

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

PUBLIC CITIZEN,)	
)	
Plaintiff,)	
)	
v.)	
)	
DEPARTMENT OF HEALTH AND)	
HUMAN SERVICES,)	Civil Action No. 11-1681
)	Judge Beryl A. Howell
Defendant,)	
)	
and)	
)	
PFIZER INC. and PURDUE PHARMA)	
L.P.,)	
)	
Defendants-Intervenors.)	
)	

**PLAINTIFF’S MOTION FOR PARTIAL RECONSIDERATION OF
OCTOBER 4, 2013, ORDER AND MEMORANDUM OPINION**

Plaintiff Public Citizen hereby moves on two grounds for partial reconsideration of this Court’s October 4, 2013, order and accompanying memorandum opinion. First, the Court overlooked a key declaration provided by Dr. Kevin Rodondi, which was submitted in support of Public Citizen’s motion for summary judgment and in opposition to the motions for summary judgment by the Department of Health and Human Services (HHS), Pfizer, Inc., and Purdue L.P. (collectively, the defendants). Dr. Rodondi’s testimony should have precluded summary judgment for the defendants on three categories of records and entitled Public Citizen to summary judgment on five other categories of records. Second, the Court overlooked Public Citizen’s argument that records revealing suspected or confirmed illegal activity cannot, as a matter of law, be “confidential” for the purpose of Freedom of Information Act (FOIA)

Exemption 4. Public Citizen also requests that the Court make one small clarification to its memorandum opinion.

To the extent that Local Civil Rule 7(m) applies to this motion, Public Citizen has asked the defendants for their position. All defendants have indicated that they do not consent.

ARGUMENT

This Court's order resolved Public Citizen's FOIA claim with respect to some categories of records but not others. It is thus interlocutory in nature under Federal Rule of Civil Procedure 54(b). *See In Def. of Animals v. NIH*, 543 F. Supp. 2d 70, 75 (D.D.C. 2008). Rule 54(b) recognizes that this Court has "inherent power to reconsider an interlocutory order as justice requires." *Wannall v. Honeywell Int'l, Inc.*, No. 10-351, 2013 WL 1966060, at *4 (D.D.C. May 14, 2013) (Howell, J.) (internal quotation marks omitted). Under the "as justice requires" standard, this Court may consider, among other things, whether it "patently misunderstood the parties" in its previous order or "made an error in failing to consider controlling law or data." *In Def. of Animals*, 543 F. Supp. 2d at 75 (internal quotation marks omitted).

I. The Court Erred by Overlooking Dr. Rodondi's Declaration When Considering the Cross-Motions for Summary Judgment.

In its order and opinion, this Court considered whether the documents sought by Public Citizen are exempt from disclosure under FOIA Exemption 4 as "commercial materials" that are either "privileged or confidential." Doc. 36, Opinion at 18 (internal quotation marks omitted). It rejected arguments that the documents are "privileged," *id.* at 38-39 n.19, and "confidential" based on likely impairment of the government's ability to obtain necessary information in the future, *id.* at 40-43. The Court thus concluded that Exemption 4 applies in this case only if documents are both "commercial" and "confidential," *id.* at 38, where the "confidential" nature of documents is based on a likelihood that disclosure will "cause substantial [competitive]

harm” to Pfizer and Purdue, *id.* at 29 (quoting *Nat’l Parks and Conserv. Ass’n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974)).

Under this standard, the Court granted summary judgment to the defendants with respect to the withholding of three categories of records at issue in this motion: (1) changes in the companies’ process for monitoring and removing Ineligible Persons; (2) Pfizer’s off-label findings and a summary of the company’s responsive action; and (3) portions of the companies’ Independent Review Organization (IRO) documents.¹ Doc. 35, Order at 1-2; Opinion at 52. In addition, this Court denied all parties’ motions for summary judgment with respect to five additional categories of records at issue in this motion: (4) Reportable Event summaries; (5) Disclosure Log summaries; (6) summaries of legal and investigatory inquiries regarding the companies; (7) company communications with the FDA; and (8) the content of Pfizer’s detailing sessions that reveal off-label promotion identified in Pfizer’s off-label findings.² Order at 2. For record categories (4) and (5), the Court held that the defendants had not demonstrated that the information is “commercial” under Exemption 4. Opinion at 26-28, 37. The Court did not consider the separate question whether those records are “confidential,” despite Public Citizen’s cross-motion for summary judgment and supporting evidence on that issue. *Id.* at 19 (stating that the Court would consider confidentiality only for those “categor[ies] of documents found to contain commercial information”). For record categories (6) through (8), the Court held that the

¹ Although the Court refers generally to the companies’ IRO documents, *see* Opinion at 48-49, 52, Public Citizen seeks in litigation only selected portions of those documents, *see* Doc. 26, Pl.’s S.J. Memo. at 28-29 & nn.11-17.

² Although the Court refers generally to Pfizer’s documents reflecting the content of detailing sessions, *see* Opinion at 48, 52, Public Citizen sought in litigation only those detailing session records that reveal off-label promotion identified in Pfizer’s off-label findings, Pl.’s S.J. Memo. at 27.

documents are “commercial,” but that the defendants had not demonstrated that the documents are “confidential.” *Id.* at 50.

In ruling on the motions for summary judgment, this Court did not cite or discuss the expert declaration of Dr. Kevin Rodondi, an Associate Professor of Clinical Pharmacy at the University of California, San Francisco, School of Pharmacy. *See* Doc. 26-4, Rodondi Decl. Dr. Rodondi’s fifteen-page declaration addresses in detail the records sought by Public Citizen, including the categories of records at issue here for which the Court granted summary judgment to the defendants, *id.* ¶¶ 22, 33-36, 44, and for which the Court denied all parties’ motions for summary judgment, *id.* ¶¶ 14, 17, 19, 25, 39, 44. Dr. Rodondi’s declaration explains why disclosure of these records is not likely to cause substantial competitive harm to Pfizer and Purdue.

As the Court recognizes, whether disclosure of the requested records is likely to cause substantial competitive harm is a material fact in this case. *See* Opinion at 39. At a minimum, Dr. Rodondi’s testimony created a “genuine dispute” over this fact with respect to record categories (1) through (3), cited above, for which the Court awarded summary judgment to the defendants. Fed. R. Civ. P. 56(a). As a result, the Court erred by granting summary judgment to the defendants for documents about changes in the companies’ process for monitoring and removing Ineligible Persons, Pfizer’s off-label findings and a summary of the company’s responsive action, and portions of the companies’ Independent Review Organization (IRO) documents sought by Public Citizen. *See id.*; *cf. In Def. of Animals v. USDA*, 656 F. Supp. 2d 68, 71 (D.D.C. 2009) (resolving by bench trial “a disputed material fact as to whether disclosure of documents withheld under FOIA Exemption 4 would cause substantial competitive harm” to a company).

Moreover, in its consideration of record categories (4) and (5) (Reportable Event summaries and Disclosure Log summaries), the Court erred by failing to reach the question whether the records are “confidential,” that is, whether disclosure of the records is likely to cause substantial competitive harm to the companies. Regardless whether the defendants could—upon a renewed motion for summary judgment—demonstrate that these records are “commercial,” they cannot prevail under Exemption 4 without showing that the records are “confidential.” The defendants have not done so, even in response to Public Citizen’s cross-motion for summary judgment on the “confidentiality” issue and the submission of Dr. Rodondi’s declaration addressing record categories (4) and (5). *See* Pl.’s S.J. Memo. at 22-23. As a result, based on the evidence overlooked by the Court, Public Citizen is now entitled to summary judgment on these records. *See* Fed. R. Civ. P. 56(e)(3).

Finally, the Court erred by denying all parties’ motions for summary judgment on the ground that the defendants had not demonstrated that record categories (6) through (8) (summaries of legal and investigatory inquiries regarding the companies, company communications with the FDA, and the content of Pfizer’s detailing sessions that reveal off-label promotion identified in Pfizer’s off-label findings) are “confidential.” Public Citizen cross-moved for summary judgment on these categories of records and, through Dr. Rodondi’s declaration, demonstrated that these records are not “confidential.” *See* Pl.’s S.J. Memo. at 24-28. Based on this evidence, which the Court overlooked, Public Citizen was entitled to summary judgment for these categories of records as well. *See* Fed. R. Civ. P. 56(e)(3).

Reconsideration of the Court’s order and opinion in light of Dr. Rodondi’s declaration is necessary to prevent harm to Public Citizen’s interests. Public Citizen’s FOIA claim has been dismissed as to several categories of records, although Dr. Rodondi’s declaration should have

precluded dismissal. Moreover, even with respect to those records for which the Court denied all parties' motions for summary judgment, Public Citizen will experience a significant delay in access to documents to which it should be entitled based on Dr. Rodondi's testimony. It has now been nearly four years since Public Citizen submitted its FOIA request to HHS, and that period of time includes a substantial amount of delay by the government during administrative proceedings. "Governmental information doesn't have to be secret forever . . . to do harm" to a requester's interest in accessing information through FOIA. *S. Alliance for Clean Energy v. U.S. Dep't of Energy*, 853 F. Supp. 2d 60, 79 (D.D.C. 2012). Delay also impairs that interest.

II. The Court Did Not Rule on Public Citizen's Argument That Suspected or Confirmed Illegal Activity Cannot Be "Confidential" Under FOIA Exemption 4.

This Court rejected Public Citizen's argument that documents reflecting suspected or confirmed illegal activity cannot be "commercial" for the purpose of Exemption 4. Opinion at 22-25. It did not address, however, Public Citizen's related argument that such documents cannot—as a matter of law—cause substantial competitive harm and thus be "confidential" under Exemption 4. The government's generalized assertions of competitive harm do not apply to records that reveal a company's likely or unlawful activity. *See* Pl.'s S.J. Memo. at 21; Doc. 34, Pl.'s Reply at 13-14. The Court erred by not ruling on this argument, which presents an alternative basis for granting summary judgment to Public Citizen with respect to Disclosure Log summaries; Reportable Event summaries; correspondence with the FDA about off-label promotion; and Pfizer's documents relating to off-label promotion in detailing sessions (as cited above, record categories (2), (4), (5), (7), and (8)).

III. Public Citizen Requests That the Court Clarify Its Reference to the Purdue Supplement.

In discussing Purdue's supplement to its first annual compliance report, the Court refers to the document as the "2009 Purdue Supplement." Opinion at 36, 38, 49. However, the supplement was part of the company's 2008, not 2009, annual report. *See* Pl.'s S.J. Memo. at 26; Doc. 19, Purdue *Vaughn* Index, Entry 22. The date is significant because Purdue also submitted a supplement to its 2009 annual report, *see* Purdue *Vaughn* Index, Entry 45, a submission that constitutes a response to an IRO report and that is covered by the Court's separate holding regarding those reports, *see* Doc. 22-2, Weinstein Decl. ¶ 30; Opinion at 38 (including within the category of "IRO reports" Purdue's response and corrective action plans to IRO reports, pursuant to § V.B.6 of Purdue's Corporate Integrity Agreement). Public Citizen respectfully requests that the Court amend its opinion to clarify that this supplement is part of Purdue's 2008 annual report.

CONCLUSION

For the foregoing reasons, Public Citizen requests that the Court grant the motion for partial reconsideration, amend its opinion accordingly, and enter the attached order.

Dated: October 17, 2013

Respectfully submitted,

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