IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

PLAINTIFF'S RENEWED MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, plaintiff Public Citizen hereby renews its motion for summary judgment in this case brought under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, on the ground that there is no genuine issue of disputed material fact and that plaintiff is entitled to judgment as a matter of law. Of the records remaining in dispute, plaintiff seeks (1) Reportable Event summaries required by § V.B.12 of the Pfizer Corporate Integrity Agreement (CIA) and § V.B.9 of the Purdue CIA; (2) Disclosure Log summaries required by § V.B.14 of the Pfizer CIA and § V.B.10 of the Purdue CIA; (3) information regarding actions taken in response to screening and removal obligations for Ineligible Persons required by § V.B.11 of the Pfizer CIA and § V.B.12 of the Purdue CIA; and (4) Pfizer documents reflecting the content of detailing sessions that reveal off-label promotion required by § V.B.17 of the Pfizer CIA.

Defendant Department of Health and Human Services (HHS) and defendant-intervenors Pfizer and Purdue have not demonstrated that these redacted or withheld records are exempt from disclosure under 5 U.S.C. § 552(b)(4). Accordingly, judgment as to these records should be entered for plaintiff.

In support of this motion and in opposition to defendant's and defendant-intervenors' motions for summary judgment, plaintiff submits the accompanying Memorandum in Support of Plaintiff's Renewed Motion for Summary Judgment and Opposition to Defendant's and Defendant-Intervenors' Renewed Motions for Summary Judgment; the Third Declaration of Julie A. Murray; and a proposed order. Plaintiff also continues to rely on its Statement of Material Facts as to Which There Is No Genuine Issue and on all evidence submitted in support of its first motion for summary judgment.

Respectfully submitted,

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March 11, 2014

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MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF PLAINTIFF'S RENEWED MOTION FOR SUMMARY JUDGMENT
AND IN OPPOSITION TO DEFENDANT'S AND
DEFENDANT-INTERVENORS' RENEWED MOTIONS FOR SUMMARY JUDGMENT

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INTRODUCTION AND BACKGROUND

Plaintiff Public Citizen brought this Freedom of Information Act (FOIA) case to seek portions of annual compliance reports that two pharmaceutical manufacturers—defendant-intervenors Pfizer and Purdue Pharma L.P.—submitted to the Office of Inspector General (OIG) of defendant U.S. Department of Health and Human Services (HHS), pursuant to those companies' Corporate Integrity Agreements (CIAs) with OIG. A description of plaintiff's request and the documents at issue are set forth in Public Citizen's first motion for summary judgment and reply and incorporated herein by reference. *See generally* Doc. 26, Pl.'s S.J. Mem.; Doc. 34, Pl.'s Reply.

In an October 4, 2013, order, this Court granted summary judgment to defendants for four categories of records, granted summary judgment to plaintiff for two categories of records, and denied summary judgment to all parties without prejudice with respect to six additional categories of records. *See generally* Doc. 35, S.J. Order.[1] The Court also ordered HHS to conduct a new search for responses by Pfizer to Independent Review Organization (IRO) reports that were missing from the agency's document production and *Vaughn* index. *Id.* at 2. The Court indicated that the parties could file renewed motions for summary judgment and supplementary *Vaughn* indices and declarations. *Id.* at 3. Public Citizen moved for partial reconsideration of the Court's order. The Court denied that motion, concluding, among other things, that its earlier

[1] The Court denied summary judgment to all parties on: "(1) the Reportable Events summaries required by § V.B.9 of the Purdue CIA and § V.B.12 of the Pfizer CIA; (2) the Disclosure Log summaries required by § V.B.10 of the Purdue CIA and § V.B.14 of the Pfizer CIA; (3) the summaries of legal and investigatory inquiries required by § V.B.13 of the Purdue CIA and § V.B.15 of the Pfizer CIA; (4) reasonably segregable portions of the 2009 Purdue Supplement that do not pertain to Purdue's promotional monitoring program; (5) company communications with the FDA required by § V.B.14 of the Purdue CIA and § V.B.16 of the Pfizer CIA; and (6) the underlying records reflecting the content of detailing sessions between HCPs and Covered persons" as required by § V.B.17 of the Pfizer CIA." S.J. Order at 2 (internal quotation marks omitted).

order had "addressed and rejected" Public Citizen's contention that documents reflecting suspected or confirmed illegal activity cannot as a matter of law be confidential, and it thus found no reason to reconsider that holding. Doc. 44, Order Denying Mot. for Reconsideration at 10.

Before filing new motions for summary judgment, defendants released to Public Citizen some documents for which this Court had denied all parties' earlier motions for summary judgment. *See* Doc. 46, Status of Records Remaining in Dispute at 3-4. The parties then jointly filed a list of documents that remained in dispute after that release. *Id.* at 2-3. The defendants moved for summary judgment as to those records and provided additional declarations. In its motion for summary judgment, HHS also introduced new evidence to support the adequacy of its search for the missing Pfizer responses to and corrective action plans based on IRO reports. *See* Doc. 51-1, 2d Brooks Decl.

Based on HHS's new evidence, Public Citizen is now satisfied that the missing Pfizer documents were either included in records accounted for in the first Pfizer *Vaughn* index (and for which this Court granted summary judgment to defendants, *see* S.J. Order at 2) or were never submitted to HHS, despite the fact that § V.B.7 of Pfizer's CIA requires such submission. Public Citizen thus no longer challenges the adequacy of HHS's search for these documents. Moreover, Public Citizen no longer seeks the supplement and corresponding cover memorandum to Purdue's First Annual Report. *See* Doc. 49, Supp. Purdue *Vaughn* Index, Entry 3.

Public Citizen renews its motion for summary judgment with respect to the following records: (1) Reportable Event summaries, as required by § V.B.12 of the Pfizer CIA and § V.B.9

of the Purdue CIA;[2] (2) Disclosure Log summaries, as required by § V.B.14 of the Pfizer CIA and § V.B.10 of the Purdue CIA;[3] (3) documents regarding company actions taken in response to screening and removal obligations for Ineligible Persons, as required by § V.B.11 of the Pfizer CIA and § V.B.12 of the Purdue CIA;[4] and (4) Pfizer documents reflecting the content of detailing sessions that reveal potential off-label promotion, as required by § V.B.17 of the Pfizer CIA.[5]

The defendants have failed to meet their burden of demonstrating that the records sought by Public Citizen are confidential for the purpose of Exemption 4. Accordingly, this Court should grant Public Citizen's renewed motion for summary judgment; deny the renewed motions for summary judgment by HHS, Pfizer, and Purdue; and order HHS to produce the requested records.

STANDARD OF REVIEW

Summary judgment is appropriate when no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. FOIA's "strong presumption in favor of disclosure places the burden on the agency to justify the withholding of

[2] *See* Doc. 48, Supp. Pfizer *Vaughn* Index, Entries 10, 41, 79, 115, 151; Doc. 49, Supp. Purdue *Vaughn* Index, Entry 4.

[3] *See* Doc. 48, Supp. Pfizer *Vaughn* Index, Entries 12, 43, 81, 117, 153; Doc. 49, Supp. Purdue *Vaughn* Index, Entries 1, 2, 5, 6.

[4] Although not identified in this Court's October 4 order, this category of records remains in dispute. *See* Doc. 46, Status of Records Remaining in Dispute at 2 n.2; *see also* Doc. 48, Supp. Pfizer *Vaughn* Index, Entries 39, 40, 77, 78, 114, 150 (identifying records); Doc. 19, First Purdue *Vaughn* Index, Entries 4, 27 (identifying records, which Purdue omitted from its supplemental *Vaughn* index).

[5] *See* Supp. Pfizer *Vaughn* Index, Entries 15B, 46, 48, 84, 86, 120, 122, 155, and 157. Public Citizen does not seek Supplemental Pfizer *Vaughn* Index Entries 15, 15A, 15C-E, 49-52, 87-90, 123-26, and 158-61. In addition, as Pfizer recognizes, summary judgment for Entry 15F, although listed in the revised *Vaughn* index, has already been granted to defendants. *See* Doc. 47-1, Pfizer 2d S.J. Mem. at 16 n.9.

any requested documents." *Dep't of State v. Ray*, 502 U.S. 164, 173 (1991). If the government cannot "carry its burden of convincing the court that one of the statutory exemptions appl[ies]," the requested records must be released to the plaintiff. *Goldberg v. Dep't of State*, 818 F.2d 71, 76 (D.C. Cir. 1987).

ARGUMENT

FOIA Exemption 4 protects from public disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). Defendants contend that the documents are both commercial and confidential and thus fall within the ambit of Exemption 4. However, the documents can be withheld as confidential only if defendants can show that their release is likely to "'cause substantial harm to the competitive position' of Pfizer or Purdue." Doc. 36, Mem. Op. at 39 (quoting *Nat'l Parks & Conserv. Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974)); *see also id.* at 43 (rejecting governmental impairment theory of confidentiality). The defendants have failed to meet their burden of demonstrating such competitive harm.

As argued in more detail below, many of defendants' assertions of harm rely on a competitive market in information about *lawful* policies and practices. In contrast, the Disclosure Log summaries, Reportable Event summaries, and documents revealing off-label promotion in detailing sessions reveal information about suspected or confirmed *illegal* activity. Defendants have not demonstrated that there is a competitive market for information about suspected or confirmed unlawful policies and practices, nor is there any reasonable likelihood that such a market exists.

Moreover, Pfizer's contention that disclosure of Reportable Event and Disclosure Log summaries might chill whistleblowers' willingness to come forward is a factor that is irrelevant

under Exemption 4, which requires that disclosure be likely to result in harm caused by *competitors*' affirmative use of the information. Pfizer's contention is also at odds with the expert opinion of one of plaintiff's experts, an authority on whistleblower behavior. Doc. 26-2, Kesselheim Decl. ¶¶ 18-19.

Finally, Pfizer's contention that competitors might use information about Pfizer's discipline of employees to portray the company as too harsh, and thus poach Pfizer's employees, is nonsensical. Pfizer has not demonstrated that there is market competition for unscrupulous employees who would be turned off by a drug company's no-tolerance policy for illegal conduct, even assuming Pfizer's records show such a stringent policy. Indeed, common sense suggests just the opposite. For these reasons and those set out below, the records are not exempt under Exemption 4 and should be released.

I. The Reportable Event Summaries Are Not Exempt from Disclosure Under Exemption 4.

Under the terms of their CIAs, Pfizer and Purdue were required to report to OIG about so-called "Reportable Events," defined, with minimal variation, as a report involving a matter "that a reasonable person would consider a probable violation of criminal, civil, or administrative laws" that apply to a federal health care program or to certain Food and Drug Administration (FDA) requirements. Doc. 22-1, Pfizer CIA at 21; Doc. 22-2, Purdue CIA at 19-20. In their annual reports, the companies were then obligated to provide a summary of Reportable Events identified during the reporting period—"including the relevant facts, persons involved, and legal and Federal health care program authorities implicated"—and the status of any corrective or preventative action. Pfizer CIA at 25-26; Purdue CIA at 28 (substantially similar language). In its summary judgment order, this Court concluded that defendants had not met their burden of demonstrating that the Reportable Event summaries were "commercial' in nature but did not

reach the question whether defendants demonstrated that the summaries were also confidential. Mem. Op. at 27.

The defendants have failed to demonstrate that release of the Reportable Event summaries is likely to cause substantial competitive harm to Pfizer and Purdue. The companies contend that the Reportable Event summaries are confidential because competitors could use information related to the companies' operations, "such as how the company interacts with health care providers, and [the company's] policies governing the selling, detailing, marketing, advertising, promoting, and branding of . . . products." Pfizer 2d S.J. Mem. at 8; *accord* Doc. 50, Purdue 2d S.J. Mem. at 7. But the companies ignore that the operations described in the Reportable Event summaries are in part going to be those a reasonable person would consider a probable violation of criminal, civil, or administrative laws. Even assuming that such information could be confidential as a matter of law, as this Court held in its October 4 order, *see* Doc. 44, Denial of Mot. for Reconsideration at 10, the companies do not explain why a competitor would seek to copy such operations, nor do they demonstrate that there is "actual competition" for information about non-compliance with the law. *See Gulf & W. Indus., Inc. v. United States*, 615 F.2d 527, 530 (D.C. Cir. 1979); *see also CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1152 (D.C. Cir. 1987). In addition, to the extent disclosure reveals corrective or preventative actions, it makes no sense to say that the companies will suffer substantial competitive harm based on the disclosure of activities designed to do nothing more than comply with generally applicable laws. All companies are aware of their legal obligations and the steps they must take to comply. *See CNA Fin. Corp.*, 830 F.2d at 1154 ("To the extent that any data requested under FOIA are in the public domain, the submitter is unable to make any claim to confidentiality—a *sine qua non* of Exemption 4."); *Nat'l Cmty. Reinvestment Coal. v. Nat'l*

Credit Union Admin., 290 F. Supp. 2d 124, 134 (D.D.C. 2003) ("Public availability of information defeats an argument that the disclosure of the information would likely cause competitive harm.").

Pfizer makes two other contentions, neither of which holds water. First, it contends that the Reportable Event summaries are confidential because it marked these documents as "FOIA confidential," and "the government obligated itself in good faith not to disclose" this information. Pfizer 2d S.J. Mem. at 8. But as this Court's earlier opinion recognized, "HHS is not obligated to accept the companies' designation of any document as FOIA exempt," and HHS in fact cautioned Pfizer with respect to an earlier CIA not to "assume that all of Pfizer's reports and other documents submitted pursuant to the CIA will be exempt from a FOIA request." Mem. Op. at 5 & n.3. In any event, FOIA "mandates that an agency disclose records on request, unless they fall within one of [the statute's] nine exemptions," which "are explicitly made exclusive." *Milner v. Dep't of Navy*, 131 S. Ct. 1259, 1262 (2011) (internal quotation marks omitted). The government cannot overcome this command simply by promising confidentiality to submitters of information.

Pfizer also argues that if Reportable Event summaries were revealed, "individuals might become less forthcoming about reporting issues or with cooperating in ongoing internal investigations or reviews." Pfizer 2d S.J. Mem. at 9. As this Court has already recognized, however, competitive harm for the purpose of Exemption 4 is "'limited to harm flowing from the affirmative use of proprietary information *by competitors*.'" Mem. Op. at 43 (quoting *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1291 n.30 (D.C. Cir. 1983)).

II. The Disclosure Log Summaries Are Not Exempt from Disclosure Under Exemption 4.

Under the CIAs, Pfizer and Purdue were obligated to maintain a disclosure program for internal whistleblowers who believed that company activities with respect to federal health care programs or FDA requirements potentially violated "criminal, civil, or administrative law[s]." Pfizer CIA at 18; Purdue CIA at 16. The CIAs mandated that the disclosure program provide a mechanism for "anonymous communications for which appropriate confidentiality [would] be maintained." Pfizer CIA at 19; Purdue CIA at 16. The companies were required to conduct an internal review of "sufficiently specific" whistleblower disclosures, and—in their annual reports—provide a summary of disclosures in the "Disclosure Log" that related to federal health care programs or FDA requirements. Pfizer CIA at 19, 26; Purdue CIA at 17, 28. This Court denied all parties' motions for summary judgment for Disclosure Log summaries on the ground that the defendants had not demonstrated the records were commercial in nature; it did not reach the question whether defendants demonstrated that the records were confidential. Mem. Op. at 28.

As with Reportable Event summaries, the companies contend that release of the Disclosure Log summaries would cause substantial competitive harm by revealing information about the companies' interactions with health care providers, and their policies regarding activities such as selling, detailing, and marketing drugs. Pfizer 2d S.J. Mem. at 13; Purdue 2d S.J. Mem. at 7. Again, however, the Disclosure Log summaries reveal company activities that at least potentially violated criminal, civil, or administrative laws. Even assuming that such information could be confidential as a matter of law, the companies have not demonstrated that there is a competitive market for cutting-edge information about how to break the law or for techniques that are likely to end up in a whistleblower's report. *See Gulf & W. Indus., Inc.*, 615

F.2d at 530 (government must demonstrate "actual competition" for Exemption 4's competitive injury prong to apply); *accord CNA Fin. Corp.*, 830 F.2d at 1152. Moreover, to the extent the Disclosure Log summaries reveal something about the companies' compliance programs, those programs are in no small part set by the terms of the CIAs, which are publicly available, a fact that defeats a claim to confidentiality. *See CNA Fin. Corp.*, 830 F.2d at 1154; *Nat'l Cmty. Reinvestment Coal.*, 290 F. Supp. 2d at 134.

Pfizer's additional contention that disclosure of the logs might chill individuals from coming forward to report possible violations of law is also misplaced. Pfizer 2d S.J. Mem. at 13-14. Whether public release of the summaries would have a chilling effect on whistleblowers is not a relevant consideration with respect to the competitive harm analysis. *See* Mem. Op. at 43 (citing *Pub. Citizen Health Research Grp.*, 704 F.2d at 1291) (making clear that competitive injury for the purpose of Exemption 4 must flow from a competitor's affirmative use of the information). In any event, Pfizer's assertion in this regard is at odds with the expert opinion of Dr. Aaron Kesselheim, who conducted "one of the most systematic studies to date of pharmaceutical whistleblower behavior." Kesselheim Decl. ¶ 18. Based on his expertise, Dr. Kesselheim opined "that people who choose to report their bosses and not participate in illegal pharmaceutical marketing behavior possess strong faith in their convictions and are unlikely to be dissuaded by the remote possibility that their names might eventually be revealed many years later through a FOIA request." *Id.* Here, of course, even if the disclosure log summaries contain names, Public Citizen has expressly indicated that it is not seeking them. "Such a caveat makes the possibility that this information will dissuade whistleblowers from coming forward even more remote." *Id.* ¶ 19.

Pfizer also falls short in contending that the Disclosure Logs might reveal how it disciplines employees and that a competitor, believing that Pfizer "is unfair or too harsh in its treatment of its employees under specific circumstances," might use the information "to steal employees from Pfizer." Pfizer 2d S.J. Mem. at 14. Pfizer has not demonstrated that there is market competition for unscrupulous employees who could be lured to a competitor because of Pfizer's strict policy against illegal conduct, even assuming Pfizer's records show such a strict policy. Indeed, common sense suggests just the opposite.

III. Documents Regarding the Companies' Actions to Screen for and Remove Ineligible Persons Are Not Exempt from Disclosure Under Exemption 4.

The CIAs required Pfizer and Purdue to screen certain individuals—including some officers, employees, and applicants—to determine whether those individuals were "Ineligible Persons." Pfizer CIA at 20; Purdue CIA at 18. "Ineligible Persons" were defined as individuals (1) who were "excluded, debarred, suspended, or otherwise ineligible to participate" in federal health care, procurement, or nonprocurement programs, or (2) who had been convicted of crimes for which mandatory exclusion was required but had not yet been excluded. Pfizer CIA at 19; Purdue CIA at 17. Ineligible Persons who are excluded from federal health care programs may not work on such programs without violating the terms of their exclusion, and drug companies—even those not subject to CIAs—face civil fines for hiring Ineligible Persons to work on such programs. *See* OIG, The Effect of Exclusion from Participation in Federal Health Care Programs, Special Advisory Bulletin (Sept. 1999), *available at* http://oig.hhs.gov/exclusions/effects_of_exclusion.asp. Accordingly, if screening revealed that an individual was an "Ineligible Person," Pfizer and Purdue were required to remove that person from all involvement with the federal health care programs in which the companies engaged and to ensure that no federal funds were used to compensate the person. Pfizer CIA at 20; Purdue CIA at 19.

In their annual reports, Pfizer and Purdue were obligated to provide OIG with (1) any changes to the process by which they fulfilled the requirement to screen for and remove Ineligible Persons; (2) the name, title, and responsibilities of any person identified as an Ineligible Person; and (3) the actions taken by the companies in line with their screening and removal obligations. Pfizer CIA at 25; Purdue CIA at 28. Although Public Citizen's first motion for summary judgment sought all three categories of information relating to Ineligible Persons, *see* Doc. 26, Pl.'s S.J. Mot. at 1 (seeking "Pfizer and Purdue records involving the screening and removal of Ineligible Persons"); *id.*, Pl's S.J. Mem. at 23-24 (arguing that a company's "actions taken to comply with its obligations to screen and remove ineligible persons" are not exempt from disclosure (internal quotation marks omitted)), the Court's October 4 order addressed only the first two, *see* Mem. Op. at 30, 46. Thus, this Court has not resolved whether information about actions taken by the companies in line with their legally-mandated screening and removal obligations is exempt from disclosure. *See* Pfizer 2d S.J. Mem. at 21 (recognizing that the Court's order did not address this issue); *see also* Status of Records Remaining in Dispute at 2-3 (identifying records).

As an initial matter, Purdue contends that none of its documents on Ineligible Persons (listed as entries 4 and 27 in the first Purdue *Vaughn* index, Doc. 19) remain at issue because those documents state that no screened persons were ineligible as defined by the CIA. Purdue 2d S.J. Mem. at 2 n.3. Purdue's reasoning is not clearly stated, but it seems to suggest that no action could be taken involving Ineligible Persons because such persons were not found through the screening process. Purdue thus omitted all documents on Ineligible Persons from its supplemental *Vaughn* index, even though the records were listed in the parties' joint filing regarding records that remain in dispute. *See* Status of Records Remaining in Dispute at 3.

Purdue's position is at odds with information provided in the first Purdue *Vaughn* index, which stated that two Purdue records (entries 4 and 27 in that index) contained information "regarding privileged communications to the OIG related to Purdue's *proposed actions regarding ineligible persons*." Doc. 19, First Purdue *Vaughn* Index, Entry 4 (emphasis added); *see also id.*, Entry 27 (same). Purdue makes no attempt to explain this discrepancy. Moreover, as copies of these documents in redacted form demonstrate, *see* 3d Decl. of Julie A. Murray ¶¶ 2-3, Ex. A, B (attached), the location of one of the redactions specifically suggests that some of the withheld information relates to the company's actions with regard to Purdue's former Chief Legal Officer, who was excluded from participation in all federal healthcare programs in 2008. Even if this person was not identified as ineligible through Purdue's screening mechanism, the redacted portion of the record strongly suggests that the withheld information relates to actions relating to the company's removal obligations with respect to an Ineligible Person. Thus, Purdue's documents on Ineligible Persons remain at issue.

Pfizer concedes that its documents on Ineligible Persons remain at issue to the extent they contain information about company actions to screen and remove such individuals. It instead defends the withholding of information about actions taken to screen and remove Ineligible Persons by contending that such information is analogous to changes to the processes for fulfilling the Ineligible Persons requirement, Pfizer 2d S.J. Mem. at 22, information for which this Court's October 4 order granted summary judgment to defendants, Mem. Op. at 45-46. Pfizer contends that disclosure of the company's actions relating to Ineligible Persons could reveal its "broader structure and operations" and allow competitors to copy Pfizer's compliance program. Pfizer 2d S.J. Mem. at 22 (internal quotation marks omitted). But even assuming a competitive market in such information, Pfizer does not argue that the withheld information

would reveal the company's structure and operations beyond those details that can already be gleaned from the public record. *See CNA Fin. Corp.*, 830 F.2d at 1154; *Nat'l Cmty. Reinvestment Coal.*, 290 F. Supp. 2d at 134. The CIA already describes in detail the process that Pfizer must use to identify Ineligible Persons and the corrective actions that the company must take. Pfizer CIA at 19-20. To the extent that Pfizer's actual actions diverged from the actions required by its CIA, Pfizer has not explained why competitors would wish to copy that non-compliant behavior, thus failing to demonstrate "actual competition" for this information. *Gulf & W. Indus., Inc.*, 615 F.2d at 530.

IV. Pfizer Documents Reflecting Off-Label Promotion During Detailing Sessions Are Not Exempt from Disclosure Under Exemption 4.

Pfizer's CIA required the company to obtain commercially available non-Pfizer records that reflected the content and subject matter of "detailing interactions," Pfizer CIA at 22, which are basically interactions in which pharmaceutical sales representatives give doctors and other health care providers details about certain drugs and their uses. Pfizer was required to identify, based on those records, instances in which it appeared that Pfizer sales representatives discussed or disseminated information for off-label uses for certain Pfizer drugs. *Id.* at 23. The company was then obligated to make findings with respect to these instances of off-label dissemination or discussion of information and to take corrective action where necessary. *Id.* In its annual reports, Pfizer was obligated to provide OIG with those findings and the underlying records to support them. *Id.* at 26. In its October 4 order, this Court held that Pfizer's off-label findings were exempt from disclosure. Mem. Op. at 47-48. However, it could not determine whether the underlying detailing session records—which the Court noted were commercially available from third parties—were confidential. *Id.* at 48. Thus, records reflecting the actual content of detailing

sessions and references to those records (identified as Pfizer *Vaughn* entries 15B, 46, 48, 84, 86, 120, 122, 155, and 157) remain at issue in this case.[6]

Pfizer first contends that Public Citizen has limited its claim to records that directly discuss or identify off-label promotion and is thus entitled to the records that remain. Specifically, Pfizer argues that detailing session documents "do not directly address, discuss, or identify off-label promotion," but merely provide doctors' recollections of detailing sessions that may suggest off-label promotion occurred. Pfizer 2d S.J. Mem. at 18. Pfizer's new argument is too clever by half. Regardless whether verbatims from detailing sessions directly address or discuss off-label promotion, they relate to off-label promotion by—as Pfizer's own declarant recognizes—acting as the impetus for additional investigations by Pfizer that confirm that the company's representatives were, in fact, engaged in unlawful behavior. *See* Doc. 47-2, Nowicki 2d Decl. ¶¶ 57-58. Because Pfizer's CIA required the company to investigate instances of potential off-label promotion revealed in the verbatims and make findings with respect to those instances, Pfizer CIA at 22-23, § III.J, Pfizer surely knows which of the detailing sessions submitted to OIG resulted in findings of off-label promotion, even if the actual detailing session records do not use the term "off-label promotion."

Pfizer separately contends that the verbatims are confidential because it has paid for them and is "contractually bound to keep them confidential." Pfizer 2d S.J. Mem. at 19 (citing Doc. 47-4, Nealon Decl. ¶ 11). Pfizer has not introduced the agreements to which its declarant refers, Nealon Decl. ¶ 11, which would provide the best evidence of the company's contractual obligations. *See* Fed. R. Evid. 1002. In addition, the verbatims do not reveal information

[6] Public Citizen no longer pursues any other records regarding off-label detailing sessions listed in the supplemental Pfizer *Vaughn* index and for which summary judgment has not already been granted.

confidential to Pfizer. As Pfizer concedes, a verbatim from a detailing session "captures a health care provider's subsequent recollection and dominant impressions" after a visit from a Pfizer sales representative. Nowicki 2d Decl. ¶ 56. Thus, it contains information available to any health care provider visited by a Pfizer representative and in fact represents the thoughts and recollections of health care providers, not Pfizer itself. Moreover, Pfizer's own declarant makes clear that verbatims are publicly available from a third party company—albeit for a price—to anyone wishing to purchase them. Nealon Decl. ¶ 11. Thus, the information in verbatims is not confidential to Pfizer and should be released.

CONCLUSION

For the foregoing reasons, this Court should grant Public Citizen's renewed motion for summary judgment and deny the renewed motions for summary judgment submitted by HHS, Purdue, and Pfizer.

Respectfully submitted,

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