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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. BAYER CORPORATION, Defendant.	Case No. 2:07-cv-00001 (JLL)(JAD) PLAINTIFF'S RESPONSE TO NATURAL PRODUCTS ASSOCIATION'S MOTION TO FILE BRIEF AS AMICUS CURIAE MOTION DATE: November 3, 2014

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INTRODUCTION

The government's motion to show cause is about one defendant's specific efficacy claims for one proprietary, three-strain mixture. Therefore, the liability phase of this contempt proceeding has only one fundamental question: Has Defendant Bayer Corporation failed to comply with this Court's 2007 Order when making specific claims about constipation, diarrhea, and gas and bloating for Phillips' Colon Health?

Although the Natural Products Association ("NPA") argues otherwise, this case is not about a change to a legal standard or an attempt by the government to re-make the dietary supplement industry. Accordingly, while the government takes no position on NPA's motion for leave to file, Dkt. No. 22, the government respectfully submits that NPA's participation in this matter is unlikely to provide any assistance to this Court, for four reasons: (1) NPA is too partial to a particular outcome in this matter to add anything meaningful; (2) NPA's claimed interests are already well represented by Bayer; (3) NPA misstates what this case is about and raises arguments not made by the parties; and (4) NPA does not and cannot seek to assist this Court on the precise question before it — whether Bayer possesses and relies upon competent and reliable scientific evidence while making specific express and implied efficacy claims about its product, Phillips' Colon Health.

LEGAL STANDARD

"'The extent, if any, to which an *amicus curiae* should be permitted to participate in a pending action is solely within the broad discretion of the district court.'" *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002) (quoting *Waste Mgmt. of Pa., Inc. v. City of York*, 162 F.R.D. 34, 36 (M.D. Pa. 1995)). While there is no rule governing the appearance of amicus curiae in the United States District Courts, Appellate Rule 29 provides guidance. *Id.* Appellate Rule 29(b) permits a party to seek leave to appear as amicus curiae by motion stating "(1) the movant's interest; and (2) the reason why an amicus brief is desirable and why the matters asserted are relevant to the disposition of the case." *Neonatology Assocs., P.A. v. Comm'r*, 293 F.3d 128, 130–31 (3d Cir. 2002).

However, "'[a]t the trial level, where issues of fact as well as law predominate, the aid of *amicus curiae* may be less appropriate than at the appellate level where such participation has become standard procedure.'" *Alkaabi*, 223 F. Supp. 2d at 592 n.16 (quoting *Yip v. Pagano*, 606 F. Supp. 1566, 1568 (D.N.J. 1985)); *see also Prof'l Drug Co. Inc. v. Wyeth Inc.*, No. 11-5479, 2012 WL 4794587, at *1–2 (D.N.J. Oct. 3, 2012) (quoting *Alkaabi* when denying a request by the Federal Trade Commission ("FTC") to appear as amicus curiae). Courts typically grant amicus curiae status when "(1) the *amicus* has a 'special interest' in the particular case; (2) the *amicus*' interest is not represented competently or at all

in the case; (3) the proffered information is timely and useful; and (4) the *amicus* is not partial to a particular outcome in the case." *Alkaabi*, 223 F. Supp. 2d at 592. Also, where a district court lacks joint consent of the parties, it should "'go slow'" to accept an amicus brief unless "'the amicus has a special interest that justifies his having a say.'" *Linker v. Custom-Bilt Mach. Inc.*, 594 F. Supp. 894, 898 (E.D. Pa. 1984) (quoting *Strasser v. Doorley*, 432 F.2d 567, 569 (1st Cir. 1970)).

ARGUMENT

I. NPA is Too Partial to a Particular Outcome in This Matter

This Court should discount NPA's brief because NPA seeks a particular outcome in a matter that applies only to Bayer. While an amicus curiae does not have to be completely impartial, *Alkaabi*, 223 F. Supp. 2d at 592, NPA's partiality suggests that this Court should give little, if any, weight to its views.

NPA wants this Court to hold, as a legal matter, that competent and reliable scientific evidence for any of Bayer's specific performance, benefits, or efficacy claims for Phillips' Colon Health cannot require a product- and population-specific randomized, controlled, clinical trial. *See* Memorandum of Law in Support of Natural Products Association's Motion to File Brief Amicus Curiae, Dkt. No. 22-1, at 5–6 ("The test the Government would impose — full blown clinical trials — could force NPA to stop selling safe and beneficial products to their customers at reasonable prices.") The logical conclusion from NPA's arguments is that it does

not want this Court to find Bayer in contempt, even though such an outcome would have no effect on NPA — or any of its constituent members — because to find contempt, the Court will have only considered the evidence related to Bayer's specific claims about constipation, diarrhea, and gas and bloating for Phillips' Colon Health. Different claims for different products might require different substantiation, and the government is not asking this Court to address such hypotheticals.

This situation is very different from the question in *Alkaabi*, where, in 2002, the court allowed the Royal Embassy of Saudi Arabia to participate as amicus curiae in one of a number of similar criminal cases against Saudi Arabian citizens and given "the heightened scrutiny faced by persons of Arab descent as a result of the events of the past year." *Id.* at 592–93. Nor is this situation like the circumstances of *Neonatology Assocs.*, a tax-related matter where amici were non-settling participants of the same insurance plan at issue in an appeal brought by settling participants. *Neonatology Assocs.*, 293 F.3d at 129–30. In that matter, the non-settling participants filed an amicus brief to make sure the appellate court did "not inadvertently stray into issues that need not be decided in this case" that could affect amici's concurrent class action suit against the insurer. *Id.* at 130. Whether this Court finds Bayer in contempt does not have any impact on NPA or its members because only Bayer sells Phillips' Colon Health using the specific

symptom-efficacy claims at issue here that are subject to the 2007 Order. Thus, NPA's partiality weighs against its brief in this matter.

II. NPA's Proffered Interests Are Well Represented by Defendant

This Court should also discount NPA's brief because its proffered interests are competently and well represented by Bayer in its own opposition to the government's motion, *see* Defendant's Brief in Opposition to the Government's Motion for an Order to Show Cause, Dkt. No. 23. An amicus brief that does "little more than duplicat[e] arguments raised by the parties" is not useful to the court. *Prof'l Drug Co. Inc.*, No. 11-5479, 2012 WL 4794587, at *2 (citing *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir.1997)). Yet that is precisely what NPA's brief does here.

Bayer's brief and NPA's brief are remarkably similar. Both seek to pick apart as "novel" the longstanding legal standard applicable to Bayer's lack of substantiation. NPA asserts that its interests cannot be competently represented by Bayer because Bayer is not a member of NPA and because NPA's interests as a trade association are not represented by Bayer. Dkt. No. 22-1, at 6. But Bayer's opposition to the government's motion is based on the very same interests as NPA's interests; NPA's role as a trade association does not automatically make those interests distinct.

A review of NPA's brief clearly shows just how well Bayer already

represents NPA's self-described interests. NPA desires to present to this Court arguments concerning (1) its advocacy "for the rights 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," Brief of Amicus Curiae Natural Products Association, Dkt. No. 22-2, at 1; (2) how "the Government's position is contrary to federal statutory law," *id.* at 2; and (3) how the substantiation required for Bayer's claims "would drive many responsible supplement companies that make and sell safe and beneficial products out of business," *id.*

NPA's assistance to the Court on these matters is unnecessary, however, because Bayer already has represented those very same interests extensively in its opposition to the United States' motion. Indeed, Bayer's entire opposition is premised on the notion that the government's case is "novel" and that the substantiation required for its specific claims conflicts with "agency guidance[] and the underlying statute." *See* Dkt. No. 23, at 1–2. Bayer also addresses the alleged potential industry fallout from this matter, noting that "the *in terrorem* effect of the government's action may well be industry-wide, potentially clearing probiotics and other dietary supplements from drugstore shelves." *Id.* at 22–23. Finally, Bayer competently presents the same consumer interests in its opposition. *Id.* at 18 (arguing that "dietary supplements provide health benefits and that consumers should be 'empowered' to make their own choices from available

information").

As a result, NPA's interests are already well represented by Bayer itself.

III. NPA's Brief Will Not be Useful to This Court Because It Misstates What This Case Is About and Raises Arguments Not Made by the Parties

NPA's brief will not assist this Court in determining whether Bayer is in contempt of the 2007 Order. NPA asserts the United States is "trying to rewrite the law" concerning dietary supplements such that it "will cause useful supplements to be pulled from the shelves and greatly increase costs to the supplement industry and consumers." *See* Dkt. No. 22-2, at 4. In addition, NPA's amicus curiae brief raises arguments that neither party has brought into dispute, such as NPA's assertion that the government is improperly using consent orders to supplant the Administrative Procedure Act, *see id.* at 11. Because this case is *not* about the above issues, NPA's brief only serves to distract this Court and waste time.

As the United States made clear in its motion and reply, this matter is only about determining whether Bayer possessed and relied upon competent and reliable scientific evidence, based on the expertise of professionals in the relevant area, at the time it made its particular efficacy claims about constipation, diarrhea,

and gas and bloating for Phillips' Colon Health.[1] Dkt. No. 4-1, at 1–7; Dkt. No. 38, at 1–7. The government also pointed out the fact that competent and reliable scientific evidence "has long been the standard for evaluating substantiation of claims like those at issue here" and "is fact-specific and flexible enough to encompass a wide variety of claims for all types of dietary supplements, from a simple mineral tablet to a proprietary compound like [Phillips' Colon Health] that contains multiple strains of bacteria." Dkt. No. 38, at 2. Therefore, this case is *not* about the government trying to establish a new, one-size-fits-all, approach to all dietary supplement claims, as NPA suggests. *See* Dkt. No. 22-2, at 4 (NPA claims that "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"). Indeed, the United States has said:

> while it is true that not every claim for every dietary supplement requires a product- and population-specific [randomized, controlled, clinical trial], a [randomized, controlled, clinical trial] is required to substantiate any of Bayer's specific claims under the FTC guidance and this Court's Order, because that is what experts in the field demand for those claims.

Dkt. No. 38, at 3. Simply put, the United States is not trying to change the way an entire industry works through its action against Bayer, and NPA's attempt to turn

[1] In its brief, NPA appears to recognize this point. *See* Dkt. No. 22-2, at 9–10 ("Obviously, consent orders are case specific: they are not designed to be applied across the industry.")

this matter into that sort of case is distracting and unhelpful to this Court.

In addition, NPA's proposed brief also raises arguments not put forth by either party as being in dispute. As this Court has recognized, "'[a]n amicus cannot initiate, create, extend, or enlarge issues.'" *Alkaabi*, 223 F. Supp. 2d at 593 n.19 (quoting *Waste Mgmt. of Pa., Inc.*, 162 F.R.D. at 36). Yet NPA's brief attempts to bring before the Court issues that neither party has argued are in dispute, such as that the government is requiring "two randomized double blind clinical trials" to substantiate all structure/function claims,[2] Dkt. No. 22-2, at 4; and that the government is improperly using consent orders to "remake the dietary supplement industry" in violation of the Administrative Procedure Act,[3] *id.* at 9, 11. As a result, NPA's brief will further distract this Court from determining whether Bayer is in contempt of the 2007 Order.

[2] Nowhere in the United States' show cause motion does it refer to a requirement for Bayer to conduct two separate clinical trials for the same claim (i.e., after obtaining statistically significant results to substantiate a claim in one trial, conducting a *second* trial for that *same* claim to see if statistically significant results are achieved again). Because Bayer makes more than one claim for Phillips' Colon Health, however, more than one clinical trial might be necessary to properly substantiate the entire array of Bayer's claims. *See* Dkt. No. 38, at 2, n.2.

[3] As discussed above, what is necessary as competent and reliable scientific evidence in this matter is based on Bayer's particular claims for a specific product, Phillips' Colon Health. Therefore, the government is not seeking to impose a new "rule[] of general applicability," as NPA suggests, *see* Dkt. No. 22-2, at 10.

IV. NPA Does Not and Cannot Seek to Assist This Court on the Precise Question Before It

Finally, NPA does not and cannot assist the Court in determining whether Bayer, as a matter of fact, possessed and relied upon competent and reliable scientific evidence when it made express and implied efficacy claims about constipation, diarrhea, and gas and bloating for Phillips' Colon Health. Unlike the United States, NPA did not provide this Court with a careful review of Bayer's advertising claims and expert gastroenterological analysis of the purported substantiation for the product and claims at issue — which is the information this Court needs to determine if Bayer is in violation of its 2007 Order. Indeed, NPA cannot shed any light whatsoever on evidence Bayer might have in its possession, nor can it aid this Court in determining Bayer's own alleged reliance on the same.

CONCLUSION

NPA has too partial of an interest in this matter, even though it will not be affected by a finding that Bayer is in contempt of this Court's 2007 Order. Moreover, NPA has failed to demonstrate that it has or will provide the Court with any useful assistance in deciding this case. Accordingly, while the government takes no position on NPA's motion for leave to file, the government respectfully submits this Court should place little, if any, weight on NPA's brief.

Dated: October 20, 2014

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