IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 2342** **12-MD-2342**
	:	**HON. CYNTHIA M. RUFE**
THIS DOCUMENT RELATES TO ALL ACTIONS	:	

SPECIAL DISCOVERY MASTER'S REPORT AND RECOMMENDATION NO. 8
(REGARDING CONFIDENTIALITY DESIGNATION
OF DOCUMENT PF100200001118 – 1123)

February 28, 2014

I. INTRODUCTION AND FACTUAL HISTORY

This matter comes before me, as Special Discovery Master, at the request of the Plaintiffs' Steering Committee to remove the "confidential" designation from a document produced in discovery by defendant Pfizer, Inc. In the course of discovery, Pfizer produced a five page document that is a printout of a chain of emails sent between June 11, 2010 and October 6, 2010.

Description of the contents in detail would destroy the confidentiality that Pfizer is claiming. This Report and Recommendation will describe the email chain only to the extent necessary to illuminate the rationale for the Recommendation.

The email chain at issue is a discussion of medical literature. Most of the comments discuss how the literature relates to labeling of one or more pharmaceuticals.

Pfizer produced this document (marked as PF100200001118-1123) and designated it as confidential, and the PSC challenges the designation.

Disputes over confidentiality designations in this litigation are governed by Pretrial Order No. 8, a protective order dated July 23, 2012. Pretrial Order No. 8 sets out procedures by which assertions of confidentiality pursuant to Federal Rule of Civil Procedure 26(c)(1)G) may be tested and challenged. The substantive test applicable to the challenge is in Fed. R. Civ. Proc. 26(c)(1);

> The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following: [. . .] (G) requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way.

Id. Pretrial Order No. 8 also defines confidential information as "trade secret or other confidential research, development, or commercial information," (Pretrial Order No. 8, ¶ 1) and provides examples of kinds of materials that may be confidential.

Pretrial Order No. 8 anticipates that the parties may produce documents that they believe "should be subject to a protective order under Federal Rule of Civil Procedure 26(c)(1)(G) or other state or federal law." (Id., ¶ 1) Where one of the parties does so, the producing party may make a confidentiality designation, subject to challenge by the other party as described below.

The procedural mechanism by which the PSC may challenge the confidentiality designation made by Pfizer pursuant to Pretrial Order No. 8 works as follows:

> If a party contends any document has been erroneously or improperly designated or not designated as Confidential Information, the document at issue will be treated as confidential until . . . this Court issues an order determine that the document is not confidential and shall not be given confidential treatment.
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> If, after 14 days of the objecting party's notification to the designating party, the parties cannot reach agreement . . . the party challenging the . . . designation . . . may move the Court for an order stating that the information designated as "Confidential" is not "Confidential Information" within the meaning of this Order and is not entitled to the protections of this Order.
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> [T]he burden of justifying the designation shall lie with the designating party.

Pretrial Order No. 8, at ¶ 8.

The PSC reviewed the email chain at issue. It notified the Special Discovery Master and Pfizer that it disputed Pfizer's confidentiality designation. After the parties could not reach agreement on the matter, they submitted short briefs to the Special Discovery Master pursuant to Pretrial Order No. 8 and Pretrial Order No. 22.

II. DISCUSSION

A. What Kind of Information May be Protected From Disclosure?

The PSC argues that the email chain does not set forth information that may be considered confidential under the standards of Fed. R. Civ. P. 26(c)(1)(G) or Pretrial Order No. 8, and that these sources of authority permit protection only if the document is "trade secret or other confidential research, development, or commercial information." Fed. R. Civ. P. 26(c)(1)(G); Pretrial Order No. 8, at ¶ 1. The PSC argues that the information in the email chain does not fall within this definition of confidential information.

The information in the email chain does not include any trade secrets as that term is discussed in Smith v. BIC Corp., 869 F.2d 194, 200 (3d Cir. 1989). There, the Court held that the classification of information as a trade secret turns on "a determination of whether the secret 'is a process or device for continuous use in the operation of the business.'" Id., at 200, citing, inter alia, Restatement of Torts § 757, Comment b (1939). The information at issue is not information about a process or a device. It is a discussion of medical literature.

It is doubtful that the information may be considered "confidential research" within the meaning of Fed. R. Civ. P. 26(c)(1)(G). It is confidential in the sense that it appears to have been set out with the expectation that it would not be shared with others. Whether it is "research" is a more complicated question. It is certainly not original research of any existing literature; it is

analysis of literature placed before Pfizer by others for comment, and that is not "research." It is also not "research and development" material within the common meaning of that term, since it was not written in order to develop any new capabilities or insights for Pfizer. See, for example, http://www.britannica.com/EBchecked/topic/499010/research-and-development. The parties have not submitted any pertinent cases or other authoritative material on what may be held to be "research" within the meaning of Rule 26, and I can find none.

Nevertheless, even if the information does not fall strictly within the definitions of "trade secret," "research" or the other terms of Rule 26(c)(1)(G), it may still be made the subject of a protective order. This is clear from New York v. United States Metals Refining Co., 771 F.2d 796 (3d Cir. 1985). In that case, the State of New York was authorized under the discovery rules to enter a smelting plant owned by United States Metals Refining Co. ("USMR") and take samples. It wrote a report of its findings. The district court entered a protective order precluding the State of New York from releasing the report summarizing its findings. Id., at 796-99. Reviewing the determination on writ of mandamus, the Third Circuit Court of Appeals considered and rejected New York's argument that the document did not embody any trade secrets. The court held that the agreed order under which the parties produced information to one another in discovery and Rule 26 itself were not limited by their terms strictly to "trade secrets" or to the other specific kinds of information listed in what is now Fed. R. Civ. Proc. 26(c)(1)(G):

> Although the revised order was issued to relieve USMR's concerns about its trade secrets, in paragraph 11 the order also provided that the parties could seek further protection regarding confidentiality. Contrary to New York's arguments, then, trade secrets were not the only basis upon which the court below could issue the protective order. Rule 26 provides very broad discovery and gives the trial court wide discretion to manage the process. *See* 4 J. Moore, J. Lucas, and G. Grother, Jr., Moore's Federal Practice para. 26.67

> (2d ed. 1984). Under section (c), the court, upon good cause shown, "may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense," and the subsequent eight subsections provide examples of the types of orders that a court can make. Thus the section serves a substantial governmental interest in preventing any abuse of the discovery process and "whether or not the Rule itself authorizes [a particular protective order] . . . we have no question as to the court's jurisdiction to do this under the inherent 'equitable powers of courts of law over their own process to prevent abuses, oppression and injustices.'" Seattle Times Co. v. Rhinehart, 467 U.S. 20, 35 (1984) (citing International Products Corp. v. Koons, 325 F.2d 403, 407-08 (2d Cir. 1963).

New York v. United States Metals Refining Co., 771 F.2d 796, 804-805 (3d Cir. 1985)(citations recast).

Neither Rule 26 nor Pretrial Order No. 8 is strictly limited in its operation to protection of trade secrets or confidential research, development or commercial information. New York v. United States Metals Refining Co., 771 F.2d 796, 804-805 (3d Cir. 1985). The information at issue may be protected from disclosure if ". . . justice requires [it] to protect a party . . . from annoyance, embarrassment, [or] oppression." Fed. R. Civ. Proc 26(c); New York v. United States Metals Refining Co., 771 F.2d 796, 804-805 (3d Cir. 1985).

B. The Standards For Determining Whether a Protective Order is Required

Under Pansy v. Borough of Stroudsburg, 23 F.3d 772 (3rd Cir. 1994), "a party wishing to obtain an order of protection over discovery material must demonstrate that 'good cause' exists for the order of protection." Pansy v. Borough of Stroudsburg, 23 F.3d 772, 786 (3d Cir. 1994). Good cause is established "when it is specifically demonstrated that disclosure will cause a clearly defined and serious injury." Glenmede Trust Co. v. Thompson, 56 F.3d 476 (3d Cir. 1995) (noting that "generalized allegations of injury" are insufficient); see also Anderson v. Cryovac, Inc., 805 F.2d 1, 7 (1st Cir. 1986) (stating that a "finding of good cause must be based

on a particular factual demonstration of potential harm, not on conclusory statements"). As Paragraph 8 of PTO No. 8 provides, consistent with these cases, "The burden of justifying the designation shall lie with the designating party. Id.; see also Heller v. Shaw Indus., 1997 U.S. Dist. LEXIS 18521, *6 (E.D. Pa. Nov. 19, 1997).

Pansy prescribes a balancing test to determine whether good cause exists to enter a protective order over confidential discovery information. See Pansy, 23 F.3d at 787 ("The balancing test should be applied by courts when considering whether to grant confidentiality orders..."). This test embraces several factors meant to "offer litigants a measure of privacy, while balancing against this privacy interest the public's right to obtain information concerning judicial proceedings." Id. at 786. More specifically, the Pansy factors include:

(1) whether disclosure will violate any privacy interests;
(2) whether the information is being sought for a legitimate purpose or for an improper purpose;
(3) whether disclosure of the information will cause a party embarrassment;
(4) whether confidentiality is being sought over information important to public health and safety;
(5) whether the sharing of information among litigants will promote fairness and efficiency;
(6) whether a party benefitting from the order of confidentiality is a public entity or official; and
(7) whether the case involves issues important to the public.

Heller, 1997 U.S. Dist. LEXIS 18521, *20 (citing Pansy, 23 F.3d at 787-91).

Here the document at issue is in the hands of the PSC solely as a result of it having been produced in discovery. It has not been entered into the records of the Court for any substantive purpose, and it has not had any impact on any substantive decision that the Court has made. In this case, therefore, the First Amendment interests of the PSC in publishing the document are not entitled to any weight. Seattle Times, supra; Cipollone v. Liggett Group, Inc., 785 F.2d 1108, 1118-20 (3d Cir. 1986). There is no right of public access to documents that were produced

solely because discovery obligations compelled the production; there exists "no such right as to discovery motions and their supporting documents" because "raw discovery" is not admitted as a record of the court. Leucadia, Inc. v. Applied Extrusion Technologies, Inc., 998 F.2d 157, 164-165 (3d Cir. 1993). The factors listed in Pansy may apply, and it remains the burden of the party seeking confidentiality to show good cause for imposition of confidentiality restrictions. Cipollone, supra. In Medeva Pharma Suisse A.G. v. Roxane Labortatories, Inc., 2011 U.S. Dist. LEXIS 96011, 2011 WL 3841377 (D.N.J. August 26, 2011), the Court considered all of the Pansy factors in determining whether the party who gained documents in the course of discovery should be precluded from disclosing them.

These cases call for consideration of the Pansy factors in light of Pfizer's burden to show that good cause exists for precluding publication or dissemination of the email chain at issue.

C. Has Pfizer Met the Standards for Imposition of Confidentiality?

The PSC correctly points out that Pfizer has not made any showing that release of the document at issue will cause immediate or substantial harm to Pfizer's business. Pfizer makes no argument that its stock will fall, that it will lose exclusive access to secret information about one of its processes, or that it will suffer the loss of a competitive advantage. In that sense, the harm that Pfizer predicts is "generalized" within the meaning of Glenmede Trust Co. v. Thompson, 56 F.3d 476 (3rd Cir. 1995). Pfizer's primary argument is that publication of the document will bring to light a private discussion about product safety that was not intended to be public. Release of the contents of a discussion like this, it is urged, will chill Pfizer's internal discussions in the future.

While most cases require a showing of the likelihood that disclosure of business information will lead to pecuniary or competitive disadvantage, the Third Circuit Court of

Appeals has recognized that a showing of harm to nonbusiness interest may constitute a good cause for preclusion of publication of information gained in discovery. In Cipollone, the court stated:

> Rule 26(c) protects parties from a broad range of troubles: "annoyance, embarrassment, oppression, or undue burden or expense." Consistent with the spirit of the Rule, courts have held that a showing of harm to nonbusiness interests may constitute a good cause. *See, e.g., Krause v. Rhodes,* 671 F.2d 212 (6th Cir.) (government's interest in conducting thorough and confidential investigations is ground for a protective order), *cert. denied,* 450 U.S. 823 (1982).

Cipollone, supra, 785 F.2d at 1114, n.10. If, as Cipollone recognizes, the interest of a public entity in conducting thorough and confidential investigations is a ground for a protective order, then so should a private company's interest in having a robust and thorough internal discussion about the safety of its own products. If the people in a company who are charged with the responsibility of considering product safety learn that their internal deliberations are, in the event of safety claims, going to be made public, they are likely to be inhibited in what they say. Perhaps they will "go offline" and confine their candid remarks to telephone calls, but it is just as likely that they will simply be afraid to say anything that is likely to be controversial later. While this may not amount to immediate pecuniary harm, it would be harmful to the company and companies like it in the long run.

On this basis, Pfizer has shown that the publication of the document will invade a privacy interest as that interest is to be considered as the first Pansy factor. Pfizer has also shown that disclosure of the information is likely to cause the kind of harm that is considered upon a motion for protective order, even if that harm is not strictly within the definition of "embarassment," as that term is used in the third of the seven Pansy factors.

The PSC has not argued that it needs to publish the document in order to promote fairness and efficiency. PSC is able to use the document in this litigation; plaintiffs not represented by members of the PSC whose cases are consolidated for discovery purposes in this MDL are able to use the document, In addition, there are state court plaintiffs who have signed a confidentiality agreement, as well, who are able to see the document. Prevention of publication does not limit the ability of many people who claim injury as a result of use of Zoloft to have access to the document. Therefore, the fifth of the seven Pansy factors does not weigh in favor of public disclosure.

The PSC urges that release of the document is important to promote an informed discussion of a matter of public safety. This provides the basis for consideration of the second, fourth and seventh of the Pansy factors.

There is no question that the safety of pharmaceutical products, including any product discussed in the email chain at issue, is a matter of public concern. Pfizer's insinuation that the document, if released, might make its way into advertising by attorneys is not convincing. There is nothing wrong with attorney advertising any more than there is something wrong with advertising by pharmaceutical companies. The possibility that the information might be part of advertising is of no moment.

However important a discussion of safety of the products mentioned in the email chain may be, the actual discussion in the email chain does not say anything that has not been said by others. The discussion includes references to literature that is well known and often cited in debates about the safety of the product at issue, with no analysis that would add to discussion that is already being held by way of motions in this Court and in the scientific literature presented to the Court.

In Bracco Diagnostics, Inc. v. Amersham Health Inc., 2007 U.S. Dist. LEXIS 51828 (D.N.J. July 18, 2007), the Court held that the defendant's clinical studies of its pharmaceutical product should remain confidential. In that case, even the raw data in the studies was held to be confidential, partly in deference to the statutory scheme whereby submissions of data to the FDA are not required to be disclosed to the public. Id., at *24-28. If raw clinical data produced in discovery that is not otherwise available to the public may be the subject of a confidentiality order, then mere commentary on publicly available scientific literature may be kept confidential. The commentary is not itself clinical information, which is much more likely to inform any public debate than is private commentary about it.

Similarly, in Smith v. BIC Corp., 860 F.2d 194 (3d Cir. 1989), the court held that product safety test information should be considered a trade secret, which may be subject to restrictions on publication. Id., at 201. See also, Heller v. Shaw, 1997 U.S. Dist. LEXIS 18521 at *16-17 (E.D. Pa. November 20, 1997) (while there is a public interest in access to product safety testing information, where information is not likely to be informative because of availability of related underlying data, privacy interests outweigh interest in access).

The PSC has shown that there is a public interest in discussion of product safety, and the email chain at issue is a discussion of product safety. Release of it, however, does not add anything to the discussion in a way that outweighs the privacy interests discussed above.

III. **CONCLUSION**

For these reasons, I recommend that the PSC's request to strike Pfizer's designation of document number PF100200001118-1123 as confidential be denied and that the designation of confidentiality be upheld.

2/28/14

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