

**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	:	
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UNNAMED PLAINTIFFS	:	<b><u>MEMORANDUM IN SUPPORT</u></b>
	:	<b><u>OF PLOS MEDICINE'S MOTION</u></b>
	:	<b><u>TO INTERVENE TO SEEK</u></b>
	:	<b><u>PUBLIC ACCESS TO</u></b>
	:	<b><u>DISCOVERY MATERIALS</u></b>
	:	
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.	:	
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## INTRODUCTION

*PLOS Medicine*, a biomedical journal published by the Public Library of Science (“PLOS”), moves to intervene in this case pursuant to Federal Rule of Civil Procedure 24(b) to seek public access to the discovery materials produced by Defendant Wyeth Pharmaceuticals, Inc., *et al.* (“Wyeth”) that relate to Wyeth’s alleged “ghostwriting” practices with regard to various hormone replacement therapy drugs, including the prescription drug Prempro.<sup>1</sup> As explained in greater detail below, *PLOS Medicine* is a top-tiered non-profit medical journal that has a particular interest in educating its readers about the ghostwriting practices of major pharmaceutical companies. *See* Declaration of Virginia Barbour, dated May 14, 2009 (“Barbour Decl.”) (attached as Exhibit A). *PLOS Medicine*’s Motion to Intervene should be granted because: (1) the Motion has been timely filed; (2) the Motion shares a question of law or fact in common with the main action; and (3) *PLOS Medicine*’s intervention will not unduly delay or prejudice the parties’ rights in the underlying litigation.

## RELEVANT FACTUAL BACKGROUND

The Plaintiffs in this case are women who consumed hormone therapy medication and suffered personal injuries as a result, and their spouses. The Master Complaint against Wyeth, which was filed on December 1, 2004, asserts twelve causes of action arising out of Wyeth’s “design, manufacture, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion and/or distribution” of the hormone replacement therapy

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<sup>1</sup> “Ghostwriting” in this context refers to “when someone contributes substantially to writing a manuscript in a medical journal and yet this author’s role is not mentioned when the manuscript is published.” Declaration of Virginia Barbour ¶ 4, dated May 14, 2009.

drug Prempro.<sup>2</sup> (Compl. ¶ 2.)

Plaintiffs specifically allege that, according to studies conducted in the late 1990s and early 2000s by the National Institute of Health (“NIH”), women who have taken Prempro have increased risks of stroke, heart attack, blood clots, cardiovascular disease, and breast cancer. (Compl. ¶ 65.) Plaintiffs further assert that, despite these dangerous risks, Wyeth “intentionally and knowingly marketed, promoted, and encouraged” women to consume Prempro on a long-term basis. (Compl. ¶ 69.)

With regard to ghostwriting, Plaintiffs allege that Wyeth, as part of its marketing and promotional efforts, “fraudulently and intentionally polluted the scientific literature related to hormone therapy in general and their hormone drugs in particular” by “hir[ing] physicians and scientists to write inaccurate and misleading scientific articles for the purpose of contaminating scientific and medical knowledge pertaining to hormone therapy and Defendants’ particular products.” (Compl. ¶ 151.)

It appears that Plaintiffs have succeeded in unearthing evidence to support their allegation of ghostwriting. In December 2008, the *New York Times* published an article indicating that the discovery produced in this case includes a “mammoth amount of material” demonstrating that Wyeth engaged in ghostwriting to promote its hormone therapy drugs. *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](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). The article also states that Senator Charles Grassley (R. Iowa) has requested “more information

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<sup>2</sup> Although a number of hormone replacement therapy medications are at issue in this case, for simplicity and brevity, this brief will refer to these medications as “Prempro.”

about the company’s involvement in medical ghostwriting” as part of a continuing congressional investigation “into drug industry influence on doctors.” *Id.* The public does not have access to these materials, however, because they were designated “Confidential” pursuant to a stipulated confidentiality order that was never supported by any showing of good cause, as required by Federal Rule of Civil Procedure 26(c). *See* Order dated July 6, 2005 (“Confidentiality Order” or “Order”) ¶¶ I(A)-(D). The Order does, however, permit “any party *or other person*” to “object[] to discovery that it believes to be otherwise improper or . . . seek[] modification of this order.” (Order ¶ X) (emphasis added).<sup>3</sup>

### **INTEREST OF MOVANT**

As set forth in greater detail in the Declaration of Virginia Barbour (attached as Exhibit A), *PLOS Medicine* has a specific and compelling interest in obtaining access to evidence relating to the ghostwriting practices of pharmaceutical companies.

*PLOS Medicine* is published by PLOS, which is a non-profit organization that has the mission of “mak[ing] the world’s biomedical literature a freely available public good.” (Barbour Decl. ¶ 2.) All of PLOS’s journals, including *PLOS Medicine*, are “open access,” meaning that every article published in a PLOS journal is free to read and reuse for all legal purposes, so long as the authors of the article are given proper credit. (Barbour Decl. ¶ 2.) Dr. Barbour, Chief Editor of *PLOS Medicine*, explains that *PLOS Medicine* considers itself to have “a greater degree of independence from the pharmaceutical industry than other medical journals,” in large part because the journal is not dependent upon the pharmaceutical industry for funding. (Barbour Decl. ¶ 3) (noting that *PLOS Medicine* does not rely on funding from paid advertisements for

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<sup>3</sup> As explained in the accompanying Motion to Unseal, because the Order was never supported by any showing of good cause, Wyeth cannot claim that it presents any barrier to the public’s right to seek access to the sealed discovery materials in this case.

drugs or medical devices or reprints of articles by pharmaceutical companies to promote the drugs that are the subject of the articles).

*PLOS Medicine* believes ghostwriting is “an unacceptable and deceptive practice,” and 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.) First, *PLOS Medicine* believes that ghostwriting 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 Dr. Barbour’s view, ghostwriting “substantially distort[s] the scientific record,” thereby “threaten[ing] the validity and credibility of medical knowledge.” (Barbour Decl. ¶ 8.)

Second, *PLOS Medicine* believes that medical ghostwriting threatens public health and safety because it can influence the prescribing behavior of doctors in sometimes harmful (or even deadly) ways. (Barbour Decl. ¶ 5.) Dr. Barbour explains that “[d]octors rely largely on medical journals to obtain up-to-date information on which treatments work and which do not.” (Barbour Decl. ¶ 8.) Because ghostwriting “keep[s] 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.) Such influence can be harmful to the public when the pharmaceutical company “carefully select[s] positive reports and deemphasize[es] the product’s risks,” which often occurs when the company ghostwrites a

medical journal article. (Barbour Decl. ¶ 8.)

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.) Dr. Barbour explains that, because of its “hidden nature,” the “exact details of how drug companies coordinate and orchestrate their ghostwriting campaigns remain unclear.” (Barbour Decl. ¶¶ 6, 10.) However, evidence of ghostwriting that is discovered in the course of litigation has proven to be one of the most important sources of information about ghostwriting practices and the effects of such practices on public health and safety. (Barbour Decl. ¶ 10.) *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.) For all of these reasons, *PLOS Medicine* has a powerful interest in obtaining access to the discovery materials involving Wyeth’s alleged ghostwriting practices.

## ARGUMENT

### **INTERVENTION IS WARRANTED BECAUSE *PLOS MEDICINE* MEETS ALL THREE REQUIREMENTS FOR PERMISSIVE INTERVENTION UNDER FEDERAL RULE OF CIVIL PROCEDURE 24(B).**

Although the appropriate procedural course for non-parties to seek public access to discovery materials has yet to be determined by this Court or the Eighth Circuit, the “majority view,” which is followed by other district courts within the Eighth Circuit, “allows a [non]-party to challenge a protective order under [Federal Rule of Civil Procedure] 24(b).” *In re Guidant Corp. Implantable Defibrillators Products Liability Litig.*, 245 F.R.D. 632, 635 (D. Minn. 2007); *see also Jochims v. Isuzu Motors, Ltd.*, 148 F.R.D. 624, 627 (S.D. Iowa 1993) (“It is widely

recognized by courts that Rule 24(b) intervention is the ‘proper method to modify a protective order.’”) (citation omitted).<sup>4</sup>

Federal Rule of Civil Procedure 24(b) states, in relevant part, “On timely motion, the court may permit anyone to intervene who . . . has a claim or defense that shares with the main action a common question of law or fact . . . . [T]he court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties’ rights.” Fed. R. Civ. P. 24(b). The Eighth Circuit has stated that “Rule 24 is to be liberally construed . . . and all doubts should be resolved in favor of allowing intervention.” *Arkansas Elec. Energy Consumers v. Middle South Energy, Inc.*, 772 F.2d 401, 404 (8th Cir. 1985) (citations omitted).

Pursuant to Rule 24(b), courts consider three factors in deciding whether to permit intervention: (1) whether the motion to intervene is timely; (2) whether the motion raises a question of law or fact in common with the main action; and (3) whether intervention will unduly delay or prejudice the adjudication of the parties’ rights. See *In re Guidant*, 245 F.R.D. at 635. As explained below, all three factors are met here.

#### **I. PLOS MEDICINE’S MOTION TO INTERVENE IS TIMELY.**

*PLOS Medicine*’s Motion to Intervene satisfies the first Rule 24(b) factor because the Multi-District Litigation (“MDL”) proceedings in this case are still on-going. This alone renders *PLOS Medicine*’s Motion timely. See, e.g., *In re Baycol Prods. Litig.*, 214 F.R.D. 542, 543 (D.

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<sup>4</sup> See also *San Jose Mercury News, Inc. v. U.S. District Court*, 187 F.3d 1096, 1100 (9th Cir. 1999) (“Nonparties seeking access to a judicial record in a civil case may do so by seeking permissive intervention under Rule 24(b)(2).”); *Beckman Indus., Inc. v. Int’l Ins. Co.*, 966 F.2d 470, 472 (9th Cir. 1992) (noting the “ample support” for recognizing Rule 24(b) intervention “as a proper method to modify a protective order”) (listing cases); *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 783 (1st Cir. 1988) (“Relying on the language of Rule 24, the Fifth Circuit has previously held that intervention is ‘the procedurally correct course’ for third-party challenges to protective orders. We agree.”) (quoting *In re Beef Indust. Antitrust Litig.*, 589 F.2d 786, 789 (5th Cir. 1979)) (emphasis in original).

Minn. 2003) (motion for permissive intervention held to be timely because “MDL proceeding [was] ongoing”). In fact, courts routinely permit intervention for the limited purpose of seeking public access to discovery materials well *after* the underlying case is resolved. *See Equal Employment Opportunity Comm’n v. Nat’l Children’s Center, Inc.*, 146 F.3d 1042, 1047 (D.C. Cir. 1998) (holding “intervention to challenge confidentiality orders may take place long after a case has been terminated”) (citation omitted); *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 779 (3d Cir. 1994) (motion to intervene for the limited purpose of modifying or vacating a protective order may be granted “even after the underlying dispute has long been settled”); *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 785 (1st Cir. 1988) (“Numerous courts have allowed third parties to intervene in cases directly analogous to this one, many involving delays measured in years rather than weeks.”) (listing cases).

Given that motions to intervene to seek access to discovery materials are routinely deemed timely even when filed *after* the underlying litigation has been resolved, there could be no serious dispute that *PLOS Medicine* has filed a timely Motion in this case. Thus, the first Rule 24(b) factor has been met.

## **II. *PLOS MEDICINE’S* MOTION TO INTERVENE SHARES A QUESTION OF LAW OR FACT IN COMMON WITH THE MAIN ACTION.**

There is also no question that *PLOS Medicine’s* Motion meets the second Rule 24(b) factor: *i.e.*, that it “shares with the main action a common question of law or fact.” Fed. R. Civ. P. 24(b). This factor is construed liberally in cases where non-parties seek intervention for the limited purpose of obtaining public access to discovery materials. The reason for this, as the D.C. Circuit has explained, is “because of the need for ‘an effective mechanism for third-party claims of access to information generated through judicial proceedings.’” *Nat’l Children’s*

*Center*, 146 F.3d at 1045-46. Thus, “despite the lack of a clear fit with the literal terms of Rule 24(b), every circuit court that has considered the question has come to the conclusion that non-parties may permissively intervene for the purpose of challenging confidentiality orders.” *Id.* at 1045 (emphasis added).

*PLOS Medicine*’s request for permissive intervention here is akin to the request for permissive intervention filed by a group of newspapers in *Pansy v. Borough of Stroudsburg*, 23 F.3d 772. There, the Third Circuit permitted the newspapers to intervene in the underlying lawsuit solely for the purpose of challenging a protective order, even though the newspapers had not technically raised any “question of law or fact” in common with the original parties’ claims or defenses. *Id.* at 778. In so ruling, the court “agree[d] with other courts . . . that the procedural device of permissive intervention is appropriately used to enable a litigant who was not an original party to an action to challenge protective or confidentiality orders entered in that action.” *Id.* (listing cases). The court concluded that, “[b]y virtue of the fact that the Newspapers challenge the validity of the Order of Confidentiality entered in the main action, they meet the requirement of Fed. R. Civ. P. 24(b)(2) that their claim must have ‘a question of law or fact in common’ with the main action.” *Id.*; see also *San Jose Mercury News, Inc. v. U.S. District Court*, 187 F.3d 1096, 1103 (9th Cir. 1999) (reversing district court order denying newspaper’s motion to intervene so that newspaper could “press the public’s right of access to discovery materials pursuant to Federal Rule of Civil Procedure 26(c)”); *In re Beef Industry Antitrust Litig.*, 589 F.2d 786, 789 (5th Cir. 1979) (noting that “[t]here is no question” that Rule 24 intervention is “the procedurally correct course” for third-party challenges to protective orders).

Every District Court within the Eighth Circuit to examine this issue has agreed that non-

party intervenors like *PLOS Medicine* may seek public access to discovery materials filed under seal without regard to any nexus (or lack thereof) between the intervenor’s challenge and the underlying law and facts at issue in the main action. *See In re Guidant*, 245 F.R.D. at 635 (financial news and data company permitted to intervene pursuant to Rule 24(b) in products liability litigation to seek public disclosure of documents relating to “whether a life-saving medical device functioned properly and whether the manufacturer sold it to the public with knowledge that the device was flawed”); *In re Baycol*, 214 F.R.D. at 543 (newspaper permitted to intervene pursuant to Rule 24(b) in products liability litigation, noting that “the clear majority view allows the use of Rule 24(b) to challenge a confidentiality order”); *see generally Jochims*, 148 F.R.D. at 627 (noting that the “requirement that the intervenor’s claim involves the same legal theory ‘is not required when intervenors are not becoming parties to the litigation’”).<sup>5</sup>

This Court should likewise follow the “majority view” adopted by the other U.S. District Courts in the Eighth Circuit and hold that, “[b]y virtue of the fact” that non-party intervenors seek public access to sealed discovery materials, “their claim must have a ‘question of law or

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<sup>5</sup> The Eighth Circuit has yet to issue a binding ruling on the matter. Although the court issued an unpublished decision declining to permit intervention by third-party to challenge a confidentiality order, *see Org. for Competitive Mkts., Inc. v. Seaboard Farms, Inc.*, 2001 WL 842029 (8th Cir. Feb. 1, 2001) (“*OCM*”), this decision may not be cited pursuant to Eighth Circuit Local Rule 32.1A, which prohibits reliance on unpublished decisions of the Eighth Circuit when other “published opinion[s] of [the Eighth Circuit] or another court” have “persuasive value on a material issue.” 8th Cir. R. 32.1A. Here, there are numerous cases from other U.S. Circuit Courts of Appeal, in addition to the cases cited above from U.S. District Courts within the Eighth Circuit, that have “persuasive value” on the issue of whether third-parties may challenge confidentiality orders under Rule 24(b). *See, e.g., Nat’l Children’s Center*, 146 F.3d at 1045; *Pansy*, 23 F.3d at 778; *see also supra*, pp. 7-8 (listing cases). Thus, *OCM* should not factor into this court’s analysis. *See also In re Baycol Products Litig.*, 214 F.R.D. 542, 543 (D. Minn. 2003) (holding that, pursuant to Eighth Circuit Local Rule 32.1A, “*OCM* does not act as a bar to [newspaper’s] motion to intervene,” noting that the Eighth Circuit in *OCM* “did not endeavor to announce its standard for limited purpose permissive intervention”).

fact in common' with the main action." *In re Baycol*, 214 F.R.D. at 543 (citation omitted).<sup>6</sup>

*PLOS Medicine* has therefore satisfied the second Rule 24(b) factor for permissive intervention.

### **III. *PLOS MEDICINE'S* INTERVENTION IN THIS CASE WILL NOT UNDULY DELAY OR PREJUDICE THE ADJUDICATION OF THE PARTIES' RIGHTS.**

Finally, *PLOS Medicine's* Motion to Intervene satisfies the third Rule 24(b) factor because intervention in the MDL proceedings before this Court will not cause undue delay or prejudice the rights of the existing parties.

As the First Circuit has explained, the "delay or prejudice" factor of Rule 24(b) "encompasses the basic fairness notion that intervention should not work a 'last minute disruption of painstaking work by the parties and the court.'" *Public Citizen*, 858 F.2d at 786 (citation omitted). This sort of "disruption," the court observed, is not an issue where – as here – the intervenor seeks "to litigate only the issue of the protective order," which is "a particularly discrete and ancillary issue." *Id.* In these types of cases, the First Circuit held, permissive intervention should be granted. *Id.*; see also *Pansy*, 23 F.3d at 780 (adopting the reasoning of the First Circuit in *Public Citizen* with respect to the "delay and prejudice" factor of Rule 24(b) intervention to hold that "a district court may properly consider a motion to intervene permissively for the limited purpose of modifying [or vacating] a [confidentiality] order even after the underlying dispute between the parties has long been settled") (citation omitted)

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<sup>6</sup> Even if this Court interprets the language of the second Rule 24(b) factor more narrowly, *PLOS Medicine* should still be permitted to intervene because PLOS's Motion "shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b). As explained above, Plaintiffs have raised numerous questions of fact regarding the extent to which Wyeth engaged in ghostwriting practices to promote Prempro (Compl. ¶ 152), evidence of which PLOS (for the reasons stated above) has a strong interest in obtaining. *PLOS Medicine's* Motion "shares with the main action a common question of law or fact" because Plaintiffs have sought, and PLOS now seeks, access to material allegedly demonstrating that Wyeth engaged in ghostwriting practices.

(alterations in original).

Here, *PLOS Medicine* seeks intervention for the sole purpose of seeking public access to discovery materials that involve the alleged ghostwriting practices of Wyeth. *PLOS Medicine* does *not* seek intervention to litigate the underlying merits of the dispute between the original parties in this case or to otherwise “work a last minute disruption of painstaking work by the parties and the court.” Any delay or prejudice to the existing parties if *PLOS Medicine* is permitted to intervene will be minimal at best, especially considering the fact that *PLOS Medicine* seeks public access to the *same* discovery materials that are being sought by Senator Grassley as part of Congress’s investigation into the drug industry’s influence on doctors. 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](http://www.nytimes.com/2008/12/12/business/13wyeth.html?_r=1&scp=3&sq=duff%20wyeth&st=cse); cf. *In re Baycol*, 214 F.R.D. at 544 (rejecting defendants’ argument that newspaper’s intervention would cause undue delay and prejudice because plaintiffs had also moved to modify or vacate the protection order). Therefore, *PLOS Medicine*’s motion to intervene satisfies the third Rule 24(b) factor.

### CONCLUSION

Because *PLOS Medicine*’s Motion to Intervene satisfies all three factors for permissive intervention under Rule 24(b), the Motion should 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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