

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

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UNITED STATES OF AMERICA,		)	
		)	
Plaintiff,		)	No. 2:07-cv-0001-JLL-JAD
		)	(Hon. Jose L. Linares)
v.		)	
		)	Motion Date: November 3, 2014
BAYER CORPORATION,		)	
		)	
Defendant.		)	
<hr/>		)	

**MEMORANDUM OF LAW IN SUPPORT OF  
NATURAL PRODUCTS ASSOCIATION'S  
MOTION TO FILE BRIEF *AMICUS CURIAE***

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Dated: October 3, 2014

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The Natural Products Association (“NPA”) moves for leave to file the accompanying proposed Brief of *Amicus Curiae*. Defendant Bayer Corporation (“Bayer”) consents to NPA’s filing of an *amicus* brief;<sup>1</sup> the Government takes no position on the motion at this time.

The decision whether to grant leave to file an *amicus* brief is within the sound discretion of the District Court. *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002). In recent years, this Court has granted numerous *amici* leave to file briefs, *see, e.g., Nat’l Union Fire Ins. Co. of Pittsburgh v. K Hovnanian Enters., Inc.*, No. 3:10-cv-6258, 2011 WL 4915899, at \*1 (D.N.J. Oct. 17, 2011); *Jama v. U.S. Immigration and Naturalization Serv.*, 334 F. Supp. 2d 662, 673 (D.N.J. 2004); *Alkaabi*, 223 F. Supp. 2d at 592, including several member associations in positions similar to NPA, *see, e.g., Foley v. Horizon Blue Cross Blue Shield of N.J., Inc.*, No. 06-6219, 2007 WL 2694069, at \*1 (D.N.J. Sept. 11, 2007) (New Jersey Association of Health Plans); *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 562 (D.N.J. 2004) (American Association for Health Freedom); *Video Pipeline, Inc. v. Buena Vista Home Entm’t, Inc.*, 192 F. Supp. 2d 321, 327 (D.N.J. 2002) (Video Software Dealers Association, National Association of Recording Merchandisers, and Motion Picture Association of America).

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<sup>1</sup> Bayer is not a member of NPA.

Because the issues presented by this case are of substantial interest to NPA and its members, and because NPA's proposed *amicus* brief would aid in the Court's consideration of those issues by addressing matters on which NPA has particular expertise, this Court should grant leave to file. *See, e.g.*, Fed. R. App. P. 29(b); *Harris v. Pernsley*, 820 F.2d 592, 603 (3d Cir. 1987) (concluding *amicus* briefs "may be advisable where third parties can contribute to the court's understanding"). NPA's participation as *amicus* satisfies all relevant factors for deciding whether to grant leave to file.

**I. THE FACTORS IN FEDERAL RULE OF APPELLATE PROCEDURE 29(B) SUPPORT GRANTING NPA LEAVE TO FILE.**

District courts often consider by analogy the requirements of Federal Rule of Appellate Procedure 29(b) in exercising their discretion whether to grant leave to file *amicus* briefs. *See, e.g.*, *Alkaabi*, 223 F. Supp. 2d at 592; *Foley*, 2007 WL 2694069, at \*1; *see also Washington Gas & Light Co. v. Prince George's Cnty. Council*, No. 08-0967, 2012 WL 832756, at \*3 (D. Md. Mar. 9, 2012) ("District courts . . . have discretion whether to grant or deny such leave and often look for guidance to Rule 29 of the Federal Rules of Appellate Procedure."); *Martinez v. Capital Cities/ABC-WPVI*, 909 F. Supp. 283, 286 (E.D. Pa. 1995) ("[t]here is no specific statute or rule . . . , and I am therefore guided by Rule 29 of the Federal Rules of Appellate Procedure."). Rule 29 provides that motions for leave to file *amicus* briefs must state "the movant's interest," as well as "the reason why an

amicus brief is desirable and why the matters asserted are relevant to the disposition of the case.” Fed. R. App. P. 29(b). NPA and its proposed *amicus* brief satisfy those requirements.

*First*, NPA and its membership have a substantial interest in the Court’s resolution of this case. Founded in 1936, NPA is the nation’s largest and oldest nonprofit organization dedicated to the natural products industry.<sup>2</sup> 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 is not an NPA member.

*Second*, NPA believes that the Court would find desirable its focused participation in this case as *amicus*. This case raises issues regarding the federal regulatory and statutory scheme governing dietary supplements. NPA played a key

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<sup>2</sup> 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.

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 Fabricant, Ph.D., previously served as the Director of Dietary Supplement Programs at the Food and Drug Administration. Given its long experience in this area, NPA has particular expertise addressing the meaning and purpose of these provisions and how they work in practice. *See Liberty Res., Inc. v. Philadelphia Housing Auth.*, 395 F. Supp. 2d 206, 209-10 (E.D. Pa. 2005) (“Courts have found the participation of an amicus especially proper where the amicus will ensure ‘complete and plenary presentation of difficult issues so that the court may reach a proper decision.’”) (quoting *Alliance of Auto Mfrs. v. Gwadowsky*, 297 F. Supp. 2d 305, 307 (D. Me. 2003)). In this way, NPA’s *amicus* brief would “contribute to the court’s understanding” of the regulatory framework in which the parties’ arguments are made. *Harris*, 820 F.2d at 603.

*Third*, NPA’s proposed *amicus* brief discusses issues central to the case. Both parties recognize the relevance of the statutory and regulatory framework



governing dietary supplements. NPA's proposed brief provides additional information on issues raised by the parties.

**II. ADDITIONAL FACTORS THIS COURT HAS CONSIDERED ALSO SUPPORT GRANTING NPA LEAVE TO FILE.**

This Court has considered four other factors in determining whether to grant *amici* leave to file, some of which overlap with the requirements in Rule 29 discussed above. These include whether (1) “the *amicus* has a ‘special interest’ in the particular case”; (2) the *amicus*'s 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. Although frequently invoked, this Court has never held these four non-exhaustive factors to be dispositive, nor that a proposed *amicus* must satisfy a particular number of them to succeed. For example, in *Alkaabi* itself, this Court granted leave to file after mentioning the four above factors but only analyzing two: that *amicus* had a “particularly strong interest” and had “submitted a thorough and well-written brief”; the Court brushed aside “partiality” as irrelevant. *See id.* at 592-93.

As addressed more fully above, NPA does have a “special interest” in the outcome of this case. This case concerns the substantiation of claims for dietary supplement products. 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 Government's motion raises questions on the regulation and operation of the supplement industry. NPA and its members will be affected disproportionately by any decision with significant impact on the industry. And, as discussed above, NPA believes its proposed *amicus* brief would be useful to the Court.

NPA's interests *as a trade association* are not represented by the parties. Bayer is not a member of NPA. NPA occupies a unique position as representative of the natural products industry as a whole. The parties necessarily focus their arguments on the particular supplements at issue, and the course of dealing between them, while NPA's proposed brief focuses on the potential implications of the Government's arguments on the entire industry. This Court has readily accepted *amicus* briefs in cases, like this one, where a trade group is filing a brief in a case involving companies or organizations in that industry.<sup>3</sup>

NPA's proposed *amicus* brief is also timely. It is tendered 21 days after the Government filed its motion and the same day that Bayer's opposition brief is due under the Court's scheduling order.

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<sup>3</sup> See, e.g., *Foley*, 2007 WL 2694069, at \*1 (granting leave to file to the New Jersey Association of Health Plans in support of party Blue Cross and Blue Shield); *Lane Labs-USA, Inc.*, 324 F. Supp. 2d at 562 (granting leave to the American Association for Health Freedom in support of party Lane Labs-USA); *Video Pipeline, Inc.*, 192 F. Supp. 2d at 327 (granting leave to the Motion Picture Association of America in support of party Buena Vista Home Entertainment).

NPA has no direct financial interest in the outcome of this specific proceeding, even if it has an interest in the legal issues presented by the case, as adoption of at least certain arguments made by the Government would cause grave harm to the dietary supplement industry, including NPA and its members. Moreover, “there is no rule that the amicus must be impartial” in an absolute sense. *Waste Mgmt. of Penn., Inc. v. City of York*, 162 F.R.D. 34, 37 (M.D. Pa. 1995); see also *Alkaabi*, 223 F. Supp. 2d at 592 (“Parties with pecuniary and policy interests have been regularly allowed to appear as *amici* in our courts,” and holding that its “partisan stance is not a bar to its appearance as *amicus*”). Indeed, the Court has cast doubt on the relevance of impartiality as a factor, recognizing that “by the very nature of things the *amicus* is not normally impartial.” *Smith v. Chrysler Fin. Co.*, No. 00-6003, 2003 WL 328719, at \*8 (D.N.J. Jan. 15, 2003) (quoting *United States v. Gotti*, 755 F. Supp. 1157, 1158 (E.D.N.Y. 1991)). Rather, *amici* “provide supplementary assistance to existing counsel and insur[e] a complete and plenary presentation of difficult issues so that the court may reach a proper decision.” *Gotti*, 755 F. Supp. at 1158. The Third Circuit has similarly questioned the continued utility of the impartiality factor, noting that the “description of the role of an amicus was once accurate and still appears in certain sources,” but “became outdated long ago.” *Neonatology Assocs., P.A. v. C.I.R.*, 293 F.3d 128, 131 (3d Cir. 2002) (Alito, J.). After all, “[t]oday, . . . Rule 29 requires that an amicus have an

‘interest’ in the case,” and the “argument that an amicus must be ‘impartial’ is difficult to square with this requirement.” *Id.* Instead, “an amicus who makes a strong but responsible presentation in support of a party can truly serve as the court’s friend.” *Id.*

### **CONCLUSION**

In light of NPA’s significant interest in this case, and the useful information its timely proposed *amicus* brief would provide the Court on important issues, NPA respectfully requests the Court grant this Motion for Leave to File Brief of *Amicus Curiae* and accept the accompanying proposed *amicus* brief for filing.

Dated: October 3, 2014

Respectfully submitted,

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