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* NATURAL PRODUCTS ASSOCIATION

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INTEREST OF THE *AMICI*

Founded in 1936, the Natural Products Association ("NPA") is the nation's largest and oldest nonprofit organization dedicated to the natural products industry.[1] NPA advocates for the right of consumers to have access to products that will maintain and improve their health, and for the right of retailers and suppliers to sell these products. NPA represents over 1,900 members (94 of which are based in New Jersey), accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. NPA unites a diverse membership, from the smallest health food store to the largest dietary supplement manufacturer. Defendant Bayer Corporation ("Bayer") is not an NPA member.

NPA played a key role in the passage of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325. This important legislation struck a balance between the need for consumers to have access to and information about safe and effective dietary supplements while also preserving the government's interest in protecting the public from unsafe products and false and misleading claims. NPA's CEO and Executive Director, Daniel

[1] Natural products are represented by a wide array of consumer goods that grow in popularity each year. These products include natural and organic foods, dietary supplements, pet foods, health and beauty products, "green" cleaning supplies and more. Generally, natural products are considered those formulated without artificial ingredients and that are minimally processed.

Fabricant, Ph.D., previously served as the Director of Dietary Supplement Programs at the Food and Drug Administration.

INTRODUCTION

The case involves a claim by the Government that defendant Bayer violated a 2007 consent judgment in its marketing of its Phillips' Colon Health probiotic supplement product, marketed as a proprietary formula of three bacteria strains. Product packaging and advertising states that the product "Helps Defend Against Occasional: Constipation, Diarrhea, Gas and Bloating." Even though the standard for claim substantiation for dietary supplements is "competent and reliable scientific evidence," the Government's Motion argues that Bayer's structure-function claims must be substantiated by randomized, controlled, and double blind clinical studies.

While NPA does not take a position on the outcome of this specific case against Bayer, it is concerned that the Government's position is contrary to federal statutory law and would reduce the availability of cost-effective dietary supplements to American consumers. Dietary supplements that are not marketed as drugs were not intended to be subject to the same standards as drugs, which do require substantiation by full clinical trial research. Requiring that standard would drive many responsible supplement companies that make and sell safe and beneficial products out of business. NPA is very concerned that the Government is

using consent orders to effectively re-write federal law on dietary supplements. Rules of general applicability should be promulgated through notice and comment rulemaking under the strictures of the Administrative Procedure Act.

BACKGROUND

NPA will leave it to the parties to this litigation to provide the Court with a full discussion of the facts and the supporting evidence. For context, NPA notes that the case arose from a 2007 consent order that required Bayer to possess "competent and reliable scientific evidence" for dietary supplement claims. (Dkt. No. 2 at 3-5). This is the same standard embodied in FTC and FDA guidance that applies generally to all dietary supplements.

The Motion now before the Court involves Phillips' Colon Health, a probiotic supplement marketed as a proprietary formula of three bacteria types that can help defend against occasional constipation, diarrhea, gas and bloating. The Government asserts that the 100 scientific papers and letters submitted by Bayer are not evidence substantiating its claims because of one doctor's opinion that the only way to substantiate the claims would be by conducting randomized, controlled, double blind clinical trials on the three bacterial strains. It does not appear that the Government submitted any evidence to the Court of the feasibility or costs of conducting such trials.

ARGUMENT

I. THE GOVERNMENT'S POSITION THAT DIETARY SUPPLEMENT CLAIMS REQUIRE SUBSTANTIATION THROUGH TWO RANDOMIZED DOUBLE BLIND CLINICAL TRIALS IS CONTRARY TO LAW.

The Government's Motion is premised on the notion that a nutritional statement claim can only be substantiated by a randomized double blind clinical trial. That position, however, is completely contradicted by DSHEA. The Government is trying to rewrite the law in a way that will cause useful supplements to be pulled from the shelves and greatly increase costs to the supplement industry and consumers. That is not what Congress intended when it unanimously passed DSHEA in 1994.

Asserting that "improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government" and that "the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies," DSHEA became law on October 25, 1994, and took effect in 1996. The statute represented a victory for the millions of consumers of dietary supplements who felt that the FDA advocated unreasonable regulatory guidelines. The language of the statute addressed this concern by stating that "the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers" and that "dietary

supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare." DSHEA § 2. DSHEA further found that "consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements. *Id.* § 2(8).

The statute defines a dietary supplement to be:

> a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

21 U.S.C. § 321(ff).

Dietary supplement labels cannot claim to treat a disease, but may contain statements of nutritional support, in which "the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes 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, or describes general well-being from consumption of a nutrient or dietary ingredient . . . ." 21 U.S.C. § 343(r)(6)(A) (emphasis added). An example of a structure/function claim is the popular dietary supplement St. John's

Wort, which a seller may claim to be a "mood-brightener" but not a cure for depression, which is a specific disease. *See, e.g.*, J. Beisler, DIETARY SUPPLEMENTS AND THEIR DISCONTENTS: FDA REGULATION AND THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994, 31 Rutgers L.J. 511, 517 n.29 (2000).

The FDA has provided specific guidance explaining the claims at issue here are permissible structure/function claims, not disease claims. *See* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000-01, 2000 WL 4559, at *1028-29 (2000); FDA, Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide (2002) (Criterion 8) (available at http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm103340.htm); *id.* at *1026 ("occasional constipation" is a structure/function claim); *id.* at *1031 ("alleviates . . . gas and bloating" are structure/function claims).

DSHEA also requires that a statement of nutritional support must have "substantiation that such statement is truthful and not misleading" and contain a disclaimer that the "statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 343(r)(6)(B)-(C).

The Government's position is contrary to the Congressional intent as reflected in DSHEA's legislative history. DSHEA was introduced to counteract "unnecessarily stringent" federal intervention into the manufacturing, sale, labelling of dietary supplements and government overregulation. 103 CONG. REC. S4577 (daily ed. Apr. 7, 1993) (statement of Sen. Hatch); 103 CONG. REC. S17049 (daily ed. Nov. 23, 1993) (statement of Sen. Hatch). The legislation concluded that consumer well-being is improved when there is greater access to dietary supplements. 103 CONG. REC. S4577 (daily ed. Apr. 7, 1993) (statement of Sen. Hatch). Supplement producers should be free from intervention as long as "the labelling and advertising are truthful, non-misleading, and there exists a reasonable scientific basis for products claims." *Id*. There isn't the slightest indication in the legislative history that a dietary supplement provider should conduct clinical trials to substantiate the labelling of the products. To the contrary, dietary supplement providers only need to provide a reasonably scientific basis for the claims. *Id*. Thus, the Government's position in this case directly contradicts Congress's intent in passing DSHEA.

The FDA has recognized that "DSHEA's purpose [is] to broaden the scope of labeling claims that may be made for dietary supplements without subjecting them to regulation as drugs." 65 Fed. Reg. 1000-01, 2000 WL 4559 at *1024. Consistent with that purpose, substantiation of structure/function claims under

DSHEA requires only that manufacturers have "competent and reliable scientific evidence," which has been defined by the FDA and FTC to include "tests, analyses, research, studies, or other evidence . . . ." Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide (Criterion 8). Under DSHEA, dietary supplement manufacturers are not required to conduct clinical trials or efficacy testing. *See* FDA Comment Request, Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act, 76 Fed. Reg. 51988-01, 2011 WL 3624830 (2011).

In *FTC v. QT, Inc.*, 512 F.3d 858 (7th Cir. 2008), the Court found that a claim could be substantiated without conducting a full clinical trial:

> Some passages in [the District Court decision] could be read to imply that any statement about a product's therapeutic effects must be deemed false unless the claim has been verified in a placebo-controlled, double blind study . . .
>
> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not yet been tested in the most reliable way cannot be condemned out of hand. The burden is on the [government] to prove that the statements are false. … Think about the seller of an adhesive bandage treated with a disinfectant such as iodine. The seller does not need to conduct tests before asserting that this product reduces the risk of infection from cuts. The bandage keeps foreign materials out of the cuts and kills some bacteria. It may be debatable how much the risk of infection falls, but the direction of the effect would be known, and the claim could not be condemned as false. Placebo-controlled, double-blind testing is not a legal requirement for consumer products.

Id. at 862. Judge Easterbrook also noted that "[a] placebo-controlled study is the best test; something less may do (for there is no point in spending $1 million to verify a claim worth only $10,000 if true) ...." *Id.*

Thus, imposing full-scale clinical trials to substantiate structure/function nutritional statement claims is not consistent with DSHEA and prior regulatory guidance and judicial decisions. As the primary sponsor of DSHEA, Sen. Hatch, made clear, supplement claims must be supported by a "reasonable scientific basis…." 103 CONG. REC. S4577 (daily ed. Apr. 7, 1993). The Government's attempt to graft a full clinical trial requirement into the law is without support.

II. THE GOVERNMENT'S ATTEMPTED USE OF INDIVIDUAL CONSENT ORDERS AND CONTEMPT PROCEEDINGS TO TRY TO REMAKE THE DIETARY SUPPLEMENT INDUSTRY IS TROUBLING.

While NPA and its members support the prevention of unfair and deceptive acts, they are concerned about the use of consent orders to impose requirements on the dietary supplement industry that exceed the scope of the law and past practices.[2] The Government's use of consent orders in this way is procedurally inappropriate and may have unintended consequences for consumers. Obviously,

[2] *See, e.g.*, *In the Matter of Nestle Health Care Nutrition, Inc.*, No. 0923087 (FTC May 18, 2010) (available at http://www.ftc.gov/sites/default/files/documents/cases/2010/07/100714nestleorder.pdf); *FTC v. Iovate Health Sciences USA, Inc.*, No. 10-cv-587 (W.D.N.Y. July 29, 2010) (available at http://www.ftc.gov/enforcement/cases-proceedings/072-3187/iovate-health-sciences-usa-inc).

consent orders are case specific: they are not designed to be applied across the industry. This case evidences that is exactly what is happening, which could have negative outcomes for consumers both from a cost perspective, but also in potentially reducing the quality and quantity of information about products available to them.

When application of extra-statutory interpretations moves from consent orders into rules of general applicability, such overreach is not beneficial to anyone and particularly to consumers. One example would be the Government's view that additional studies and research are necessary prior to advertising, specifically, a requirement to conduct two double-blind, randomized control trials to support legal structure/function statements, which is not a current legal or regulatory requirement.

This is not only outside of the statute, but leads to unnecessary and inefficient use of resources, which chills innovation and dis-incentivizes the very research needed to substantiate claims.

Moreover, this is being done without any cost-benefit analysis on behalf of consumers or the economy. If the Court issues the order to show cuase it would send a message that companies would no longer be able to rely on the variety of studies conducted on their products. Moreover, randomized controlled trials for supplements are not always possible or ethical, and in many instances are cost

prohibitive. Applying a standard agreed to in *some consent decrees*, but not others, as a rule of general applicability would actually result in less information being available to consumers – not more. This is a critical concern, as it appears to violate the Administrative Procedure Act ("APA"), Pub. L. 79–404, 60 Stat. 237. An agency may not adopt rules that reverse or depart radically from its own long-standing policy without invoking the notice-and-comment process. *See, e.g., Jean v. Nelson*, 711 F.2d 1455, 1476 (11th Cir. 1983); *Boyd v. Glickman*, 12 F. Supp. 2d 1261, 1270 (M.D. Ala. 1998) ("If an agency adopts rules that reverse or depart radically from prior longstanding policy, the agency must invoke the notice-and-comment process required by the APA.").

The Government is attempting to eliminate the difference between structure/function and disease claims for dietary supplements using litigation-driven settlements with individual companies. The Government's strategy has caused confusion in the industry on how to comply with DSHEA and existing FDA and FTC guidance, increasing the risks to companies in the supplement market. As discussed above, overregulation of dietary supplements was the driving force behind passage of DSHEA in 1994. Despite that statute and the clear intent of Congress, the use of consent orders is moving the industry to a point where it appears the Government is equating structure/functional nutritional statement claims with drug claims. If that happens, safe and effective supplements will

disappear from store shelves, particularly products formulated, made and sold by small businesses that will simply be unable to afford the huge costs associated with the same kind of clinical trials required to bring drugs to market, *i.e.*, multiple randomized, double blind trials. The only possible alternative would be to avoid making otherwise scientifically-supported structure/function claims, which would have the constitutionally-suspect effect of deterring protected commercial speech and depriving consumers of useful information. *See, e.g.*, *Pearson v. Shalala*, 130 F. Supp. 2d 105, 114-19 (D.D.C. 2001) (claim cannot be suppressed as misleading when at least one credible study had shown the ingredient to be effective).

Assuming *arguendo* that the legal standard the Government wants could be obtained without repealing DSHEA, at the very least the Government must implement the change through the proper procedures, including notice and comment rulemaking under the APA. That process would permit the supplement industry, consumers and other stakeholders to participate in a full analysis and discussion of the costs and benefits of changes to the regulatory scheme. The *ad hoc* nature of regulatory changes using consent orders – and contempt proceedings – improperly limits the discussion to only the litigants (and any *amici*) and excludes the public. It would also enable NPA's members to know what the standard is. The current approach where DSHEA and agency guidance says one thing, and the Government in litigation documents takes the opposite position, is

disruptive and counterproductive as it chills protected speech and limits consumers access to safe and effective supplements.

CONCLUSION

NPA does not take a position on the ultimate issue in this case. NPA and its members, however, do have serious concerns about the Government's attempts to rewrite DSHEA and impose costly drug-like clinical trial requirements on safe and beneficial dietary supplements with structure/function claims. The standard the Government is attempting to impose is inconsistent with law. NPA also opposes the Government's efforts to make these changes in litigation through imposing and enforcing consent orders.

Dated: October 3, 2014

Respectfully submitted,

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