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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
COUNCIL FOR RESPONSIBLE
NUTRITION'S MOTION FOR
LEAVE 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 Council for Responsible Nutrition ("CRN") 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 CRN's motion for leave to file, Dkt. No. 24, the government respectfully submits that CRN's participation in this matter is unlikely to provide any assistance to this Court, for four reasons: (1) Bayer has a direct and leadership role in CRN, meaning that CRN is too partial to a particular outcome in this matter to add anything meaningful; (2) CRN's claimed interests are already well represented by Bayer; (3) CRN misstates what this case is about and raises arguments not made by the parties; and (4) CRN 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. Because Bayer HealthCare Has a Direct and Leadership Role in CRN, CRN Is Too Partial to a Particular Outcome in This Matter

CRN’s participation is essentially a second opportunity for Bayer to present its views using an industry association. While an amicus curiae does not have to be completely impartial, *Alkaabi*, 223 F. Supp. 2d at 592, CRN is far from an unbiased participant here. CRN notes that Bayer HealthCare LLC, a subsidiary of Bayer Corporation, is a member of CRN. Memorandum in Support of Motion for Leave to File Brief as Amicus Curiae, Dkt. No. 24-1, at 2 n.1. Yet the relationship with Bayer is much deeper than CRN revealed.

Bayer has had a longstanding, and continued, role in CRN. Critically, Phillips’ Colon Health is a brand of Bayer HealthCare. Decl. of Crystal D. Ostrum, Ex. 18, Dkt. No. 4-5, at 1. Even more, since at least 2009 — covering nearly the entire time Phillips’ Colon Health has been on the market — representatives from Bayer HealthCare have been on CRN’s Board of Directors.

Bayer in-house counsel David Christensen held a CRN officer position in 2009 and 2010 (Treasurer), followed by another two years on CRN's Board's *Executive Committee* and a third year as a member of CRN's Board. Certification of Shannon L. Pedersen, Exs. 1–5. While serving on CRN's Executive Committee, Mr. Christensen signed a certification for Bayer in response to the FTC's investigation of Phillips' Colon Health. *See id.*, Ex. 7 (signed in September 2011). A different Bayer HealthCare employee then became a member of CRN's Board in 2014. *Id.*, Ex. 6.

Perhaps it is no surprise, then, that CRN seeks a particular outcome in a matter that applies only to Bayer. As mentioned, while an amicus curiae does not have to be completely impartial, *Alkaabi*, 223 F. Supp. 2d at 592, CRN's partiality suggests that this Court should give little, if any, weight to its views.

CRN 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* Dkt. No. 24-1, at 2 (“[T]he standard the FTC proposes is a significant departure from past government precedent that, if adopted and applied, would have implications not only for Bayer but also for the entire dietary supplement industry”) The logical conclusion from CRN'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 CRN — or any of its other 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, 133–34. Whether this Court finds Bayer in contempt does not have any impact on CRN or its members (other than Bayer) because only Bayer sells Phillips’ Colon Health using the specific symptom-efficacy claims at issue here that are subject to the

2007 Order. Thus, CRN's partiality weighs against its brief in this matter.

Because of Bayer's longstanding participation on CRN's Board of Directors, CRN's interest in this matter is far too close to Bayer's own. As a result, CRN is doing little more than providing Bayer a second opportunity to express its own views that it is not in contempt of this Court's 2007 Order.

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

Even if CRN did have special interests in this matter separate from that of Bayer, this Court should still discount CRN's brief because those 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 CRN's brief does here.

Bayer's brief and CRN's brief read like two peas in a pod. Both seek to pick apart as "novel" the longstanding legal standard applicable to Bayer's lack of substantiation. CRN asserts that its interests cannot be competently represented by Bayer because Bayer "is a single company" and does not represent the "dietary supplement industry as a whole." Dkt. No. 24-1, at 7. But Bayer's opposition to

the government's motion is based on the very same interests as CRN's interests; CRN's role as a trade association does not automatically make those interests distinct.¹

A review of CRN's brief clearly shows just how well Bayer already represents CRN's self-described interests. CRN desires to present to this Court arguments concerning (1) how the government's position in this case is "novel, erroneous, and inconsistent with agency guidance," Brief of Amicus Curiae Council for Responsible Nutrition, Dkt. No. 25-2, at 2; (2) that adoption of this supposedly "novel" standard would cause industry confusion, *see id.* at 19–21, resulting in dietary supplement companies changing claims and denying consumers "important and truthful information" about dietary supplements, *id.* at 4; and (3) that the standard is in violation of the First Amendment, *id.* at 16–19.

¹ CRN's reference to *C&A Carbone, Inc. v. Cnty. of Rockland*, No. 08-6459, 2014 WL 1202699 (S.D.N.Y. Mar. 24, 2014), is unavailing. *See* Dkt. No. 24-1, at 6–7. There, the court noted that "it is fairly evident that the ultimate outcome of this litigation could prove dispositive in future disputes over flow control ordinances that extend to recyclables," and as a result, "trade associations representing various interests in the recyclable materials market" could assist the court in addressing how the ordinance at issue's "treatment of recyclables differs from those that have previously been examined." *C&A Carbone*, 2014 WL 1202699, at *4. Here, as discussed above, the outcome of this litigation will only be dispositive concerning Bayer's compliance with this Court's 2007 Order based on Bayer's particular and very specific claims for one product, Phillips' Colon Health, and the parties have already provided this Court with a fulsome presentation of the issues concerning the alleged novelty of the government's action.

CRN'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." *See* Dkt. No. 23, at 1. Bayer even makes a more aggressive argument concerning 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 First Amendment argument in its opposition. *Id.* at 16–18.

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

III. CRN'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

CRN's brief will not assist this Court in determining whether Bayer is in contempt of the 2007 Order. CRN asserts the United States is attempting to make a "change in law" and a "wholesale change in the governing substantiation standard" used for dietary supplement claims. Dkt. No. 24-1, at 7–8. In addition, CRN's amicus curiae brief raises arguments that neither party has brought into dispute, such as that the government has relied on the wrong area of expertise, Dkt. No. 25-1, at 12. Because this case is *not* about the above issues, CRN'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. 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, “drug-like approach” to the substantiation necessary for “non-disease claims made for dietary supplements,” as CRN suggests.² *See* Dkt. No. 24-1, at 4. 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,

² Indeed, in its brief, CRN appears to concede this point. *See* Dkt. No. 25-1, at 19 (noting that “randomized, double-blind clinical studies *generally* are not required to substantiate dietary supplement structure/function claims”) (emphasis added).

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 CRN's attempt to turn this matter into that sort of case is distracting and unhelpful to this Court.

In addition, CRN's 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 CRN's brief attempts to bring before the Court issues that neither party has argued is in dispute, such as that the government has relied on the wrong area of expertise,³ and that it may be infeasible to substantiate Bayer's claims for Phillips' Colon Health as required.⁴ *See* Dkt. No. 25-1, at 12, 14. As a result, CRN's brief will further distract this Court from determining whether Bayer is in contempt of the 2007 Order.

³ In its brief, CRN asserts that the government has not established how gastroenterology is the relevant area of expertise, *see* Dkt. No. 25-1, at 13, even though the government described that relevancy in its motion, *see* Dkt. No. 4-1, at 16 (explaining that gastroenterology is the directly relevant area of expertise because constipation, diarrhea, and gas and bloating are digestive symptoms).

⁴ In its brief, CRN provides no evidence supporting this assertion; instead, it merely proposes a number of hypothetical situations allegedly supporting its argument. *See* Dkt. No. 25-1, at 14–15.

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

Finally, CRN 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, CRN 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, CRN 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

CRN's interest in this matter is no different from that of Bayer's interest, as evidenced by the fact that Bayer HealthCare has had a direct and leadership role on CRN's Board of Directors. Moreover, CRN 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 CRN's motion for leave to file, the government respectfully submits this Court should place little, if any, weight on CRN's brief.

Dated: October 20, 2014

Respectfully submitted,

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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)

CERTIFICATION OF
SHANNON L. PEDERSEN

I, Shannon L. Pedersen, hereby certify as follows:

1. I am a Trial Attorney in the U.S. Department of Justice's Consumer Protection Branch. I am an attorney of record for Plaintiff United States of America, and I have personal knowledge of the facts set forth below.

2. Attached hereto as Exhibit 1 is a true and correct copy of a January 12, 2009, Council for Responsible Nutrition (“CRN”) press release. I downloaded this press release from CRN’s website on October 6, 2014, found at http://www.crnusa.org/prpdfs/CRNPR09_StartsNewYearWithNewChair011209.pdf.

3. Attached hereto as Exhibit 2 is a true and correct copy of a December 17, 2009, CRN press release. I downloaded this press release from CRN’s website on October 6, 2014, found at <http://www.crnusa.org/prpdfs/CRNPR121709.pdf>.

4. Attached hereto as Exhibit 3 is a true and correct copy of a January 3, 2011, CRN press release. I downloaded this press release from CRN’s website on October 6, 2014, found at http://www.crnusa.org/prpdfs/CRNPR11_Announces2011ChairBoardOfficers010311.pdf.

5. Attached hereto as Exhibit 4 is a true and correct copy of a January 19, 2012, CRN press release. I downloaded this press release from CRN’s website on October 6, 2014, found at <http://www.crnusa.org/prpdfs/CRNPR120120BoardReleaseFinal.pdf>.

6. Attached hereto as Exhibit 5 is a true and correct copy of a January 10, 2013, CRN press release. I downloaded this press release from CRN’s website on October 6, 2014, found at <http://www.crnusa.org/prpdfs/CRNPR13->

Board011013.pdf.

7. Attached hereto as Exhibit 6 is a true and correct copy of a January 7, 2014, CRN press release. I downloaded this press release from CRN's website on October 6, 2014, found at <http://www.crnusa.org/prpdfs/CRNPR14-SevenNewBOD010714.pdf>.

8. Attached hereto as Exhibit 7 is a true and correct copy of a Certificate of Compliance provided to the Federal Trade Commission that is signed by Senior Counsel for Bayer Corporation, David Christensen, on September 27, 2011. I received this document from Federal Trade Commission.

9. I hereby certify that the above facts are true to the best of my knowledge. I understand that I am subject to punishment if any of the above facts are willfully false.

Dated: October 20, 2014

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EXHIBIT 1



Council for Responsible Nutrition

The Science Behind the Supplements

FOR IMMEDIATE RELEASE

Contact: Season Solorio 202-204-7682

**CRN STARTS NEW YEAR WITH NEW CHAIR
AND NEW BOARD OF DIRECTORS, OFFICERS**

WASHINGTON, D.C., *January 12, 2009*—The Council for Responsible Nutrition (CRN), the dietary supplement industry's leading trade association, is pleased to announce Mark LeDoux, CEO of Natural Alternatives International, Inc., has been elected chair of the association's Board of Directors. Mr. LeDoux, who will hold the office through 2010, succeeds Marjorie Fine, senior vice president and general counsel, Shaklee Corporation. Ms. Fine will continue to serve on the Board of Directors as immediate past chair.

Mark LeDoux has been a highly regarded leader for the dietary supplement industry for over 20 years since he founded Natural Alternatives International, Inc. in 1980. A visible and active leader in CRN, Mr. LeDoux has served as the chair-elect of the Board during 2007-2008, chair of the CRN Political Action Committee (PAC) since its inception in 2004, and previously served as chair of the association's International Trade and Market Development Committee.

"I have been an avid supporter of CRN for more than a decade and look forward to continuing the association's aggressive agenda and initiatives," said Mr. LeDoux. "During my two-year term, my goal is to strengthen CRN's position as the responsible, leading voice of the dietary supplement industry. This association and its members are advocates for reasonable regulation that promotes unfettered consumer access anywhere in the world to well-made, properly labeled dietary supplements at any potencies that are demonstrated to be safe by appropriate scientific measures."

Working with Mr. LeDoux on CRN's Board of Directors will be 27 member company representatives and CRN President & CEO Steve Mister. The Board will include the following newly elected officers: Chair-elect—Janice Binger, Archer Daniels Midland Company; Treasurer—David Christensen, Bayer HealthCare; Secretary—Kristen Blanchard, Nutramax Laboratories, Inc.; Immediate Past Chair—Marjorie Fine, Shaklee Corporation.

Additionally the following committee chairs have been appointed:

- Government Relations Committee, Howard Scholick, Abbott Nutrition
- International Trade and Market Development Committee, John Venardos, Herbalife International of America, Inc.
- Media Relations Committee, Doug Jones, Pharmavite LLC
- Membership Committee, Chuck Brice, Kemin Health, L.C., and Dave Eckert, Cognis Nutrition & Health (co-chairs)
- Regulatory Affairs Committee, Heidi Horn, Perrigo, and Paul Bolar, Pharmavite LLC (co-chairs)
- Senior Scientific Advisory Council, Zoraida DeFreitas, Kemin Health, L.C.

The newly elected Executive Committee is comprised of the Board officers and additional Board members: (Executive committee is in bold.)

- **Janice Binger, Archer Daniels Midland Company**
- **John Blair, NSA, Inc.**
- **Kristen Blanchard, Nutramax Laboratories, Inc.**
- Paul Bolar, Pharmavite LLC
- Michael Bradley, Perrigo Company
- **David Christensen, Bayer HealthCare**
- Bruce Daggy, GlaxoSmithKline
- Jodi Drexler-Billet, Country Life Vitamins
- Larry Esposito, Innophos, Inc.
- **Marjorie Fine, Shaklee Corporation**
- **Jim Hamilton, DSM Nutritional Products, Inc.**
- David Henstrom, Cargill Health & Nutrition
- Byron Johnson, Amway Corporation
- Harvey Kamil, NBTY, Inc.
- Don Kerrigan, Wyeth Consumer Health
- **Mark LeDoux, Natural Alternatives International, Inc.**
- Doug Lioon, Douglas Laboratories
- Kathy McKnight, Natural Factors Nutritional Products, Inc.
- David Morrison, The Vitamin Shoppe
- Greg Ris, Indena USA, Inc.
- Nick Shackley, BASF Corporation
- Robert Sinott, Mannatech, Inc.

- Don Stanek, Linnea, Inc.
- David Sullivan, General Nutrition Centers, Inc.
- **Bill Van Dyke, B&D Nutritional Ingredients, Inc.**
- **John Venardos, Herbalife International of America, Inc.**
- **Tyler Whitehead, Pharmanex LLC**
- **Bruce Wood, Schiff Nutrition International**

“This is a particularly strong Board representing the diversity of the industry, with company representatives from large companies, small companies, ingredient suppliers, finished product manufacturers, pharmaceutical companies with supplement divisions and companies that make only natural products. Under Mark’s leadership, we expect to continue our growth and aggressive representation of the industry,” said Steve Mister, president & CEO, CRN.

###

Note to Editor: The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement manufacturers and ingredient suppliers. CRN members agree to adhere to voluntary guidelines for manufacturing, labeling and marketing and CRN’s Code of Ethics. Visit www.crnusa.org.

EXHIBIT 2



Council for Responsible Nutrition

The Science Behind the Supplements

FOR IMMEDIATE RELEASE

Contact: Season Solorio 202-204-7682

CRN ANNOUNCES NEWLY ELECTED BOARD OF DIRECTORS MEMBERS

WASHINGTON, D.C., *December 17, 2009*—The Council for Responsible Nutrition (CRN), the dietary supplement industry's leading trade association, is pleased to announce the following executives have been elected to serve on the CRN Board of Directors, effective January 2010: Chuck Brice of Kemin Health L.C., Larry Esposito of Innophos, Inc., Ron Fugate of Alacer Corporation, Scott Hagerman of Chemi Nutra, Carl Hastings of Reliv International, Inc., and Vic Neufeld of Jamieson Laboratories Ltd.

In addition, Jim Hamilton of DSM Nutritional Products, Inc. has been named CRN's new Chair-Elect, replacing Janice Binger, formerly of Archer Daniels Midland.

“This has been a year of change for the dietary supplement industry, particularly with the shift of power in Washington, D.C.,” said Mark LeDoux, CRN Chair. “Similarly the coming year will bring many challenges, but with those challenges comes the prospect of great opportunity. CRN's Board of Directors will strategically lead CRN to meet those challenges and pursue those opportunities both here and abroad.”

Following is a list of CRN's Board of Directors, including Officers, for 2010:

- Natalie Bartner, Pfizer Consumer Healthcare
- John Blair, NSA, Inc.
- Kristen Blanchard, Nutramax Laboratories, Inc. (Secretary)
- Paul Bolar, Pharmavite LLC
- Michael Bradley, Perrigo Company
- Chuck Brice, Kemin Health L.C.
- David Christensen, Bayer Healthcare (Treasurer)
- Greg Dodson, Archer Daniels Midland
- Larry Esposito, Innophos, Inc.
- Marjorie Fine, Shaklee Corporation
- Ron Fugate, Alacer Corporation

-more-

- Scott Hagerman, Chemi Nutra
- Jim Hamilton, DSM Nutritional Products, Inc. (Chair-Elect)
- Carl Hastings, Reliv International, Inc.
- David Henstrom, Cargill Health & Nutrition
- Byron Johnson, Amway Corporation
- Harvey Kamil, NBTY, Inc.
- Mark LeDoux, Natural Alternatives International, Inc. (Chair)
- Doug Lioon, Douglas Laboratories
- Kathy McKnight, Natural Factors Nutritional Products, Inc.
- Raj Mishra, GlaxoSmithKline
- Steve Mister, CRN (President & CEO)
- David Morrison, The Vitamin Shoppe
- Vic Neufeld, Jamieson Laboratories, Ltd.
- Ona Scandurra, Country Life Vitamins
- Nick Shackley, BASF Corporation
- Robert Sinott, Mannatech, Inc.
- Don Stanek, Linnea, Inc.
- David Sullivan, General Nutrition Centers, Inc.
- Bill Van Dyke, B&D Nutritional Ingredients, Inc.
- John Venardos, Herbalife International of America, Inc.
- Tyler Whitehead, NuSkin Enterprises
- Bruce Wood, Schiff Nutrition International

###

Note to Editor: The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement manufacturers and ingredient suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety, our 70+ manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as CRN's Code of Ethics. Visit www.crnusa.org.

EXHIBIT 3



Council for Responsible Nutrition

The Science Behind the Supplements

FOR IMMEDIATE RELEASE

Contact: Katie Stevenson 202-204-7682

CRN ANNOUNCES NEW CHAIRMAN, BOARD OF DIRECTORS, OFFICERS

WASHINGTON, D.C., *January 3, 2011*—The Council for Responsible Nutrition (CRN), the dietary supplement industry's leading trade association, is pleased to announce Jim Hamilton, president of DSM Nutritional Products, USA, Inc., has been elected chair of the association's Board of Directors. Mr. Hamilton, who will hold the chairman post through 2012, succeeds Mark LeDoux, CEO of Natural Alternatives International, Inc. Mr. LeDoux will continue to serve on the Board as immediate past chair.

Currently based at the DSM Nutritional Products USA headquarters in Parsippany, N.J., Mr. Hamilton has held posts in Europe, Canada and the United States over the course of his 25 year career in the nutrition industry. His knowledge of the nutrition industry has made him a valuable contributor to CRN. He has served on the CRN Board for more than five years, most recently as chair-elect.



Jim Hamilton

According to Mr. Hamilton, "Our industry will continue to face challenges over the next two years, and CRN is ready to face those challenges head-on. With a new Congress and increased scrutiny from the regulatory agencies, it is imperative that we continue to work with our champions on Capitol Hill and educate new staffers not familiar with the Dietary Supplement Health and Education Act (DSHEA) and that we urge

for stronger enforcement of the laws in place and step-up our own self-regulatory efforts. I look forward to working with my colleagues on CRN's Board to continue to fulfill CRN's mission."

CRN's new Board of Directors is comprised of 31 member company representatives and CRN President & CEO Steve Mister. CRN's Board elected a slate of new officers to serve alongside Mr. Hamilton during his two-year term: Chair-elect—John Blair, NSA, LLC (Juice Plus+ ®); Treasurer—Ron Fugate, Alacer Corporation; Secretary—Kristen Blanchard, Nutramax Laboratories, Inc.; and Immediate Past Chair—Mark LeDoux, Natural Alternatives International, Inc. In his capacity as CRN President & CEO, Mr. Mister will continue to serve as a Board officer.

The following executives were recently re-elected to serve on CRN's Board of Directors, effective immediately: Ona Scandurra, Country Life Vitamins; Greg Dodson, Archer Daniels Midland; and David Henstrom, Cargill Health & Nutrition. Michael Zeher, Nutrition 21, was newly elected to serve on the board.

Following is a list of CRN's Board of Directors, including the Executive Committee (in bold) and the Officers (as noted), for 2011:

- **John Blair, NSA, LLC (Juice Plus+ ®) (Chair-elect)**
- **Kristen Blanchard, Nutramax Laboratories, Inc. (Secretary)**
- Paul Bolar, Pharmavite LLC
- Michael Bradley, Perrigo Company
- Chuck Brice, Kemin Health
- **David Christensen, Bayer Healthcare**
- Greg Dodson, Archer Daniels Midland
- Larry Esposito, Innophos, Inc.
- Marjorie Fine, Shaklee Corporation
- **Ron Fugate, Alacer Corporation (Treasurer)**
- **Jim Hamilton, DSM Nutritional Products, Inc. (Chair)**
- Carl Hastings, Reliv International, Inc.
- **David Henstrom, Cargill Health & Nutrition**
- **Harvey Kamil, NBTY, Inc.**
- **Mark LeDoux, Natural Alternatives International, Inc. (Immediate Past Chair)**
- Doug Lioon, Atrium Innovations
- **Todd Magazine, Pfizer Consumer Healthcare**
- Niall McStay, BASF Corporation
- **Steve Mister, CRN (President & CEO)**
- David Morrison, The Vitamin Shoppe
- Vic Neufeld, Jamieson Laboratories, Ltd.
- Ona Scandurra, Country Life Vitamins
- Robert Sinnott, Mannatech, Inc.

- Don Stanek, Linnea, Inc.
- Michelle Stout, Amway/Nutrilite
- David Sullivan, General Nutrition Centers, Inc.
- Sharon Tonetta, Bausch & Lomb
- Bill Van Dyke, B&D Nutritional Ingredients, Inc.
- John Venardos, Herbalife Ltd.
- **Tyler Whitehead, Nu Skin Enterprises, Inc.**
- **Bruce Wood, Schiff Nutrition International**
- Michael Zeher, Nutrition 21

Additionally, the following committee chairs have been appointed:

- Government Relations Committee—Diane Turpin, Herbalife Ltd.
- International Trade and Market Development Committee—John Venardos, Herbalife Ltd.
- Media Relations Committee—Doug Jones, Pharmavite
- Membership Committee—Bill Van Dyke, B&D Nutritional Ingredients, Inc.
- Regulatory Affairs Committee—Kevin Boot, Embria Health Sciences and Jesus Muniz, Pfizer Consumer Health
- Senior Scientific Advisory Council—Michael McBurney, DSM Nutritional Products

“We are so appreciative of the involvement of these executives who serve on our Board and lead our committees as they provide the leadership and strategic direction that enables CRN to be so successful. I am looking forward to working closely with Jim as we navigate the future for our association and for this changing industry,” said Steve Mister, president & CEO, CRN.

For a complete list of CRN member companies, visit [CRN’s website](#). For information on membership with CRN, please contact Joyce Nyero, member services coordinator, at 202-204-7670 or jnyero@crnusa.org.

###

The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. In addition to complying with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety, our 75+ manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as CRN’s Code of Ethics. Learn more about us at www.crnusa.org.

EXHIBIT 4



FOR IMMEDIATE RELEASE

Contact: Katie Stevenson, 202-204-7682

CRN ELECTS NEW BOARD MEMBERS, NEW COMMITTEE CHAIRS

WASHINGTON, D.C., *January 19, 2012*—The Council for Responsible Nutrition (CRN), the dietary supplement industry’s leading trade association, is pleased to announce the addition of five newly elected directors for its Board.

Effective immediately, the following executives will join 29 colleagues on the CRN Board: Mike DeGennaro, Lonza, Inc.; Paul Dijkstra, InterHealth Nutraceuticals Inc.; Jim Hyde, Albion Laboratories, Inc.; Mike Satow, Nutrition 21; and Brian Schaneberg, Mars Botanical.

Following is a list of CRN’s Board of Directors, including the Executive Committee (in bold) and the Officers (as noted), for 2012:

- **John Blair, NSA, LLC (Juice Plus+ ®) (Chair-elect)**
- **Kristen Blanchard, Nutramax Laboratories, Inc. (Secretary)**
- Paul Bolar, Pharmavite LLC
- Michael Bradley, Perrigo Company
- **David Christensen, Bayer HealthCare**
- Richard D’Aloisio, Kraft Foods
- Mike DeGennaro, Lonza, Inc.
- Paul Dijkstra, InterHealth Nutraceuticals Inc.
- Greg Dodson, Archer Daniels Midland Company
- Noelle Cloud Dugan, Pfizer Consumer Healthcare (Acting)
- Larry Esposito, Innophos, Inc.
- Marjorie Fine, Shaklee Corporation
- Pierre Fitzgibbon, Atrium Innovations, Inc.
- **Ron Fugate, Alacer Corp. (Treasurer)**
- **Jim Hamilton, DSM Nutritional Products (Chair)**
- Carl Hastings, Reliv International, Inc.
- **David Henstrom, Cargill Health & Nutrition**
- Jim Hyde, Albion Laboratories, Inc.
- Samy Jandali, BASF Corporation
- **Harvey Kamil, NBTY, Inc.**
- **Mark LeDoux, Natural Alternatives International, Inc. (Immediate Past Chair)**
- **Steve Mister, CRN (President & CEO)**

-more-

- **David Morrison, The Vitamin Shoppe**
- Vic Neufeld, Jamieson Laboratories Ltd.
- Al Powers, NOW Foods
- Mike Satow, Nutrition 21
- Ona Scandurra, Country Life Vitamins
- Brian Schaneberg, Mars Botanical
- Michelle Stout, Amway/Nutriline
- David Sullivan, General Nutrition Centers, Inc.
- Sharon Tonetta, Bausch & Lomb
- Debbie Trinker, Kemin Health, L.C.
- John Venardos, Herbalife, Ltd.
- **Tyler Whitehead, Nu Skin Enterprises, Inc.**

In addition, CRN Chairman Jim Hamilton, President of DSM Nutritional Products, in consultation with CRN staff, has appointed new Committee chairs as follows:

- Government Relations Committee—Florence Okaro, NBTY, Inc.
- Government Relations State Subcommittee—Ken Rowe, Airborne, Inc.
- Sports Nutrition Working Group—Keith Wheeler, Abbott Nutrition

Other Committee chairs include:

- Communications and Media Outreach Committee—Doug Jones, Pharmavite LLC
- International Trade and Market Development Committee—John Venardos, Herbalife, Ltd.
- Regulatory Affairs Committee—Kevin Boot, Embria Health Sciences and Jesus Muniz, Pfizer Consumer Healthcare (co-chairs)
- Senior Scientific Advisory Council—Michael McBurney, DSM Nutritional Products

CRN also has numerous subcommittees and working groups.

For a complete list of CRN member companies, visit [CRN's website](#). For information on membership with CRN, please contact Carl Hyland at chyland@crnusa.org or 202-204-7674.

###

The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement manufacturers and ingredient suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety, our 75+ manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as CRN's Code of Ethics. Visit www.crnusa.org.

EXHIBIT 5



FOR IMMEDIATE RELEASE

Contact: Katie Stevenson, 202-204-7682

CRN ANNOUNCES NEW CHAIRMAN, BOARD OF DIRECTORS, OFFICERS

WASHINGTON, D.C., *January 10, 2013*—The Council for Responsible Nutrition (CRN), the dietary supplement industry’s leading trade association, is pleased to announce John Blair, senior vice president of NSA, LLC (JuicePlus+®), has been named chair of the association’s Board of Directors. Mr. Blair, who will hold the chairmanship through 2014, succeeds Jim Hamilton, president of DSM Nutritional Products, USA, Inc.

Mr. Blair, in 1992, spearheaded NSA’s decision to enter the nutrition field, based on NSA’s Juice Plus concept. During his time at NSA, Mr. Blair managed the development of the global manufacturing team that produces the entire Juice Plus line and managed the worldwide clinical research effort for the product line. His knowledge of the health and wellness industry makes him a valuable provider to CRN. He has served on the board most recently as chair elect, and was the conference chair of CRN’s 2012 Annual Conference.

“Our industry will continue to face challenges over the course of the next two years, but we’re prepared for them and this industry is positioned like never before for strong growth,” said Mr. Blair.

“Moving forward in 2013, we’ll work to educate the 113th Congress on health benefits that dietary supplements provide and how they are regulated; we’ll challenge the industry to ensure complete compliance with the laws and regulations already in place; and we’ll be zealous advocates on behalf of our members to promote a commercial marketplace and a regulatory framework supported by sound science. I’m excited about the next two years as CRN’s chairman and look forward to advancing CRN’s mission.”

CRN’s Board also elected a lineup of new officers to serve along with Mr. Blair during his two-year term: Chair Elect—Harvey Kamil, NBTY, Inc.; Treasurer—Debbie Trinker, Kemin Health, L.C.;

Secretary—Kristen Blanchard, Nutramax Laboratories, Inc.; and Immediate Past Chair—Jim Hamilton, DSM Nutritional Products. Mr. Mister, CRN President & CEO, will continue to serve as a Board Officer.

“I am delighted to hand the gavel to John Blair. His experience and capabilities make him uniquely qualified to lead the organization going forward,” said Jim Hamilton, who just completed his two-year term as chairman of CRN’s Board of Directors. “CRN’s Board is composed of an incredibly dedicated group of executives, committed to providing direction and leadership to the valuable work of CRN. I appreciate the opportunity to have been able to act as Chair, look forward to continued contributions as immediate past chair, and wish John much success in his new role.”

Separately, CRN’s membership has elected the new Board of Directors for 2013. Michael Bentley, SierraSil Health Inc.; Paul Dijkstra, InterHealth Nutraceuticals, Inc.; and Paul Faganel, Embria Health Sciences, were newly elected to serve on the Board. Carl Hastings, Reliv International, Inc.; and Vic Neufeld, Jamieson Laboratories Ltd., were re-elected for a second three-year term.

CRN’s new Board of Directors is comprised of 34 member company representatives and CRN President & CEO Steve Mister. Following is a full list of CRN’s Board of Directors, including the Executive Committee (in bold) and the Officers (as noted), for 2013:

- **John Blair, NSA, LLC (Juice Plus+®) (Chair)**
- Michael Bentley, SierraSil Health Inc.
- **Kristen Blanchard, Nutramax Laboratories, Inc. (Secretary)**
- Paul Bolar, Pharmavite LLC
- Michael Bradley, Perrigo Company
- David Christensen, Bayer HealthCare
- Richard D’Aloisio, Mondēlez International, Inc.
- Mike DeGennaro, Lonza, Inc.
- Paul Dijkstra, InterHealth Nutraceuticals, Inc.
- Greg Dodson, Archer Daniels Midland Company
- Paul Faganel, Embria Health Sciences
- Marjorie Fine, Shaklee Corporation
- Pierre Fitzgibbon, Atrium Innovations, Inc.
- **Jim Hamilton, DSM Nutritional Products (Immediate Past Chair)**
- Carl Hastings, Reliv International, Inc.
- **David Henstrom, Cargill Health & Nutrition**
- **T.J. Higgins, Pfizer Consumer Healthcare**
- Jim Hyde, Albion Laboratories, Inc.
- Samy Jandali, BASF Corporation

- **Harvey Kamil, NBTY, Inc. (Chair Elect)**
- Allison Levy, AdvoCare International, LP
- **Steve Mister, CRN (President & CEO)**
- David Morrison, The Vitamin Shoppe
- Vic Neufeld, Jamieson Laboratories Ltd.
- **Al Powers, NOW Foods**
- Michelle Potorski, Procter & Gamble
- Mike Satow, Nutrition 21
- Ona Scandurra, Country Life Vitamins
- Brian Schaneberg, Mars Botanical
- **Michelle Stout, Amway/Nutriline**
- David Sullivan, General Nutrition Centers, Inc.
- Sharon Tonetta, Bausch & Lomb
- **Debbie Trinker, Kemin Health, L.C. (Treasurer)**
- **John Venardos, Herbalife, Ltd.**
- **Tyler Whitehead, Nu Skin Enterprises, Inc.**

Additionally, the following committee chairs will serve CRN during the coming year:

- Government Relations Committee—Florence Okaro, NBTY, Inc.
- International Trade and Market Development Committee—John Venardos, Herbalife, Ltd.
- Communications and Media Outreach Committee—Doug Jones, Pharmavite
- Regulatory Affairs Committee—Michael Lelah, NOW Foods, and Haresh Madeka, BASF Corporation
- Senior Scientific Advisory Council—Michael McBurney, DSM Nutritional Products, and Barry Ritz, Atrium Innovations

For a complete list of CRN member companies, visit CRN's [website](#). For information on membership with CRN, please contact Carl Hyland, director, membership development, CRN, at 202-204-7674 or chyland@crnusa.org.

###

Note to Editor: The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 100+ dietary supplement manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org and www.lifesupplemented.org. Follow us on Twitter [@crn_supplements](#) and [@wannabewell](#) and on [Facebook](#).

EXHIBIT 6

Press Release

www.crnusa.org



Council for Responsible Nutrition

The Science Behind the Supplements

For Immediate Release

Contact: Nancy Stewart, 202-204-7684
Ana Wilbert, 202-204-7665

CRN Announces Seven New Board Directors –CRN Chair Appoints Three New Committee Chairs–

WASHINGTON, D.C., *January 7, 2014*—The Council for Responsible Nutrition (CRN), the dietary supplement industry’s leading trade association, today announced seven newly seated Directors to its governing board, and three newly appointed Committee Chairs.

The seven new executives joining CRN’s Board of Directors are: Mark Hartman, Banner Life Sciences; Connie Hallquist, Healthy Directions, LLC; Mark LeDoux, Natural Alternatives International, Inc.; Bret Scholtes, Omega Protein/Nutegrity; Jennifer Spalding, Abbott Nutrition; Steve Strickland, Sensient Pharmaceutical Coating Systems; and James Watson, Watson Inc.

CRN’s new Board of Directors is comprised of 36 member company representatives and CRN President & CEO Steve Mister. Below is the full list of CRN’s Board of Directors and Executive Committee (in bold) and the Officers (as noted) for 2014:

- Michael Bentley, SierraSil Health, Inc.
- **John Blair, The Juice Plus+ Company (Chair)**
- **Kristen Blanchard, Nutramax Laboratories, Inc. (Secretary)**
- Paul Bolar, Pharmavite LLC
- Michael Bradley, Perrigo Company
- Manuela Buxo, Bayer HealthCare LLC
- Mike DeGennaro, Lonza, Inc.
- Paul Dijkstra, InterHealth Nutraceuticals Inc.
- Paul Faganel, Embria Health Sciences
- Marjorie Fine, Shaklee Corporation

- more -

- Pierre Fitzgibbon, Atrium Innovations, Inc.
- Connie Hallquist, Healthy Directions, LLC
- **Jim Hamilton, DSM Nutritional Products (Immediate Past Chair)**
- Mark Hartman, Banner Life Sciences
- Carl Hastings, Reliv International, Inc.
- **T.J. Higgins, Pfizer Consumer Healthcare**
- Jim Hyde, Albion Laboratories, Inc.
- Samy Jandali, BASF Corporation
- **Harvey Kamil, NBTY, Inc. (Chair Elect)**
- Mark LeDoux, Natural Alternatives International Inc.
- Allison Levy, AdvoCare International, LP
- Suzanne LoGalbo, Reckitt Benckiser Group PLC
- **Steve Mister, CRN (President & CEO)**
- David Morrison, The Vitamin Shoppe
- Vic Neufeld, Jamieson Laboratories Ltd.
- Michelle Potorski, Procter & Gamble
- **Al Powers, NOW Foods**
- Mike Satow, Nutrition 21
- Bret Scholtes, Omega Protein/Nutegrity
- Fred Smetana, Church and Dwight Co. Inc.
- Jennifer Spalding, Abbott Nutrition
- **Michelle Stout, Amway/Nutriline**
- Steve Strickland, Sensient Pharmaceutical Coating Systems
- **Debbie Trinker, Kemin Health, L.C. (Treasurer)**
- **John Venardos, Herbalife, Ltd.**
- James Watson, Watson Inc.
- **Tyler Whitehead, Nu Skin Enterprises, Inc.**

In addition, the three newly appointed Committee chairs for 2014 are as follows:

- Communications and Media Outreach Committee—Caron Blitz, BASF Corporation
- Government Relations Committee—Kate Houston, Cargill Health & Nutrition
- Senior Scientific Advisory Council—Barry Ritz, Atrium Innovations, Inc.

Other Committee chairs who continue in their positions include:

- International Trade and Market Development Committee—John Venardos, Herbalife, Ltd.
- Regulatory Affairs Committee—Michael Lelah, NOW Foods, and Haresh Madeka, BASF Corporation

For a complete list of CRN member companies, visit [CRN's website](#). For information on membership with CRN, please contact Carl Hyland, director of membership development, at

202-204-7674 or chyland@crnusa.org.

###

Note to the editor: The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 100+ dietary supplement manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org and www.lifesupplemented.org. Follow us on Twitter [@crn_supplements](https://twitter.com/crn_supplements) and [@wannabewell](https://twitter.com/wannabewell) and on [Facebook](#).

EXHIBIT 7

Certificate of Compliance

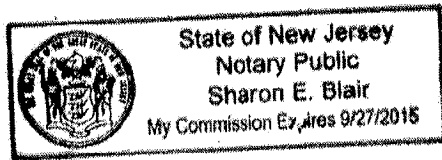
I hereby certify that, to the best of my knowledge, all documents and information requested in the August 5, 2011, Inquiry and Request for Documents re: United States v. Bayer, No. 2:07-cv-001 (D.N.J. Jan. 3, 2007) issued by the Federal Trade Commission to Bayer Corporation which are in the possession, custody, control, or knowledge of Bayer Corporation, have been provided. If a document responsive to the Inquiry and Request for Documents has not been submitted, the objection to its submission and the reasons for the objection have been stated.

Signature David C. Christensen
Title Senior Counsel

Sworn to before me this day

September 27, 2011

Sharon E. Blair
Notary Public



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)

CERTIFICATE OF SERVICE

I, Shannon L. Pedersen, certify that copies of the items listed below were served electronically via the CM/ECF system on October 20, 2014, upon all counsel of record:

1. Plaintiff's Response to Council for Responsible Nutrition's Motion for Leave to File Brief as Amicus Curiae; and
2. Certification by Shannon L. Pedersen and Exhibits 1-7.

s/ Shannon L. Pedersen
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