shalala*, the lack of scientific agreement about health claims by a dietary-supplement manufacturer does not allow the government to declare that speech false or misleading or ban it. 164 F.3d 650, 655 (D.C. Cir. 1999).

In the gray area between advertising claims that are provably true under the government's drug-approval standard and claims that are false or misleading are claims involving legitimate scientific debate. The D.C. Circuit correctly described the government's argument that "health claims lacking 'significant scientific agreement' are inherently misleading" as "almost frivolous," *id.*, and the government does not openly renew that argument here. As a result, any regulation limiting such claims can be upheld only if (1) "the asserted governmental interest is substantial"; (2) "the regulation directly advances the governmental interest asserted"; and (3) "it is not more extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980); *see also Sorrell*, 131 S. Ct. at 2659 (holding that "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the . . . First Amendment" and striking down a statute that burdened such speech).

Congress, in enacting DSHEA, deliberately distinguished dietary supplements from drugs so that claims in support of supplements—which it viewed as generally safe and useful products—would be subject to a more lenient standard. *See* DSHEA § 2, (2), (13), (14). There is no "substantial" government interest in countermanding Congress's mandate by holding dietary supplements to the same standard as drugs. Nor, in any event, could the government plausibly contend that requiring drug-like RCT proof for dietary supplement structure/function claims "is

not more extensive than is necessary" to achieve any legitimate purpose of protecting against fraud. *Pearson*, 164 F.3d at 656–58.

The government's position in this case thus likely violates the First Amendment. But the Court need not wrestle with that constitutional question. As explained above, the government's contempt motion is premised on a legal standard that is contrary to DSHEA, so the Court can and should reject it without regard to the constitutional concerns it raises. At the very least, however, the government's proposed standard is certainly not unambiguously compelled by DSHEA, and to the extent the Court finds ambiguity in the statute, the Court should construe the statute to avoid these First Amendment concerns. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988).

Moreover, as Bayer explains at greater length, even if the government's new substantiation standard could somehow be reconciled with DSHEA and the First Amendment, the government cannot remotely satisfy its burden to show that the consent decree unambiguously required Bayer to meet that standard for the claims at issue here. *See* Bayer Brief at 33–35. To the contrary, the decree simply required "competent and reliable scientific evidence," which was universally and correctly understood to set a lower and more flexible bar than the FDCA's "substantial evidence" requirement for drug approval—until the FTC embarked on

its current campaign to erase the distinction between those two standards. Because the decree did not put Bayer on clear notice that structure/function claims had to be supported by the same RCT proof as drug claims, Bayer cannot be held in contempt for failing to meet that standard and the Court need not go any further. *See Harris v. City of Phila.*, 47 F.3d 1342, 1348–49 (3d Cir. 1995) (to be "placed at risk of contempt," a defendant must have been "given specific notice of the norm to which [it] must pattern [its] conduct" and must have violated "clear and unambiguous provision of the consent decree"); *see also Garden of Life*, 845 F. Supp. 2d at 1335–37 (rejecting FTC's effort to "read additional requirements into the Consent Decree"); *Basic Research*, Memorandum and Order at 26–27 (rejecting FTC's effort to "require[] a level of substantiation that exceeds the requirements of the [consent decree]").

II. The FTC's Effort To Use Contempt Sanctions To Redefine The Substantiation Standard Raises Troubling Due Process Issues And Runs Afoul Of Fundamental Principles Of Administrative Law.

Not only is the government's effort to impose a drug-like substantiation standard on dietary supplement structure/function claims contrary to DSHEA as well as the FTC's own guidance, but the government's effort to implement this unfounded legal standard through the back door of contempt actions deprives citizens of fair notice and contravenes basic principles of administrative law.

A. Bayer Lacked Sufficient Notice That RCT Proof Would Be Required For Its Claims.

Consistent with DSHEA, the FTC itself long recognized that the competent-and-reliable-scientific-evidence standard contained in Bayer's consent decree is lower and more flexible than the substantial-evidence standard applicable to drugs. In fact, almost fourteen years ago, in the only guidance the FTC has ever published on the subject, the FTC explained that, unlike with drugs, "[t]here is no fixed formula for the number or type of studies required" to measure "the adequacy of the scientific support for a specific advertising claim" for a dietary supplement. Advertising Guide at 9. Instead, what is needed to substantiate a dietary supplement claim depends on many factors, including the type of product, the type of claim, the benefits of a truthful claim, the cost of developing substantiation, the consequences of a false claim, and the amount of substantiation that experts in the field believe is reasonable. *Id.* at 8–9. While "well-controlled human clinical studies are the most reliable form of evidence," they are not necessarily required; animal studies, *in vitro* studies, and epidemiological evidence will often suffice. *Id*. at 10.

The FTC has neither withdrawn nor amended its Advertising Guide and has negotiated scores of consent decrees that mirror its "flexible" standard, Advertising Guide at 3, including the consent decree Bayer agreed to here. *See, e.g.*, Consent Decree at 2 (Doc. 2); *In re NBTY, Inc.*, FTC File No. 102-3080, 2011 WL 3346435

(Mar. 22, 2011) (Consent Order); *In re Brain-Pad, Inc.*, FTC File No. 122-3073, 2012 WL 3597372 (Aug. 16, 2012) (Agreement Containing Consent Order); *In re Native Essence Herb Co.*, FTC File No. 9328, 2009 WL 1420305 (May 12, 2009) (Consent Order); *In re Herbs Nutrition Corp.*, FTC File No. 9325, 2008 WL 258310 (Jan. 17, 2008) (Consent Order); *In re Hi-Health Supermart Corp.*, FTC File No. 032-3239, 2005 WL 568483 (Feb. 15, 2005) (Consent Order).

In recent years, however, the FTC has engaged in what can only be described as a bait and switch. When it comes to enforcing these consent decrees, the FTC has at times argued that the substantiation standard they contain is not "flexible" at all. Instead, the FTC argues—as it has here—that even the most basic health-benefit claims require at least one product-specific, double-blind RCT on par with the RCTs required for drugs under the FDCA. *See* FTC Brief at 16 (arguing that all claims must meet drug standards); *Basic Research*, Memorandum and Order at 7 (similar); *Garden of Life*, 845 F. Supp. 2d at 1335 (similar); *Nat'l Urological Grp.*, Doc. 332-1, at 3–4 (similar).

Courts have recently rejected these efforts. *See Basic Research*, Memorandum and Order at 26–27; *Garden of Life*, 845 F. Supp. 2d at 1335. As two courts recently recognized, when a consent decree speaks only of "competent and reliable scientific evidence," the government cannot redefine it through expert testimony or otherwise. *Garden of Life*, 845 F. Supp. 2d at 1335–37 (rejecting

FTC's effort to "read additional requirements into the Consent Decree"); *see also Basic Research*, Memorandum and Order at 26–27 (rejecting FTC's effort to "require[] a level of substantiation that exceeds the requirements of the [consent decree]"). But the government's pursuit of contempt sanctions against Bayer shows that it has not been deterred by those courts' criticisms and is determined to pursue its effort to smuggle the FDA drug-approval standard into consent decrees that track the Advertising Guide's standard.

Basic principles of notice and due process require, however, that companies like Bayer have sufficient notice of what conduct may be met with the sledgehammer of contempt. Before the government may impose penalties in an enforcement action—let alone contempt sanctions—it has an obligation to provide "fair warning of the conduct" prohibited. *Gates & Fox Co. v. Occupational Safety & Health Review Comm'n*, 790 F.2d 154, 156 (D.C. Cir. 1986) (overturning citation when agency regulation did not clearly proscribe conduct for which employer was cited). Because nothing in Bayer's consent decree or the agency's guidance suggests that even basic health-benefit claims like those at issue here must be supported by the same substantiation required of drug claims, enforcing that standard via contempt would cause precisely the kind of "unfair surprise" the Supreme Court has repeatedly warned against. *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2167–68 (2012) (internal quotation marks

omitted); *see NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 295 (1974) (agency should not change an interpretation in an adjudicative proceeding where doing so would impose "new liability . . . on individuals for past actions which were taken in good-faith reliance on [agency] pronouncements" or in a case involving "fines or damages"); *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170–71 (2007) (agency should act in all matters to prevent "unfair surprise" of regulated public); *cf. Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 158 (1991) ("adequacy of notice to regulated parties" is key factor relevant to reasonableness of agency's interpretation).

When Bayer and numerous other dietary supplement manufacturers agreed to consent decrees employing a substantiation standard lauded by the FTC for its flexibility, they could have had no notice whatsoever that they could be held in contempt for making structure/function claims without proof from RCTs. To be sure, in recent years, the FTC has been able to persuade some companies to agree to have RCT proof for certain health-benefit claims (mostly weight and fat-loss claims). *See, e.g.*, *In re HealthyLife Sciences, LLC*, FTC File No. 122 3287, 2014 WL 4651907 (Sept. 11, 2014) (Consent Order) (requiring two RCTs for all weight-loss and fat-loss claims); *FTC v. Iovate Health Sciences*, No. 10-cv-587, Slip op. at 7 (W.D.N.Y. July 29, 2010) (Stipulated Final Judgment) (requiring two RCTs for all weight-loss and fat-loss claims). But imposing the FDCA drug-approval

standard on structure/function claims for dietary supplements was not even a gleam in the FTC's eye when it entered into the consent decree at issue here in 2007—which explains why the decree does not set forth any such requirement.

The government suggests (Br. at 9) that decrees where the FTC succeeded in obtaining specific language imposing the drug-approval standard, on the one hand, and decrees where the FTC did *not* succeed in imposing that standard, on the other, all mean the same thing. That defies logic. In reality, the FTC has used different standards in different decrees *because* those standards are different. When the FTC intends to require RCT proof for certain claims, it knows how to do so. *See In re L'Occitane, Inc.*, FTC File No. 122 3115, 2014 WL 187444 (Jan. 7, 2014) (Agreement Containing Consent Order) (requiring two RCTs for "substantial" fat or weight-loss claims but employing the Advertising Guide's substantiation standard for claims that a supplement "eliminates cellulite or affects body fat or weight"). In any event, the terms of a settlement cannot speak to the question of what the law is; the fear of reputational injury or devastating contempt sanctions may have induced some companies to acquiesce to the FTC's effort to impose the FDCA drug-approval standard on dietary supplement claims, but that does not make that standard the law. The government cannot bootstrap a few companies' agreement via settlement to meet drug-approval standards into a conclusion that the FTC Act (or DSHEA) imposes that standard.

This Court should join its sister courts and refuse to hold Bayer in contempt for not meeting a substantiation standard that appears nowhere in the consent decree and finds no support in the law. *See Basic Research*, Memorandum and Order at 26–27; *Garden of Life*, 845 F. Supp. 2d at 1335.

B. The Government Is Circumventing The Administrative Process.

The FTC has never engaged in rulemaking on the subject of advertising for dietary supplements. The only official statement it has ever made, in fact, is its Advertising Guide issued in 2001 that recites the flexible substantiation standard that has been the law for decades. *Compare* Advertising Guide at 9 *with In re Pfizer, Inc.*, 81 F.T.C. 23, 1972 WL 127465, at *30–31 (July 11, 1972). And since Congress enacted DSHEA in 1994, the FTC has repeatedly made clear that manufacturers of dietary supplements can make ordinary claims regarding the health benefits of their products without drug-like RCTs so long as those statements have reasonable support.

Instead of withdrawing the Advertising Guide or otherwise formally changing its position, the FTC has simply ignored this history. Unhappy with the flexibility that this long-held standard provides and suspicious of the dietary supplement industry, the FTC has recently decided that a "more precise" substantiation standard is needed, Remarks by David C. Vladeck at 11, and is on a campaign to tighten up its regulation of the industry, *see* Mary K. Engle, Associate

Director for Advertising Practices, *The FTC's Advertising Priorities* (Arnold & Porter Roundtable Breakfast Series Oct. 22, 2009).[4]

But rather than go to Congress to ask for this change in law, the FTC instead has sought to change well-settled law through the "potent weapon" of contempt, *Int'l Longshoremen's Ass'n, Local 1291 v. Phila. Marine Trade Ass'n*, 389 U.S. 64, 76 (1967), counting on the threat of large penalties and reputational injury to induce companies to accept a standard that has no basis in law. As the Supreme Court recently admonished, "[i]t is one thing to expect regulated parties to conform their conduct to an agency's [regulatory policy] once the agency announces [it]; it is quite another to require regulated parties to divine the agency's [policy] in advance or else be held liable." *Christopher*, 132 S. Ct. at 2168 (internal quotations and citation omitted). Holding Bayer in *contempt* for not divining the FTC's current policy in advance would take the lack of proper notice decried in *Christopher* to an entirely new level.

CONCLUSION

For the foregoing reasons, the Court should deny the government's motion to hold Bayer in contempt.

[4] *Available at* http://www.arnoldporter.com/resources/documents/FalseAdvertisingDisputesRoundtableMaterials102209.pdf (last visited Feb. 19, 2015).

Dated: February 20, 2015

Respectfully submitted,

/s/ Austin A. Evans

Austin A. Evans
Bar No. 04127-2005
KING & SPALDING LLP
1180 Peachtree Street, NE
Atlanta, GA 30309
Telephone: (404) 572-4600
Facsimile: (404) 572-5100
aevans@kslaw.com

Of counsel
Jeffrey S. Bucholtz
David M. Barnes
KING & SPALDING LLP
1700 Pennsylvania Ave., NW
Washington, D.C. 20006
Telephone: (202) 737-0500
Facsimile: (202) 626-3737
jbucholtz@kslaw.com
dbarnes@kslaw.com

Of counsel:
Merritt E. McAlister
KING & SPALDING LLP
1180 Peachtree Street, NE
Atlanta, GA 30309
Telephone: (404) 572-4600
Facsimile: (404) 572-5100
mmcalister@kslaw.com

Of counsel:
Kathryn Comerford Todd
Steven P. Lehotsky
U.S. CHAMBER
LITIGATION CENTER, INC.
1615 H Street, NW
Washington, D.C. 20062
Telephone: (202) 463-5337
Facsimile: (202) 463-5346
KTodd@USChamber.com
SLehotsky@USChamber.com

CERTIFICATE OF SERVICE

I hereby certify that on February 20, 2015, a copy of the foregoing was electronically filed with the Clerk of the Court using CM/ECF system, which will send notification to all counsel of record.

/s/ Austin A. Evans
Austin A. Evans

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

UNITED STATES OF AMERICA, Plaintiff, v. BAYER CORPORATION, Defendant.	No. 2:07-cv-0001-JLL-JAD (Hon. Jose L. Linares) Motion Date: March 16, 2015

[PROPOSED] ORDER

THIS MATTER, having been opened to the Court on the motion of the Chamber of Commerce of the United States ("Chamber"), by counsel, for entry of an Order granting the Chamber leave to appear and participate as *amicus curiae*; and all parties, by counsel, having received due notice of the motion and having the opportunity to be heard; and the Court having reviewed all papers and arguments relevant to the Chamber's motion;

IT IS on this ___ day of _____, 2015,

ORDERED that Chamber's Motion be and hereby is **GRANTED**.

IT IS FURTHER ORDERED that Chamber be and hereby is granted leave to appear and participate as *amicus curiae* in this case.

IT IS FURTHER ORDERED that Chamber's proposed *amicus* brief attached to Chamber's Notice of Motion shall hereby be deemed filed.

_____

Hon. Jose L. Linares
United States District Judge