

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION**

In re: : MDL Docket No: 4:03CV1507WRW
: :
PREMPRO PRODUCTS LIABILITY : ALL CASES
LITIGATION :
: :
_____ :

UNNAMED PLAINTIFFS

v.

WYETH, and its divisions :
WYETH PHARMACEUTICALS, INC. :
and ESI LEDERLE, :
PFIZER, INC., :
PHARMACIA and UPJOHN COMPANY, :
PHARMACIA CORPORATION, :
GREENSTONE, LTD., :
BARR PHARMACEUTICALS, INC., :
BARR LABORATORIES, :
DURAMED PHARMACEUTICALS, INC., :
BRISTOL-MYERS SQUIBB COMPANY, :
NOVARTIS PHARMACEUTICALS :
CORPORATION, :
SOLVAY PHARMACEUTICALS, INC., :
formerly known as REID-ROWELL, INC., :
SOLVAY AMERICA, INC., :
SOLVAY S.A., :
GALEN HOLDINGS, PLC, :
WARNER CHILCOTT, :
BERLEX LABORATORIES, INC., :
SCHERING, AG, :
WATSON PHARMACEUTICALS, INC., :
ABBOTT LABORATORIES, :
MYLAN LABORATORIES, INC., and :
ORTHO-MCNEIL :
PHARMACEUTICAL, INC. :

Defendants. :
_____ :

MEMORANDUM IN SUPPORT OF
PLOS MEDICINE’S MOTION FOR
ACCESS TO DISCOVERY
MATERIALS INVOLVING
GHOSTWRITING PRACTICES

INTRODUCTION

PLOS Medicine, a medical journal published by the Public Library of Science (“PLOS”), is moving to intervene in this Multi-District Litigation (“MDL”) proceeding for the limited purpose of seeking access to the discovery materials produced by Defendant Wyeth Pharmaceuticals, Inc., *et al.* (“Wyeth”) involving alleged “ghostwriting” practices on the part of Wyeth to promote its hormone replacement therapy drugs.¹ *PLOS Medicine* believes that ghostwriting is “an unacceptable and deceptive practice,” and has published numerous articles on the dangers that ghostwriting poses to medical science and the public health. *See* Declaration of Virginia Barbour ¶¶ 8-9, dated May 14, 2009 (“Barbour Decl.”) (attached as Exhibit A to *PLOS Medicine*’s Motion to Intervene). In light of both *PLOS Medicine*’s and the public’s interest in exposing ghostwriting practices, *PLOS Medicine* asks this Court to grant public access to discovery materials produced in this case relating to such practices.

As explained below, Wyeth has never met its burden under Federal Rule of Civil Procedure 26(c) of demonstrating that “good cause” exists for keeping these materials confidential. The only basis for allowing continued secrecy with respect to these materials would be a showing by Wyeth that it *now* possesses good cause to bar public access to these materials. Particularly in light of the compelling public interest in access to evidence regarding the ghostwriting practices of pharmaceutical companies, it is difficult to imagine that any such showing could ever be made in this case. *PLOS Medicine* therefore requests that this Court grant its request for access to these materials.

¹ *PLOS Medicine*’s Motion to Intervene is being filed contemporaneously herewith. *See* Motion to Intervene of *PLOS Medicine* to Seek Public Access to Discovery Materials.

RELEVANT FACTUAL BACKGROUND

As explained in greater detail in *PLOS Medicine*'s Brief in Support of its Motion to Intervene, the underlying action in this MDL proceeding involves allegations that Wyeth's "design, manufacture, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion and/or distribution" of its hormone replacement therapy drugs, including the drug marketed under the name "Prempro," caused personal injuries to women who consumed these drugs. (Compl. ¶ 2.)² Studies conducted by the National Institute of Health ("NIH") in the late 1900s and early 2000s revealed that women who have taken Prempro have an increased risk of stroke, heart attack, blood clots, cardiovascular disease, and breast cancer. (Compl. ¶ 65.) The Master Complaint, filed in this Court on December 1, 2004, alleges that, despite these dangerous risks, Wyeth "intentionally and knowingly marketed, promoted, and encouraged" women to consume Prempro on a long-term basis. (Compl. ¶ 69.)

In December 2008, the *New York Times* published an article indicating that, in the course of discovery in this case, Wyeth produced a "mammoth amount of material" that allegedly reveals that Wyeth engaged in ghostwriting to promote its prescription drug Prempro. *See* Duff Wilson, *Drug Maker Said to Pay Ghostwriters for Journal Articles*, N.Y. TIMES, Dec. 12, 2008, available at http://www.nytimes.com/2008/12/12/business/13wyeth.html?_r=1&scp=3&sq=duff%20wyeth&st=cse (attached as Exhibit 16 to Barbour Decl.) (quoting Plaintiffs' Attorney James F. Szaller). This material is not available for public inspection, however, because Wyeth unilaterally designated this material "Confidential" pursuant to a stipulated confidentiality order that was never supported by any showing of good cause as required by Federal Rule of Civil

² Although a number of hormone replacement therapy drugs are at issue in the underlying litigation in this case, for simplicity and brevity, this brief will refer to these drugs as "Prempro."

Procedure 26(c). See Order dated July 6, 2005 (“Confidentiality Order” or “Order”) ¶¶ I(A)-(D). *PLOS Medicine* has moved to intervene in this MDL proceeding for the limited purpose of gaining access to the discovery materials involving Wyeth’s alleged ghostwriting practices, and now moves this Court for access to these materials.

INTEREST OF MOVANT

As set forth in greater detail in the Declaration of Virginia Barbour (attached as Exhibit A to *PLOS Medicine*’s Brief in Support of Motion to Intervene), *PLOS Medicine* – a top-tiered non-profit medical journal that aims to “make the world’s biomedical literature a freely available public good” – has a specific and compelling interest in obtaining access to the discovery materials in this case involving Wyeth’s alleged ghostwriting practices. (Barbour Decl. ¶ 2.)

Dr. Barbour, Chief Editor of *PLOS Medicine*, explains that ghostwriting is “an unacceptable and deceptive practice,” and *PLOS Medicine* has published numerous articles on the very real dangers that the practice of ghostwriting poses to medical science and the public health. (Barbour Decl. ¶¶ 8-9.) Among other things, *PLOS Medicine* believes that ghostwriting is dangerous because it threatens the accuracy of medical science by “giv[ing] corporate research a veneer of independence and credibility.” (Barbour Decl. ¶ 4.) As Dr. Barbour explains:

We believe that the scientific integrity of any medical journal article depends not just on the quality of the science being reported, but on the honesty and transparency of the authorship. In other words, our faith in the scientific record depends a great deal upon our faith in honest authorship. Ghostwriting is a deceitful and manipulative practice that threatens the scientific record.

(Barbour Decl. at ¶ 9.) In *PLOS Medicine*’s view, ghostwriting “substantially distort[s] the scientific record,” thereby “threaten[ing] the validity and credibility of medical knowledge.”

(Barbour Decl. ¶ 8.)

PLOS Medicine also seeks to expose evidence of ghostwriting practices because of the public health concerns that are implicated when “readers are unaware that [a pharmaceutical] company was ever involved in shaping the article’s contents.” (Barbour Decl. ¶ 5.) As Dr. Barbour explains, “[d]octors rely largely on medical journals to obtain up-to-date information on which treatments work and which do not,” (Barbour Decl. ¶ 8.), but “[b]y keeping the company’s role in the article hidden, the article has greater credibility in the eyes of the medical community, and thus a greater opportunity for influencing the prescribing behavior of physicians.” (Barbour Decl. ¶ 5.) Ghostwritten articles, then, have “a major impact on how doctors treat patients,” even in cases where, had the corporation’s involvement in drafting the article been disclosed, doctors may have afforded the article less weight. (Barbour Decl. ¶ 8.) *PLOS Medicine* therefore believes that the practice of ghostwriting threatens public health and safety because it potentially impacts the prescribing behavior of doctors in harmful (or even deadly) ways. (Barbour Decl. ¶ 5.)

This case is of particular interest to *PLOS Medicine* because it presents “a tremendous opportunity to find out more about corporate ghostwriting and its influence upon the medical literature and on public health.” (Barbour Decl. ¶ 11.) Because of the “hidden nature” of ghostwriting, the “exact details of how drug companies coordinate and orchestrate their ghostwriting campaigns remain unclear.” (Barbour Decl. ¶¶ 6, 10.) According to the *New York Times*, this case may have unearthed a treasure trove of materials containing precisely this sort of detailed information. *PLOS Medicine* believes that “[t]he documentation of a systematic campaign by a company, especially one that may have led to the concealment of serious side effects, will lead to further calls to bring this practice to an end.” (Barbour Decl. at ¶ 14.)

ARGUMENT

THIS COURT SHOULD GRANT PUBLIC ACCESS TO DISCOVERY MATERIALS CONTAINING EVIDENCE OF MEDICAL GHOSTWRITING.

I. THE PARTIES' STIPULATED CONFIDENTIALITY ORDER IS NO BARRIER TO PUBLIC ACCESS BECAUSE IT WAS NEVER SUPPORTED BY ANY SHOWING OF GOOD CAUSE FOR SECRECY.

As a threshold matter, it is important to note that the discovery materials at issue were designated “confidential” pursuant to a stipulated umbrella Confidentiality Order that was never supported by a showing of “good cause.” It is well-established that discovery materials are publicly accessible unless the party seeking confidentiality has demonstrated “good cause” for a confidentiality order. *General Dynamics Corp. v. Selb Manufacturing Co.*, 481 F.2d 1204, 1212 (8th Cir. 1973). This “good cause” requirement is set forth in Federal Rule of Civil Procedure 26(c), which provides, in relevant part:

A party or any person from whom discovery is sought may move for a protective order in the court where the action is pending The court may, *for good cause*, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense

Fed. R. Civ. P. 26(c) (emphasis added). Federal courts have consistently held that, in the absence of a confidentiality order supported by good cause, discovery materials should be publicly accessible. *See Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 789-90 (1st Cir. 1988) (“Rule 26(c)’s good cause requirement means that, ‘[a]s a general proposition, pretrial discovery must take place in the public unless compelling reasons exist for denying the public access to the proceedings.’”) (quoting *American Telephone & Telegraph Co. v. Grady*, 594 F.2d 594, 596 (7th Cir. 1978)); *In re Agent Orange Product Liability Litig.*, 821 F.2d 139, 145 (2d Cir. 1987) (“[I]f good cause is not shown, the discovery materials in question should not receive

judicial protection and therefore would be open to the public for inspection.”).

The “good cause” requirement imposes a heavy burden on the party seeking confidentiality. The Eighth Circuit has interpreted Rule 26(c) to require the party who requests a confidentiality order “to show the necessity of its issuance, which contemplates ‘a particular and specific demonstration of fact, as distinguished from stereotypes and conclusory statements.’” *General Dynamics*, 481 F.2d at 1212 (citations omitted); *see also Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (“Good cause is established on a showing that disclosure will work a clearly defined and serious injury to the party seeking closure. The injury must be shown with specificity.”) (citation omitted). Federal courts therefore require parties to show “specific examples” of harm that would likely occur in the absence of a confidentiality order before the court will agree to issue such an order. *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986); *accord Anderson v. Cryovac*, 805 F.2d 1, 7 (1st Cir. 1986) (“A finding of good cause must be based on a particular factual demonstration of potential harm, not on conclusory statements.”) (citing 8 C. Wright & A. Miller, *Federal Practice and Procedure* § 2035, at 264-65 (1970)).

Within the Eighth Circuit, federal courts have routinely refused to grant protective orders when the parties requesting such orders failed to show, with “specific demonstrations of fact,” that “good cause” existed for the issuance of the order. *See, e.g., Reese v. Reyes*, 2008 WL 2186330, at *1 (W.D. Ark. May 23, 2008) (denying motion for protective order when party requesting order failed to “demonstrate[] how he would be harmed by the disclosure of his medical records”); *Pyle v. Stone*, 2008 WL 5045681, at *2 (W.D. Ark. Nov. 21, 2008) (party failed to demonstrate good cause for protective order when he argued that a request for bank

records was “overly broad and cover[ed] too many years,” but failed to “articulate specific facts showing a specific harm that would arise from disclosure of [his] bank records”); *Wal-Mart Stores, Inc. v. Vidalakis*, 2007 WL 4591569, at *5 (W.D. Ark. Dec. 28, 2007) (denying Wal-Mart’s motion for a protective order on the ground that “Wal-Mart has not supported its Motion . . . with any affidavits which explain[] why the requested information cannot be reasonably obtained” and instead only offered “conclusory statements”). Rule 26(c) therefore imposes a significant burden on parties who seek confidentiality orders: without *specific demonstrations* of why a *clearly defined and serious injury* will result in the absence of confidentiality, such an order may not be granted.

It is especially important to note that Rule 26(c) makes no distinction between parties who seek confidentiality with respect to only a limited number of documents and parties who seek broad umbrella confidentiality orders (such as that entered in this case). In both instances, the burden remains the same: the party (or parties) seeking confidentiality must demonstrate good cause for the confidentiality order by showing specific examples of harm that would result absent the order. *See, e.g., Shingara v. Skiles*, 420 F.3d 301, 306 (3d Cir. 2005) (noting that, when a court enters an umbrella confidentiality order, “there must be good cause to maintain the order in the face of a motion to vacate it, particularly when, as here, the moving party did not have an opportunity to oppose the entry of the protective order in the first instance”); *Jepson, Inc. v. Makita Elec. Works, Ltd.*, 30 F.3d 854, 858 (7th Cir. 1994) (“Even if the parties agree that a protective order should be entered, they still have ‘the burden of showing that good cause exists for the issuance of that order.’”) (quoting *Public Citizen*, 858 F.2d at 789); *In re Agent Orange*, 821 F.2d at 148 (recognizing that, although “the unusual scope of the Agent Orange

litigation warranted imposition of the protective orders at issue, . . . the orders had been improvidently granted because the district court never required appellants to make the requisite good cause showing”). Thus, even in cases (such as this) where the court enters an umbrella confidentiality order during the discovery process, the parties must still meet their burden of demonstrating good cause for keeping the discovery materials confidential.

Courts have generally identified two ways in which parties can meet their burden of showing good cause for an umbrella confidentiality order. First, as the Seventh Circuit has recognized, the parties can identify discrete categories of material for which good cause for confidentiality exists (*e.g.*, trade secrets), and the court can issue an umbrella protective order limited to just those categories of material. *See Citizens First Nat’l Bank of Princeton v. Cincinnati Ins. Co.*, 178 F.3d 943, 946 (7th Cir. 1999) (umbrella protective order is only appropriate “provided the judge (1) satisfies himself that the parties know what a trade secret is and are acting in good faith in deciding which parts of the record are trade secrets and (2) makes explicit that either party and any interested member of the public can challenge the secreting of particular documents.”).

Second, as the Third Circuit has recognized, the court may issue a “broad umbrella protective order upon a threshold showing by the [party or parties seeking confidentiality] of good cause,” so long as others “have the opportunity to indicate precisely which documents [they] believe[] not to be confidential.” *Pansy*, 23 F.3d at 787 n.17. The Third Circuit explained that, after delivery of the documents under a broad umbrella confidentiality order, the party opposing confidentiality should be permitted to identify those categories of documents that should be publicly accessible, and then “the party seeking to maintain the seal would have the

burden [of proving good cause] with respect to those documents.” *Id.* (citing *Cipollone*, 785 F.2d at 1122); *see also Phillips v. General Motors Corp.*, 126 F. Supp. 2d 1328, 1331 (D. Mont. 2001) (“Documents under a blanket protective order are subject to challenge to determine whether good cause exists to include any particular document under the protective order.”).

In this case, because the Confidentiality Order was entered by stipulation of the parties, Wyeth has never attempted to demonstrate that good cause exists for keeping the discovery materials secret. For this reason, the Order does not pose a legally cognizable barrier to public access. The only justification for upholding the Order at this point would be a showing by Wyeth that good cause presently exists for keeping the discovery materials in question confidential under Rule 26(c). However, as explained in the next section, in light of the tremendous public interest in these materials – and in light of *PLOS Medicine*’s specific interest in gaining access to evidence of ghostwriting practices – it is highly unlikely that Wyeth could ever make such a showing here.

II. *PLOS MEDICINE*’S INTEREST IN OBTAINING ACCESS TO THE ALLEGED GHOSTWRITING MATERIALS MILITATES AGAINST ANY FINDING OF GOOD CAUSE FOR CONTINUED SECRECY.

Because the discovery materials at issue are not currently available for public inspection, *PLOS Medicine* is hamstrung in its ability fully to evaluate the extent to which these materials contain any legitimately confidential material that would justify protection under Rule 26(c). *PLOS Medicine* notes, however, that it is difficult to imagine how materials evidencing “ghostwriting practices,” which are clearly not trade secrets, could possibly contain legitimately confidential information.³ Be that as it may, *PLOS Medicine* is in a position to explain why there

³ For example, any allegations on Wyeth’s part that disclosure of these materials would unduly prejudice the public against it would not provide any basis for a good cause finding under Rule

is a compelling public interest in access to the materials at issue – an interest so strong that it is virtually certain to outweigh any articulable interest in confidentiality that Wyeth may proffer to the Court.

It is well understood that the public interest in access to discovery materials is a strong factor that must be weighed when evaluating good cause for secrecy under Rule 26(c). Federal courts generally adopt a “balancing process” between the public interest in disclosure and the parties’ interest in secrecy in determining whether good cause exists for a confidentiality order. *Pansy*, 23 F.3d at 787; *see also Gill v. Gulfstream Park Racing Ass’n*, 399 F.3d 391, 402 (1st Cir. 2005) (noting that “considerations of the public interest, the need for confidentiality, and privacy interests are relevant factors to be balanced” when determining whether to vacate or modify a confidentiality order); *Cook, Inc. v. Boston Scientific Corp.*, 206 F.R.D. 244, 246 (S.D. Ind. 2001) (“The ‘good cause’ standard requires a balancing of the public and private interests involved”); *Welsh v. San Francisco*, 887 F. Supp. 1293, 1302 (N.D. Cal. 1995) (“In applying the ‘good cause’ test under Rule 26(c), the Court must weigh potential harm caused by disclosure against the prospect of benefits to the public of disclosing the information”); *Hawley v. Hall*, 131 F.R.D. 578, 584 (D. Nev. 1990) (“A showing of Rule 26(c) good cause requires a balancing of

26(c). *See, e.g., Shingara*, 420 F.3d at 307 (“[T]he concern that the disclosure of discovery materials to the media *could* unduly prejudice the public is exactly the type of broad, unsubstantiated allegation of harm that does not support a showing of good cause.”) (emphasis in original). Nor could Wyeth support a finding of good cause by arguing that it relied on the confidentiality order to its detriment. *See, e.g., San Jose Mercury News, Inc. v. U.S. District Court*, 187 F.3d 1096, 1101 (9th Cir. 1999) (“[T]o the extent the Defendants relied on the stipulated protective order in making the decision to forgo a motion for reconsideration, such reliance was unreasonable. The right of access to court documents belongs to the public, and the Plaintiffs were in no position to bargain that right away.”). Further, Wyeth could not demonstrate “good cause” by arguing that the release of the discovery materials here would cause the company embarrassment, as it is “especially difficult for a business enterprise, whose primary measure of well-being is presumptively monetizable, to argue for a protective order on this ground.” *Cipollone*, 785 F.2d at 1121.

the interests of the parties competing to open or close the civil discovery process to the public.”).

Even in cases where a party is able to prove a need for confidentiality, a court may still find that the party failed to demonstrate “good cause” for a protective order if the public’s interest in obtaining that material outweighs the party’s need for secrecy. *See, e.g., In re Agent Orange*, 821 F.2d at 148 (holding that good cause did not exist for confidentiality order because party’s interest in keeping material confidential, although legitimate, was “outweighed by the enormous public interest in the Agent Orange litigation and the compelling need for class members and non-class members alike to evaluate fully the efficacy of settling this litigation”); *Miller v. Boston*, 549 F. Supp. 2d 140, 142 (D. Mass. 2008) (denying protective order on the ground that “concerns about the individual Defendants’ privacy interests . . . are strongly outweighed by public interest considerations,” including the public’s “interests in examining allegations of official misconduct”); *Jones v. Clinton*, 12 F. Supp. 2d 931, 933 (E.D. Ark. 1998) (modifying confidentiality order to permit public access to discovery materials after media entities intervened and argued that “compelling public interest in the conduct of one of the most public officials in the world” outweighed parties’ interests in keeping materials sealed).

In cases where the public’s interest in the materials pertains to health and safety concerns in particular, courts are extremely reluctant to find that the need for confidentiality outweighs the public’s interest in obtaining access to the materials. As the Third Circuit has explained, “[c]ircumstances weighing against confidentiality exist when confidentiality is being sought over information important to public health and safety.” *Pansy*, 23 F.3d at 787; *see generally Shingara*, 420 F.3d at 306 (noting that “whether confidentiality is being sought over information important to public health and safety,” and “whether the case involves issues important to the

public,” are factors that weigh against a finding of good cause) (citation omitted); *In re Agent Orange*, 821 F.2d at 146 (noting that public access “is particularly appropriate when the subject matter of the litigation is of special public interest”).

This case is precisely the type of case where the public’s interest in access to the discovery material far outweighs any conceivable interest the parties may have in keeping the material confidential. As explained above, ghostwriting poses a serious threat to the public health and safety because, among other things, it “gives corporate research a veneer of independence and credibility.” (Barbour Decl. ¶¶ 2, 4, 8-9.) Even if a ghostwritten article does not technically contain any inaccuracies, a pharmaceutical company’s hidden role in ghostwriting an article may “substantially distort the scientific record” by creating a facade of objectivity, thereby conferring on the article “greater credibility in the eyes of the medical community, and thus a greater opportunity for influencing the prescribing behavior of physicians.” (Barbour Decl. ¶ 5.) If the *New York Times* is to be believed, this case in particular presents a tremendous opportunity to document the ghostwriting practices of a pharmaceutical company and the effects of such practices on the public health. (Barbour Decl. at ¶ 14.) For all of these reasons, *PLOS Medicine*’s interest in obtaining access to discovery materials involving Wyeth’s alleged ghostwriting campaign likely far outweighs Wyeth’s interest in keeping these materials confidential. As such, it is doubtful that Wyeth could ever meet its burden of demonstrating that good cause exists for the continued confidentiality of these materials.

CONCLUSION

For the foregoing reasons, *PLOS Medicine* respectfully requests that its Motion to Seek Public Access to Discovery Materials be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on this ____ day of June 2009, a true and correct copy of the foregoing document was forwarded by U.S. mail to the parties listed on the service list below.

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