UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

MEMORANDUM OPINION

The plaintiff, Public Citizen, has requested, under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, annual reports that were required to be submitted by two companies, Pfizer, Inc. ("Pfizer") and Purdue Pharma L.P. ("Purdue"), to the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS"), as part of the companies' compliance with settlement agreements arising from the companies' illegal off-label promotion of drugs reimbursed by federal health care programs.[1] Between forty and one hundred times each year over the last decade, HHS' OIG has participated in such settlement agreements by entering into Corporate Integrity Agreements ("CIAs") with companies seeking to

[1] Off-label marketing of drugs for non-FDA approved uses is "considered by the FDA to be a violation of the Food Drug and Cosmetic Act," and is "dangerous for the public health" due to the "lack of supporting data for the off-label uses and exposure of patients "to risk of serious adverse effects without any clear evidence that the drug will be effective for the intended purpose." Declaration of Aaron Kesselheim, M.D., J.D., M.P.H., Asst. Professor of Medicine, Harvard Medical School, ("Kesselheim Decl.") ¶ 8, ECF No. 26-2.

resolve civil and administrative health care fraud cases and avoid costly exclusion from participation in Federal health care programs. *See* Declaration of Gregory E. Demske, Asst. Inspector General for Legal Affairs, OIG, HHS, ("Demske Decl.") ¶¶1-2, ECF No. 22-1. In return for these benefits, under the CIA, the companies must agree to enhanced compliance measures, subject to auditing by an outside independent party and monitoring by the OIG. *Id.* ¶ 2.

Public Citizen is a "nonprofit public interest organization," which has, *inter alia*, "fought for safe, effective, and affordable drugs and medical devices; responsible controls over the delivery of health care; consumer access to health care information," and issued publications on these topics. Declaration of Sidney Wolfe, M.D., Public Citizen Health Research Group Director, ("Wolfe Decl.") ¶ 2, ECF No. 26-1. Noting that Pfizer has entered into three serial CIAs with HHS' OIG, due to the company engaging in allegedly illegal behavior at the same time it was subject to a CIA, the plaintiff filed the FOIA requests at issue in the instant suit to address "a serious question about the adequacy of OIG oversight of companies during the CIA process." *Id*. ¶¶ 11, 14; *see also* Declaration of Edward Nowicki, Pfizer Vice-President and Asst. General Counsel, Deputy Compliance Officer – Global Programs, ("Nowicki Decl.") ¶ 4, ECF No. 22-1 ("The 2004 CIA expired in 2009. Since that time, Pfizer entered into a new CIA with HHS in 2009."). The plaintiff explains that "[t]o the extent that the annual reports [required by the CIA] reveal instances of illegal activity by the companies, the public has a strong interest in knowing that OIG had access to this information and in knowing whether OIG acted forcefully in responding to it." Wolfe Decl. ¶ 14.

HHS has withheld the bulk of the requested records on grounds that they contain confidential, commercial information exempt from disclosure under FOIA Exemption 4 and

private, personal information exempt from disclosure under FOIA Exemption 6. 5 U.S.C. § 552(b)(4) and (6). The plaintiff challenges HHS' withholdings for eight categories of records, as well as the adequacy of HHS' search for records pertaining to one of the companies. Pending before the Court, are cross-motions for summary judgment by HHS and the defendant-intervenors Pfizer and Purdue, and by the plaintiff. For the reasons stated below, these motions are granted in part and denied in part.

I. BACKGROUND

A. Annual Reports Required To Be Submitted Under Corporate Integrity Agreements With Pfizer And Purdue

In May 2004, Pfizer entered into a CIA with HHS' OIG as part of a larger settlement agreement with the United States and various States "related to Pfizer's promotional practices of a Pfizer product." Nowicki Decl. ¶ 4; *see also* Def.'s Mot. Summ. J., Ex. 1 ("Pfizer Corporate Integrity Agreement") ("Pfizer CIA") at 1, ECF No. 22-1. This CIA superseded a prior CIA that Pfizer had entered with HHS' OIG in October 2002. *Id.* "Among other things, the CIA required Pfizer to implement, update and/or review its policies and procedures relating to compliance with relevant federal regulations," and to submit to the OIG annually over the five-year period while the CIA was in force an Annual Report that addressed at least twenty enumerated items. Nowicki Decl. ¶ 4; Pfizer CIA at 24–27. Pfizer claims these annual reports "contain highly sensitive, confidential commercial information," and, consequently, marked the documents submitted as "Confidential and FOIA Exempt." Nowicki Decl. ¶ 14. The 2004 Agreement expired in 2009.[2] *Id.* ¶ 4.

In May 2007, Purdue entered into a CIA with HHS "contemporaneously with a settlement agreement between Purdue and the United States which resolved an investigation by

[2] Although Pfizer entered into a new CIA in 2009, the FOIA request at issue was limited to the 2004 CIA. Nowicki Decl. ¶ 4. *See also* Compl. ¶ 5, ECF No. 1.

the U.S. Attorney . . . over Purdue's marketing of OxyContin® Tablets." Decl. of Bert Weinstein, Purdue Vice President of Corporate Compliance, ("Weinstein Decl.") ¶¶ 1, 4, ECF No. 22-2. "Purdue has been required to . . . submit[] its Annual Reports to HHS each year since 2007" as part of its obligations under the CIA. *Id.* ¶ 1. Purdue also claims these reports contain "highly confidential and proprietary information," and, consequently, marked the Annual Reports at issue as "Confidential and FOIA Exempt." *Id.* ¶¶ 1, 9.

Both Pfizer and Purdue agreed to the terms set forth in their respective CIAs with the OIG "as part of the resolution of civil and administrative health care fraud cases." Demske Decl. ¶ 2. They both contain the standard provisions that "the OIG agrees not to seek an exclusion of that entity from participation in Federal health care programs," on condition that the company subject to the CIA "adopts measures designed to promote compliance," with Federal laws and regulations, including "hiring [] a compliance officer, establish[ing] a code of conduct and policies and procedures, employee training, confidential disclosure mechanisms, and reporting of violations of law." *Id.* Also, both CIAs require review of the company's compliance with these measures by an independent party, called an Independent Review Organization ("IRO"), which submits annually to the company a report "addressing the requirements of the CIA and including the results of the audits and reviews." *Id.* ¶ 3. The IRO Report is later submitted to the HHS as part of the company's Annual Report, along with any responses to IRO Report's findings from the company. *Id.*; Purdue CIA at 28; Pfizer CIA at 25. The CIAs themselves are posted on the HHS website. Demske Decl. ¶ 3.

As part of the CIAs, the companies are given the opportunity to "clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under

the Freedom of Information Act (FOIA), 5 U.S.C. § 552." Def. Mot. Summ J., Ex. 6 ("Corporate Integrity Agreement between the [OIG] of the [HHS] and Purdue Pharma L.P.") ("Purdue CIA") at 30, ECF No. 22-2; *see also* Pfizer CIA at 28. At the same time, the CIAs direct that the company "shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA." *Id*. HHS is not obligated to accept the companies' designation of any document as FOIA exempt. Indeed, based on the materials released, HHS disagreed with the companies' designations, at least in part, with respect to certain documents, which have been partially released to the plaintiff. *See, e.g.*, Declaration of Julie A. Murray, Counsel for Public Citizen, ("Murray Decl.") Ex 3 Attachs. A, D, E, F, G, H, ECF No. 26-3 (released documents bearing legend "Confidential and FOIA Exempt.").[3]

B. The Plaintiff's FOIA Request

On November 12, 2009, the plaintiff submitted a FOIA request to HHS seeking "all annual reports submitted to the [OIG] by Purdue Pharma L.P. pursuant to the May 2007 Corporate Integrity Agreement between OIG and Purdue Pharma L.P," and "by Pfizer, Inc. pursuant to the May 2004 Corporate Integrity Agreement between OIG and Pfizer." Decl. of Robin R. Brooks, HHS OIG FOIA Officer, ("Brooks Decl.") Ex. A at 1, ECF No. 22-1.[4] In response, HHS conducted a search of its CIA database and "the Compliance File room where active compliance case files and Implementation and Annual Reports are maintained." Brooks

[3] In connection with Pfizer's submission of documents pursuant to an earlier CIA executed on October 24, 2002, HHS was prompted to caution the company that "[t]o date almost all of the documents submitted pursuant to the CIA have been stamped 'FOIA exempt.' As a result we would like to advise you that in the event that Pfizer's CIA materials are requested under FOIA, such materials may not be fully exempt as you have noted . . . . Therefore, you should not assume that all of Pfizer's reports and other documents submitted pursuant to the CIA will be exempt from a FOIA request." Murray Decl., Ex. 3 Attach. G (HHS letter, dated November 19, 2003, to Pfizer) at 1–2, ECF No. 26-3.

[4] Public Citizen's request for a fee waiver was granted, following an administrative appeal of HHS's initial denial of this request. *See* Brooks Decl. ¶¶ 4, 6, 8, 11.

Decl. ¶ 13. HHS's FOIA liaison also "confirmed with the attorneys monitoring the CIA's [sic] that all responsive records had been accounted for." *Id.*

Under Executive Order 12,600, HHS was required to "notify submitters of records containing confidential commercial information . . . when those records are requested under the [FOIA]." 52 Fed. Reg. 23,781 § 1 (June. 23, 1987). HHS regulations also require such a "predisclosure notification." *See* 45 C.F.R. § 5.65(d); Brooks Decl. ¶ 24. Consequently, HHS notified Pfizer and Purdue of the plaintiff's request and consulted with them "regarding the release of their information." Brooks Decl. ¶ 24.

On June 22, 2010, HHS notified the plaintiff that it had "located 1177 pages of records responsive" to the Purdue portion of the FOIA request. Brooks Decl. Ex. J. Of those pages, 1,093 were withheld in their entirety under FOIA Exemptions 4 and 6, *see* 5 U.S.C. §§ 552(b)(4), (b)(6), while 84 pages were partially released with portions redacted under the same exemptions. *Id.* With respect to the Pfizer portion of the FOIA request, HHS notified the plaintiff, on September 21, 2010, that 9,432 pages of responsive records had been located, with 5,216 pages withheld in their entirety as well as portions of 4,216 pages, under FOIA Exemptions 4 and 6. Brooks Decl. Ex. L; *see also* Fed. Def.'s Combined Reply Supp. Def.'s Mot. Summ. J. and Opp'n to Pl.'s Cross Motion for Summ J. ("Def.'s Reply") at 2, ECF No. 29 (noting that search "netted more than 9000 pages of records and more than 4,200 of those pages were released to the plaintiff, with portions withheld under Exemptions 4 and 6"). The plaintiff appealed these withholding determinations under Exemptions 4 and 6 to HHS. *See* Brooks Decl. Exs. K, M. On April 12, 2011, HHS denied the plaintiff's appeal of the Purdue withholdings and redactions. Brooks Decl. Ex. N. "A decision was not made on the appeal regarding Pfizer's documents prior to the filing of this lawsuit." Brooks Decl. ¶ 20.

C. Procedural History

The plaintiff filed the instant lawsuit on September 16, 2011, against HHS. *See* Compl. ¶ 1. The unopposed motions of Pfizer and Purdue to intervene were granted on November 18 and December 7, 2011, respectively. *See* Minute Orders dated November 18, 2011 and Dec. 7, 2011. HHS thereafter filed two *Vaughn* indices, one pertaining to Pfizer and one pertaining to Purdue, on March 7, 2012. *See Vaughn* Index of Withheld Pfizer Inc. Documents ("Pfizer *Vaughn* Index"), ECF No. 18; *Vaughn* Index of Withheld Purdue Pharma L.P. Documents ("Purdue *Vaughn* Index"), ECF No. 19.

The plaintiff now challenges the adequacy of HHS's search for "Pfizer IRO responses and corrective action plans," which the plaintiff claims "were not clearly identified in the *Vaughn* Index of withheld Pfizer documents." Pl.'s Mem. Supp. Pl.'s Mot. Summ. J. and Opp'n to Def.'s and Def.-Intervenor's Mots. Summ. J. ("Pl.'s Mem.") at 38, ECF No. 26. In addition, the plaintiff challenges HHS's withholdings under Exemptions 4 and 6 of the following eight categories of records included in the Annual Reports: (1) "Reportable Events";[5] (2) Disclosure Log summaries;[6] (3) screening and removal of Ineligible Persons;[7] (4) summaries of government investigations or legal proceedings; (5) communications with the Food and Drug Administration

[5] The CIAs define "Reportable Events" as "anything that involves a matter . . . that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or any FDA requirements relating to the labeling or promotion of products for which penalties or exclusion may be authorized." Purdue CIA at 19–20; *see* Pfizer CIA at 21.

[6] Each company was required by its CIA to "maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews." Purdue CIA at 17; Pfizer CIA at 19. The referenced disclosures were made in connection with "a disclosure program," which "includes a mechanism . . . to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Pfizer's policies, conduct, practices, or procedures with respect to a Federal health care program requirements [sic] or FDA requirements believed by the individual to be a potential violation of criminal, civil, or administrative law." Pfizer CIA at 18; *see also* Purdue CIA at 16 (same).

[7] An "Ineligible Person" "is currently excluded, debarred, suspended, or otherwise ineligible to participate in Federal health care programs or in Federal procurement or nonprocurement programs; or has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible." Pfizer CIA at 19; Purdue CIA at 17

("FDA") about off-label promotion; (6) portions of Pfizer's off-label findings and detailing sessions;[8] (7) portions of IRO reports pertaining to, *inter alia*, the IRO's findings and recommendations, the companies' compliance programs, "corrective action taken by the company," and the "IRO's description of the company's systems, policies, procedures, and practices," Pl.'s Mem. at 28–29;[9] and (8) Purdue's supplement, dated June 18, 2009, to its first Annual Report, which was submitted on September 25, 2008 ("2009 Purdue Supplement").[10] *See* Pl.'s Mem. at 9–13 & n.3, ECF No. 27.

With the exception of the 2009 Purdue Supplement, the parties have not identified the specific documents in the *Vaughn* indices that are covered by each of the broad challenged categories and, thus, has left the Court to speculate as to which specific withheld documents are actually at issue in this lawsuit and which documents the parties agree were appropriately withheld. Certainly, the combined use *Vaughn* indices and detailed declarations is an acceptable practice for an agency to justify its application of an exemption. *See Judicial Watch, Inc. v. FDA*, 449 F.3d 141, 148 (D.C. Cir. 2006) (agency's "decision to tie each document to one or more claimed exemptions in its index and then summarize the commonalities of the documents in a supporting affidavit is a legitimate way of serving the same functions" of the *Vaughn* index by "organiz[ing] the withheld documents in a way that facilitates litigant challenges and court review of the agency's withholdings"). Nevertheless, the declarations are most helpful when tied

[8] "Detailing sessions" are mandated intensive reviews of commercially available records Pfizer was required to obtain to determine the content of any discussions between Pfizer sales representatives and health care providers regarding potential off-label uses for Pfizer medications during a one week period each quarter. *See* Pfizer CIA at 22–23. Pfizer was required to make findings based on this review and take any corrective action necessary. *Id.* at 23. The findings and corrective actions were required to be submitted to the OIG. *Id.* Purdue's CIA did not contain this requirement.

[9] Pfizer and Purdue were required to retain "Independent Review Organizations" to "assess[] and evaluate[] [their] systems, processes, policies, and practices" relating to certain programs. Pfizer CIA at 14; *see also* Purdue CIA at 14.

[10] The plaintiff refers to this document as a "cover memorandum for a supplement to its first annual report," Pl.'s Mot. at 2, ECF No. 26, and attached the heavily redacted released copy of the document as an exhibit. Murray Decl. Ex. 3, Attach. E at 30-37, ECF No. 26-3.

to the specific documents described in the indices. *See id.* at 150 (remanding case for further explanation, noting that "[p]roving the merits of the exemption does no good if the court cannot tie the affidavits to the documents"); *Judicial Watch, Inc. v. U.S. Dep't of Justice*, 800 F. Supp. 2d 202, 214 (D.D.C. 2011) (finding "that the DOJ's Vaughn indices and declarations are adequate" where "declarations work in conjunction with the Vaughn indices by dividing the withheld documents into specific categories based on the nature of the document (the category numbers are cross-referenced accordingly in the Vaughn indices), linking each category (and in turn each document) to a particular FOIA exemption, and articulating what the documents in each group reflect and why they fall within the specified FOIA exemption"). The lack of specificity in this case regarding both the identification of withheld documents in the *Vaughn* indices that are at issue and the precise connection between the documents discussed in the declarations and the documents listed in the *Vaughn* indices, has significantly complicated the Court's task of resolving the plaintiff's challenge.

II. LEGAL STANDARD

Congress enacted the FOIA as a means "to open agency action to the light of public scrutiny." *Am. Civil Liberties Union v. U.S. Dep't of Justice*, 655 F.3d 1, 5 (D.C. Cir. 2011) (quoting *Dep't of Air Force v. Rose*, 425 U.S. 352, 361 (1976)). As the Supreme Court has "consistently recognized [] the basic objective of the Act is disclosure." *Chrysler Corp. v. Brown*, 441 U.S. 281, 290 (1979). At the same time, the statute represents a "balance [of] the public's interest in governmental transparency against legitimate governmental and private interests that could be harmed by release of certain types of information." *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 559 (D.C. Cir. 2010) ("*United Technologies*") (internal citations omitted). Reflecting that balance, the FOIA contains nine exemptions set forth in 5

U.S.C. § 552(b), which "are explicitly made exclusive and must be narrowly construed." *Milner v. U.S. Dep't of Navy*, 131 S. Ct. 1259, 1262 (2011) (internal quotations and citations omitted) (citing *FBI v. Abramson*, 456 U.S. 615, 630 (1982)); *see also Pub. Citizen v. Ofc. of Mgmt. and Budget*, 598 F.3d 865, 869 (D.C. Cir. 2010). "[T]hese limited exemptions do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act." *Rose*, 425 U.S. at 361.

The agency invoking an exemption to the FOIA has the burden "to establish that the requested information is exempt." *Fed. Open Market Comm. of Fed. Reserve Sys. v. Merrill*, 443 U.S. 340, 351-352 (1979); *see also Assassination Archives & Research Ctr. v. CIA*, 334 F.3d 55, 57 (D.C. Cir. 2003) (holding that the agency "bears the burden of establishing the applicability of the claimed exemption"). In order to carry this burden, an agency must submit sufficiently detailed affidavits or declarations, a *Vaughn* index of the withheld documents, or both, to demonstrate that the government has analyzed carefully any material withheld, to enable the court to fulfill its duty of ruling on the applicability of the exemption, and to enable the adversary system to operate by giving the requester as much information as possible, on the basis of which he can present his case to the trial court. *Oglesby v. United States Dep't of the Army*, 79 F.3d 1172, 1176 (D.C. Cir. 1996) ("The description and explanation the agency offers should reveal as much detail as possible as to the nature of the document, without actually disclosing information that deserves protection…[which] serves the purpose of providing the requestor with a realistic opportunity to challenge the agency's decision."); *Tax Analysts v. IRS*, 410 F.3d 715, 720 (D.C. Cir. 2005) (noting that, to avoid voluminous *Vaughn* index submissions, court permissibly relied on a mix of deposition testimony, declarations, a *Vaughn* index, and *in camera* review to evaluate agency's withholding determinations).

A district court must review the *Vaughn* index and any supporting declarations "to verify the validity of each claimed exemption." *Summers v. Dep't of Justice*, 140 F.3d 1077, 1080 (D.C. Cir. 1998). The FOIA provides federal courts with the power to "enjoin the agency from withholding records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. 552(a)(4)(B). Moreover, a district court has an "affirmative duty" to consider whether the agency has produced all segregable, non-exempt information. *Elliott v. U.S. Dep't of Agric.*, 596 F.3d 842, 851 (D.C. Cir. 2010) (referring to court's "affirmative duty to consider the segregability issue *sua sponte*") (quoting *Morley v. CIA*, 508 F.3d 1108, 1123 (D.C. Cir. 2007)); *Stolt-Nielsen Transp. Group LTD. v. United States*, 534 F.3d 728, 733-735 (D.C. Cir. 2008) ("'[b]efore approving the application of a FOIA exemption, the district court must make specific findings of segregability regarding the documents to be withheld'") (quoting *Sussman v. U.S. Marshals Service*, 494 F.3d 1106, 1116 (D.C. Cir. 2007)); *Trans-Pacific Policing Agreement v. U.S. Customs Serv.*, 177 F.3d 1022, 1027-1028 (D.C. Cir. 1999) ("we believe that the District Court had an affirmative duty to consider the segregability issue *sua sponte*…even if the issue has not been specifically raised by the FOIA plaintiff"); *see also* 5 U.S.C. § 552(b) ("Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection.").

Summary judgment is appropriate when "there is no genuine dispute as to any material fact." FED. R. CIV. P. 56. "In FOIA cases, '[s]ummary judgment may be granted on the basis of agency affidavits if they contain reasonable specificity of detail rather than merely conclusory statements, and if they are not called into question by contradictory evidence in the record or by evidence of agency bad faith.'" *Judicial Watch, Inc. v. U.S. Secret Serv.*, 726 F.3d 208, at *14 (D.C. Cir. 2013) (quoting *Consumer Fed'n of Am. v. U.S. Dep't of Agric.*, 455 F.3d 283, 287

(D.C. Cir. 2006) and *Gallant v. NLRB*, 26 F.3d 168, 171 (D.C. Cir. 1994)). "Ultimately, an agency's justification for invoking a FOIA exemption is sufficient if it appears 'logical' or 'plausible.'" *Judicial Watch, Inc. v. U.S. Dep't of Defense*, 715 F.3d 937, 941 (D.C. Cir. 2013) (quoting *ACLU v. U.S. Dep't of Defense*, 628 F.3d 612, 619 (D.C. Cir. 2011)); *Larson v. U.S. Dep't of State*, 565 F.3d 857, 862 (D.C. Cir. 2009) (quoting *Wolf v. CIA*, 473 F.3d 370, 374-75 (D.C. Cir 2007)).

III. DISCUSSION

The plaintiff raises two issues regarding HHS's response to its FOIA request: the adequacy of the defendant's search and the appropriateness of the Exemption 4 withholdings.[11] Each of these issues is addressed *seriatim* below.

A. The Adequacy of HHS's Search

The plaintiff contends that the defendant's search for records responsive to the request for Pfizer Annual Reports was inadequate because certain documents referenced in released documents were not identified in the *Vaughn* Index of withheld Pfizer documents or released to the plaintiff. *See* Pl.'s Mem. at 38. Specifically, the plaintiff contends that Pfizer stated in each of its Annual Reports that the company's response to the IRO's findings and recommendations, and any other observations, would be provided to the OIG, as necessary, under separate cover, at

[11] All of the documents withheld by the defendant under Exemption 6, which exempts from disclosure "personnel or medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy," 5 U.S.C. § 552(b)(6), are also withheld under Exemption 4. In construing Exemption 6, the D.C. Circuit has held that "the disclosure of names and addresses is not inherently and always a significant threat to the privacy of those listed; whether it is a significant or a *de minimis* threat depends upon the characteristic(s) revealed by virtue of being on the particular list, and the consequences likely to ensue." *Nat'l Ass'n of Retired Fed. Employees v. Horner*, 879 F.2d 873, 877 (D.C. Cir. 1989). "Exemption 6's requirement that disclosure be 'clearly unwarranted' instructs us to 'tilt the balance (of disclosure interests against privacy interest) in favor of disclosure.'" *Morley*, 508 F.3d at 1127 (D.C. Cir. 2007) (quoting *Wash. Post Co. v. U.S. Dep't of Health and Human Servs.*, 690 F.2d 252, 261 (D.C. Cir. 1982)). Here, the defendant's declarant states that the only information withheld under Exemption 6 consists of "employee names and personal identifying information, such as telephone numbers and email addresses." Brooks Decl. ¶ 27. The plaintiff has clarified that it is not challenging the withholding of names, phone numbers, signatures, or email addresses of any individuals. Pl.'s Mem. at 36. Thus, given that the plaintiff is not contesting the application of Exemption 6 to the information withheld on this basis, no Exemption 6 challenge is before the Court.

a later date. Murray Decl., Ex. 3 Attach. H (containing Pfizer's statements regarding later submission of CIA Section III.D Responses in Annual Reports submitted for 2004-2009, at OIG-000066; OIG-001862; OIG-003715; OIG-005864; OIG-007893). These responses were specifically required by Section V.B.6 of Pfizer's CIA ("Section V.B.6 documents"). Pfizer CIA at 25. The plaintiff contends that the Section V.B.6 documents, which Pfizer was required to submit, and presumably did submit to the OIG, are "missing" and the defendant "does not appear to have acknowledged these missing documents or attempted a follow-up search to find them." *Id.* at 38. The defendant does not dispute that Pfizer submitted to the OIG its comments responding to the IRO Reports, as required in Section V.B.6 of the CIA and referenced in each Annual Report, or that such documents are responsive to the FOIA request. Rather, the defendant disputes that Pfizer's Section V.B.6 documents are missing and instead asserts that they were identified in the search and withheld, as described in the Pfizer *Vaughn* index entries 174, 175 and 176. *See* Def.'s Reply at 5.

In support of its position that "the very information that Plaintiff claims establishes that the search was inadequate is accounted for in the Vaughn index," the defendant highlights the information set forth in the Pfizer *Vaughn* index entries 174, 175 and 176. *Id*. These three entries, 174, 175 and 176, describe three letters, which were released with virtually all text redacted, from Pfizer's counsel to the OIG, dated February 13, 2006, February 19, 2008 and November 11, 2009, respectively, as follows: "This letter and the accompanying attachments contain confidential information related to communication with the OIG regarding Pfizer's responses to the OIG's review of Pfizer's Annual Report. *These documents contain confidential information regarding IRO reviews and reports as well as Pfizer's responses thereto and excerpts from certain Pfizer policies and verbatim*." *Id*. (emphasis in original).

The defendant's response that the plaintiff's challenge to the adequacy of the search for Pfizer documents "fails as a factual matter," Def.'s Reply at 5, has two fundamental problems. First, the documents described in the Pfizer *Vaughn* Index entries 174, 175 and 176 relate only to the first, third, and possibly the final 2009 Annual Reports. *See* Supplemental Decl. of Julie Murray, Counsel to Public Citizen, ("Murray Suppl. Decl.") Ex. 1, Attachs. D, E, F, ECF No. 34-1 (Feb. 13, 2006 letter states submission is "regarding Pfizer's first Annual Report;" Feb. 19, 2008 letter states "Re: Follow-up to the Third Annual Report;" and the last letter is dated Dec. 11, 2009 letter, which is after submission of fifth Annual Report). Thus, the Section V.B.6 documents released in part and described in the Pfizer *Vaughn* index are only for three Annual Reports (first, third and last), even though the company indicated in its Annual Reports for all five years that it was filing Section V.B.6 documents. Nowicki Decl. ¶ 12. Thus, it appears that Pfizer's Section V.B.6 documents for at least two years were neither released to the plaintiff nor referenced in the *Vaughn* index and, thus, are correctly deemed "missing" by the plaintiff. Pl.'s Mem. at 38.

Second, the plaintiff challenges whether the documents described at Pfizer *Vaughn* Index entries 174, 175 and 176, which the defendant points to as evidence of the adequacy of its search, are actually the Section V.B.6 documents. *See* Pl's Reply in Supp. Pl.'s Mot. Summ. J. ("Pl.'s Reply") at 20–21, ECF No. 34. The plaintiff's declarant submitted copies of the heavily redacted versions of the documents corresponding to *Vaughn* index numbers 174, 175 and 176. *See* Murray Suppl. Decl., Ex. 1 Attachs. D, E, and F (Bates Nos. OIG-009386, OIG-009420, OIG-009428). The opening paragraphs of each letter indicate that Pfizer is responding to specific OIG requests for additional information, but nowhere indicate that this information is provided to comply with the CIA's Section V.B.6. The plaintiff claims that these documents "provide only

'supplemental information that [OIG] requested' in response to Pfizer's annual reports," Pl.'s Reply at 20, rather than submitting Pfizer's own independent "review [of] the Internal Review Organizations findings and recommendations, and any other observations . . . pursuant to Section III.D" of the CIA. *See, e.g.*, Murray Decl. Ex. 3 Attach. H, Bates No. OIG-003715; Murray Suppl. Decl. Ex. 1 Attach. F, Bates No. OIG-009428. Thus, as a factual matter, the plaintiff has raised a significant question as to whether the letters listed in the *Vaughn* index entries 174, 175 and 176 actually correspond to the information referenced in the CIA's Section V.B.6.

The defendant nowhere adequately explains these factual discrepancies. Rather, the defendant's fallback position is that the law does not require the agency to do any more searching since the agency has demonstrated in affidavits that it "conducted a reasonable search," and no bad faith has been alleged. Def.'s Reply at 4. While "the adequacy of a FOIA search is generally determined not by the fruits of the search, but by the appropriateness of the methods used to carry out the search," *see Iturralde v. Comptroller of Currency*, 315 F.3d 311, 315 (D.C. Cir. 2003), "if a review of the record raises substantial doubt, particularly in view of 'well defined requests and positive indications of overlooked materials, summary judgment is inappropriate," *Valencia-Lucena v. U.S. Coast Guard*, 180 F.3d 321, 326 (D.C. Cir. 1999) (quoting *Founding Church of Scientology v. Nat'l Sec. Agency*, 610 F.2d 824, 837 (D.C. Cir. 1979)).

In this case, the defendant concedes the existence of Pfizer Section V.B.6 documents required to be submitted to the OIG on an annual basis under the CIA, by pointing to the three heavily redacted letters described in the Pfizer *Vaughn* Index entries 174, 175 and 176. Moreover, the existence of these documents is confirmed by the released portions of five annual reports referencing the "later" submission of the Section V.B.6 documents. *See* Murray Decl. Ex.

3 Attach. H (Bates Nos. OIG-000066, OIG-001862, OIG-003715, OIG-005864 and OIG-007893). Therefore, at a minimum, Pfizer's Section V.B.6 documents for two annual reports, which the defendant does not dispute should exist and should have been accounted for, are not represented in the *Vaughn* index, nor has the defendant provided any explanation as to what steps it undertook to track down these missing documents.

That the defendant was under an obligation to do so is made clear in *Campbell v. United States Department of Justice*, 164 F.3d 20, 28 (D.C. Cir. 1998). In *Campbell*, the D.C. Circuit held that an agency must "revise its assessment of what is [a] 'reasonable' [search] in a particular case to account for leads that emerge during its inquiry." *Id.* at 28. In other words, when leads to other documents arise during the course of a search for responsive records, the agency must expand the scope of its search. *Id.* This does not mean that "mere reference to other files" that are relevant to a FOIA request triggers an obligation for the agency to expand a search since "[i]f that were the case, an agency responding to FOIA requests might be forced to examine virtually every document in its files, following an interminable trail of cross-referenced documents like a chain letter winding its way through the mail." *Steinberg v. U.S. Dep't of Justice*, 23 F.3d 548, 552 (D.C. Cir. 1994); *see also Morley*, 508 F.3d at 1121. Yet, when, as here, the agency concedes that responsive documents exist and, further, that its search should have recovered those documents, by stating as a factual matter that they were, in fact, located, summary judgment is inappropriate when the plaintiff raises substantial factual questions about those assertions. Indeed, the D.C. Circuit has instructed that "a court may place significant weight on the fact that a records search failed to turn up a particular document in analyzing the adequacy of a records search." *Iturralde*, 315 F.3d at 315 (citing *Krikorian v. U.S. Dep't of State*, 984 F.2d 461, 468 (D.C. Cir. 1993)). As the D.C. Circuit explained in *Valencia-Lucena*, "what causes us

to conclude that the search was inadequate arises from the fact that the record itself reveals positive indications of overlooked materials." 180 F.3d at 326 (internal quotations omitted).

Here, there can be no doubt that, in the course of a search for responsive records, the defendant was or became aware that Pfizer's Section V.B.6 documents for five annual reports, not just three such reports, should exist. Yet, the defendant offers no explanation, and cites to no produced document, to account for the missing records for at least two annual reports. Although the defendant is correct that "a search is not unreasonable simply because it fails to produce all relevant material," *Meeropol v. Meese*, 790 F.2d 942, 952-53 (D.C. Cir. 1986), the defendant was affirmatively obligated to make an effort to find the two missing year's responses when the "leads" to those documents are obvious. *See Campbell*, 164 F.3d at 28.

Moreover, neither the redacted records produced nor the Pfizer *Vaughn* Index sufficiently indicates that entries 174, 175 and 176 are actually the Section V.B.6 documents that Pfizer was required to produce under Section III.D and Section V.B.6 of the CIA, as all three letters appear to be responding to direct questions from the OIG, rather than Pfizer's own findings and recommendations in response to an IRO Report. Therefore, the defendant has not sustained its burden of showing the adequacy of its search and may either supplement its declarations to address the factual questions raised by the plaintiff about the Pfizer Section V.B.6 documents or perform an additional search to locate the missing records.[12]

[12] The defendant also argues that because no challenge to the adequacy of the search was raised during the administrative appeal, the plaintiff has failed to exhaust its administrative remedies. *See* Def.'s Reply at 5 n.1. As the plaintiff rightfully points out, however, the inadequacy of the defendant's search was not apparent until after the agency filed its *Vaughn* indices, which show that Pfizer Section V.B.6 documents for at least two, if not all five, annual reports are missing. The Court, therefore, rejects this defense to the plaintiff's challenge to the adequacy of the search.

B. Exemption 4 Withholdings

Under the FOIA, "trade secrets and commercial or financial information obtained from a person" that is "privileged or confidential" may be withheld from disclosure. 5 U.S.C. § 552(b)(4).[13] If the documents are not trade secrets, to sustain the burden of showing that Exemption 4 was properly applied, an agency must establish that the withheld records are "(1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential." *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983). No party to this action disputes the second prong of this test, nor could they, as the statute makes clear that a "person includes an individual, partnership, *corporation*, association, or public or private organization other than an agency." 5 U.S.C. § 551(2) (emphasis added). Nor do the defendant and defendant-intervenors claim that the withheld documents are "financial." *See* Def. Mem. *generally*; Declaration of Peter J. Claude, Partner at PricewaterhouseCoopers, LLP ("Claude Decl."), ECF No. 22-2; Mem. Supp. Def.-Intervenor Pfizer's Mot. Summ. J. ("Pfizer Mem."), ECF No. 23-1, *generally*.

The parties contest only whether, under the first and third prongs of the test, the eight categories of challenged, withheld documents are "commercial" materials and, if so, whether they are "privileged or confidential." To resolve this dispute, the Court will first examine the scope of the term "commercial" in the FOIA context and address the plaintiff's contention that any document referring to illegal or potentially illegal activity falls outside the meaning of this

[13] Although neither of the companies whose documents are at issue have claimed trade secret protection, the defendant HHS has asserted, with only limited evidentiary support and no further discussion, that "the materials withheld under Exemption 4 also constitute trade secrets." Def. Mem., 8 n.1, ECF No. 22; *see also* Declaration of Peter J. Claude, Partner at PricewaterhouseCoopers LLP ("Claude Decl.") ¶ 13, ECF No. 22-2 ("In addition to being commercially valuable, some of these procedures should be considered to contain trade secrets, as I understand that term is defined by the OIG. These procedures are the product of innovation and are developed through substantial effort."). These conclusory statements, without any effort to show that the documents satisfy the requisite elements for trade secret protection, are wholly insufficient to support such a finding. Thus, as do the parties, the Court will focus on whether the withheld records are "commercial" information."

term. Next, the Court will review each category of documents at issue and assess whether the defendant and defendant-intervenors have met their burden of showing that challenged, withheld records contain commercial information. Finally, for any category of documents found to contain commercial information, the Court will evaluate whether the information is confidential or privileged.

1. *Scope of "Commercial" Information.*

The term "commercial" is not defined in the FOIA.[14] Absent a precise statutory definition or clarity from the legislative history, the D.C. Circuit has "consistently held that [this] term . . . in [Exemption 4] should be given [its] ordinary meaning[]." *Pub. Citizen Health Research Group*, 704 F.2d at 1290; *see also Nat'l Ass'n of Home Builders v. Norton*, 309 F.3d 26, 38 (D.C. Cir. 2002); *Bd. of Trade v. Commodity Futures Trading Co.*, 627 F.2d 392, 403-404 (D.C. Cir. 1980) *abrogated on other grounds by U.S. Dep't of State v. Wash. Post Co.*, 456 U.S. 595 (1982); *accord Perrin v. United States*, 444 U.S. 37, 42 (1979) ("A fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning."). "[I]nformation is commercial under this exemption if, in and of itself, it serves a commercial function or is of a commercial nature." *Nat'l Ass'n of Home Builders*, 309 F.3d at 38 (citing *Am. Airlines, Inc. v. Nat'l Mediation Bd.*, 588 F.2d 863, 870 (2d Cir. 1978)) (internal quotations omitted). Thus, "records that actually reveal basic commercial operations, such as sales statistics, profits and losses, and inventories, or relate to the income-producing aspects of a business," fall within the scope of "commercial" information. *See Pub. Citizen Health Research Grp.*, 704 F.2d at 1290. For instance, documents

[14] The D.C. Circuit has concluded that the legislative history about the meaning of the key terms used in Exemption 4 is "unhelpful," since while "Congress clearly indicated that Exemption 4 as a whole could cover such materials as 'business sales statistics, inventories, customer lists, [and] scientific or manufacturing processes or developments,' H.R. REP. No. 1497, 89th Cong., 2d Sess. 10, reprinted in 1966 U.S. CODE CONG. & AD. NEWS 2418, 2427, it offered no guidance concerning which prong of the exemption would protect each of these diverse types of information." *Pub. Citizen Health Research Grp.*,704 F.2d at 1286.

that contain "revenue, net worth, income, and EBITDA" information are plainly commercial. *Kahn v. Fed. Motor Carrier Safety Admin.*, 648 F. Supp. 2d 31, 36 (D.D.C. 2009); *see also Greenberg v. FDA*, 803 F.2d 1213, 1216 (D.C. Cir. 1986*)* (holding that customer lists constitute commercial information); *Rural Hous. Alliance v. U.S. Dep't of Agric.*, 498 F.2d 73, 75 (D.C. Cir. 1974) (holding that loan application information in agency report was subject to Exemption 4); *Racal-Milgo Gov't Sys., Inc. v. Small Bus. Admin.*, 559 F. Supp. 4, 6 (D.D.C. 1981) (finding that Exemption 4 shielded information "much more sensitive than mere prices," such as "audits of private concessions in national parks; technical proposals for development of a system to analyze gases generated by petroleum refineries; general selling prices, inventory balances, profit margins, purchase activity, freight charges, costs of goods sold, and customer names, obtained from a utility in the course of a government investigation; appraised value for customs duty assessment purposes of imported machinery parts; design recommendations, design concepts, a customer list, and biographical data on key employees; and computer usage, manpower allocation, travel costs, biographical data on employees, and detailed cost data from a contract with the Government") (internal citations omitted).

The scope of "commercial" information has also been applied more broadly to records containing information in which the provider of the records has "a commercial interest." *Baker & Hostetler LLP v. U.S. Dep't of Commerce*, 473 F.3d 312, 319 (D.C. Cir. 2006) (finding letters describing favorable market conditions for domestic lumber companies "plainly contain commercial information within the meaning of Exemption 4"). For example, in *Public Citizen Health Research Group*, the court found that "documentation of the health and safety experience of [the company's] products" was commercial because such documentation was "instrumental in gaining marketing approval for their products." 704 F.2d at 1290. At issue in *Public Citizen*

Health Research Group were reports submitted to the FDA about the safety of certain medical devices in order to show the products were sufficiently safe to enter the marketplace. *Id.* Although not "commercial" in the sense of reflecting sales or profit-and-loss figures, the court found that the reports fit comfortably within the broader definition of "commercial" that examines whether the provider has a commercial interest in the documents because they are helpful or "instrumental" to its business interests. *Id.*; *see also Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 830 F.2d 278, 281 (D.C. Cir. 1987) (holding that non-profit organization's reports describing the operations of members' nuclear power plants contained "commercial" information since disclosure of health and safety problems resulting from operation of nuclear power facilities could materially affect "commercial fortunes" of members).

Pfizer urges an even broader construction of Exemption 4, stating that "a company has a 'commercial interest' in all records that relate to every aspect of the company's trade or business." Pfizer's Mem. in Opp'n to Pl.'s MSJ & Reply in Supp. of Def.'s MSJ ("Pfizer Reply") at 6, ECF No. 31. This is plainly incorrect. *See, e. g., Getman v. NLRB*, 450 F.2d 670, 673 (D.C. Cir. 1971) ("a bare list of names and addresses of employees which employers are required by law to give the [agency] . . . cannot be fairly characterized as . . . 'financial' or 'commercial' information"); *Nat'l Bus. Aviation Ass'n v. FAA*, 686 F. Supp. 2d 80, 86–87 (D.D.C. 2010) (list of aircraft registration numbers was not sufficiently "commercial" to qualify for Exemption 4 withholding even though certain commercial information could be deduced from other publicly available sources in conjunction with the requested documents); *Chicago Tribune Co. v. FAA*, No. 97 C 2363, 1998 WL 242611 at *3 (N.D. Ill. May 7, 1998) (finding that Federal Aviation Administration records pertaining to in-flight medical emergencies did not have a sufficiently "direct relationship with the operations of a commercial venture" to qualify for

withholding under Exemption 4). Indeed, the D.C. Circuit has explained that "the reach of the exemption for 'trade secrets or commercial or financial information' is not necessarily coextensive with the existence of competition in any form." *Wash. Research Project, Inc. v. U.S. Dep't of Health, Educ. and Welfare*, 504 F.2d 238, 244 (D.C. Cir. 1974). Thus, the D.C. Circuit has cautioned that, consistent with the narrow construction given to FOIA exemptions, "[n]ot every bit of information submitted to the government by a commercial entity qualifies for protection under Exemption 4." *Pub. Citizen Health Research Grp.*, 704 F.2d at 1290.

The plaintiff argues that many of the challenged withheld documents fail to qualify as "commercial" information because "[i]nformation about a company's violation of laws and regulations is not commercial in nature." Pl.'s Mem. at 17. In support, the plaintiff seizes upon language in *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871 (D.C. Cir. 1992) (en banc) ("*Critical Mass*"), generally describing the exemptions in the FOIA as designed to protect "legitimate governmental and private interests." *Id.* at 872. Thus, according to the plaintiff's argument, the FOIA necessarily excludes from the coverage of Exemption 4 "information about suspected or confirmed illegal conduct by the companies or their employees and the companies' corrective action . . . to comply with applicable laws," Pl.'s Mem. at 17, because protecting against the disclosure of potential illegal conduct is a non-legitimate goal.

The defendant counters that commercial information does not lose the protection of Exemption 4 "even when that information was directly related to the potential wrongdoing." Def.'s Reply at 8. The Court agrees with the defendant for three reasons. First, the language from *Critical Mass* relied upon by the plaintiff is too thin a reed to support the weight of its argument. The D.C. Circuit's use of the qualifying word "legitimate," referred to the interests served by the *entire FOIA*, not just Exemption 4. *See Critical Mass*, 975 F.2d at 872. This

judicial qualifier does not apply as an over-arching limit on the scope of any particular term used in the FOIA and, thus, cannot be read to limit the types of "commercial" activities subject to Exemption 4.

Second, the plaintiff's proposed construction of Exemption 4 would impose on this statutory provision a limitation which is simply not supported by the plain text. On the contrary, the term "commercial" is generally defined to mean "engaged in commerce" or "having reference to, or bearing on commerce." *Commercial*, NEW OXFORD AM. DICTIONARY at 341 (2d Ed. 2005) ("concerned with or engaged in commerce; making or intending to make a profit"); *Commercial*, MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY at 231 (10th Ed. 1999) ("occupied with or engaged in commerce or work intended for commerce; viewed with regard to a profit"); *Commercial Activity*, BLACK'S LAW DICTIONARY at 38, (9th Ed. 2009) ("An activity, such as operating a business, conducted to make a profit); *see also Carlson v. U.S. Postal Serv.*, 504 F.3d 1123, 1129 (9th Cir. 2007) ("[I]nformation is commercial if it relates to commerce, trade, or profit") (internal quotation marks and citation omitted). Thus, using its ordinary meaning, the term "commercial" is not limited only to lawful activities but also extends more broadly to any type of activity bearing on commerce.

Several of the cases cited by the defendant support this plain text meaning of the term "commercial." [15] In *ISC Group, Inc. v. United States Department of Defense*, Civ. A. No. 88-0631, 1989 WL 168858, at *2-3 (D.D.C. May 22, 1989), the court found that "financial summaries and forecasts, inventory and labor data, and other financial analyses" contained in a

[15] Two of the cases relied upon by the defendant are unhelpful since the parties in those cases did not dispute whether the requested documents were "commercial;" consequently, the courts did not confront, let alone consider, the issue of whether documents containing information about illegal conduct could also qualify as "commercial" under Exemption 4. *See Am. Mgmt. Servs., LLC v. Dep't of the Army*, 842 F. Supp. 2d 859, 880 (D.D.C. 2012) ("It is undisputed that the information in question is 'commercial or financial.'"); *Hersh & Hersh v. U.S. Dep't of Health and Human Servs.*, C 06-4234, 2008 WL 901539, at *7 (N.D. Cal. Mar. 31, 2008) ("[S]ince there is no other dispute as to whether the information qualifies as commercial or financial . . . .").

report investigating potential fraud in Department of Defense contracts were "commercial or financial" information subject to Exemption 4. The fact that certain of this financial information also reflected fraudulent activity was not a disqualifier for withholding. *See also M/A-Com Info. Sys., Inc. v. U.S. Dep't of Health and Human Servs.*, 656 F. Supp. 691, 692 (D.D.C. 1986) (holding that the agency properly withheld under Exemption 4 documents containing "accounting and other internal procedures [the submitting company] was willing to undertake to obtain by consent dismissal of the debarment action without admission of liability or resolution of the facts in dispute.").

Similarly, in *Watkins v. United States Bureau of Customs and Border Protection*, 643 F.3d 1189 (9th Cir. 2011), the Ninth Circuit rejected a FOIA requester's contention that "Notices of Seizures" for allegedly counterfeit goods were not "commercial" because they pertained to "the unlawful importation of counterfeit goods, and not any sort of legitimate commercial activity." *Id.* at 1195. Noting that such Notices are not "final determinations that goods seized are counterfeit," but are more "akin to a finding of probable cause," the court explained that "we cannot conclude that information contained in a Notice of Seizure is non-commercial just because it's likely — perhaps even very likely — that the merchandise seized is counterfeit." *Id.* Since the Notices disclose "intimate aspects of an importers business such as supply chains and fluctuations of demand for merchandise," the court further found that they "contain plainly commercial information." *Id.*

Finally, the third reason to reject the plaintiff's argument to exclude from the scope of "commercial" any "suspected or confirmed unlawful conduct," Pl.'s Mem. at 1, is that it is based on an error of reasoning by fallaciously imputing the properties of a "part" to the properties of the "whole." Specifically, the overall commercial nature of an undertaking is not altered when

some aspect of that activity is suspected to constitute, or actually results in, a violation of a rule, regulation or statutory requirement. This is particularly true in the context of a heavily regulated industry, such as pharmaceuticals. The Ninth Circuit in *Watkins* implicitly recognized the fundamental unfairness that would result if the protection of Exemption 4 were unavailable to withhold otherwise confidential commercial documents of a company simply because the company was accused of wrongdoing, noting that, in some cases, "importers sometimes acquiesce in the Agency's seizure and forfeiture of *legitimate* goods," even without proof of legal violation. 643 F.3d at 1195 (emphasis in original).

Although the Court finds unpersuasive the plaintiff's argument that any information related to potential wrongdoing categorically falls outside Exemption 4, this does not mean that all of the withheld information submitted pursuant to the CIAs is automatically commercial. The defendant must provide sufficient justification about each category of challenged documents to show that the withheld documents are, indeed, "commercial" within the meaning of Exemption 4. As discussed in more detail below, the *Vaughn* indices and declarations fall short in many instances of the level of specificity the FOIA requires.

2. *Sufficiency of Showing That Withheld Documents Are "Commercial"*

Set against the broad scope of the term "commercial," the Court next examines each challenged category of withheld documents to determine whether they meet this prerequisite for application of Exemption 4. In this regard, the Court is mindful that the defendants bear the burden of establishing the applicability of this exemption and that "conclusory and generalized allegations of exemptions are unacceptable." *Morley*, 508 F.3d at 1115 (internal quotation marks omitted). With respect to each category of withheld documents, the defendant makes only the conclusory statement that "[t]he records contain Pfizer and Purdue's commercial or financial information." Brooks Decl. ¶ 25. The *Vaughn* indices offer no additional details on this critical

question. *See* Pfizer *Vaughn* Index, Purdue *Vaughn* Index, *generally*. Consequently, as set forth below, the Court relies primarily upon the declarations of the defendant-intervenors to tease out any information regarding whether the withheld documents are "commercial" for the purposes of Exemption 4.

a. Reportable Event Summaries

Under the terms of the CIAs, Reportable Events are those events where "a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or any FDA requirements relating to the labeling or promotion of products for which penalties or exclusion may be authorized." Purdue CIA at 19–20; *see also* Pfizer CIA at 21. Each company was required to notify the OIG within 30 days of "determining that the Reportable Event exists." Purdue CIA at 20; Pfizer CIA at 21. In those reports, the companies were required to provide "a complete description of the Reportable Event, including relevant facts, persons involved, and legal and Federal health care program authorities implicated," "a description of [the company's] actions taken to correct the Reportable Event," and "any further steps [the company] plans to take to address the Reportable Event and prevent it from recurring." Pfizer CIA at 21–22; *see also* Purdue CIA at 20.

Similarly to HHS, Purdue's declarant does not discuss whether the Reportable Event summaries are commercial at all but merely skips over this critical factor to focus on the "highly confidential and privileged" nature of this information. *See* Weinstein Decl. ¶ 25 ("Because a Reportable Event is the subject of highly confidential and privileged internal investigations undertaken at Purdue to determine the underlying facts and potential violations, public disclosure of the event would cause Purdue commercial injury."); Brooks Decl. *generally*. Pfizer's declarant states that "[t]he Reportable Event summary logs contain highly sensitive commercial information about the Reportable Event itself as well as Pfizer's internal investigation of the

Reportable Event and any corrective actions taken." Nowicki Decl. ¶ 26. More specifically, "[t]he Reportable Event summaries *often* contain sales and marketing tactics, analysis of compliance with the CIA and any corrective actions taken." *Id*. ¶ 27 (emphasis added). The import of this statement is that Pfizer's summaries do not *always* contain information regarding "sales and marketing."

The Court could speculate that Reportable Event summaries could reveal information about the companies' activities in a specific place, at a specific time, and involving specific activity with respect to a particular product and customer, all of which could in context be considered "commercial" information. Such speculation is not the Court's job, however. *See Coastal States Gas Corp. v. U.S. Dep't of Energy*, 617 F.2d 854, 870 (D.C. Cir. 1980) ("The courts will not speculate as to whether [the] Exemption [] might, under some possible congruence of circumstances not proven or even asserted be properly applied to these documents, nor will we assume that all the necessary conditions are met merely because the agency invokes an exemption."); *Founding Church of Scientology*, 603 F.2d at 949 ("The reviewing court should not be required to speculate on the precise relationship between each exemption claim and the contents of the specific document.").

Without more information about the commercial nature of the information contained in the Reportable Event summaries, the Court has insufficient information to evaluate whether the summaries contain commercial information and are being properly withheld. Consequently, the Court denies summary judgment to the plaintiff and the defendants regarding the challenged category of withheld documents containing Reportable Event summaries.

b. Disclosure Log Summaries

The companies were required by their CIAs to "maintain a disclosure log, which shall include a record and summary of each disclosure received" by the company's compliance officer

regarding the potential violation of "criminal, civil, or administrative law." *See* Purdue CIA at 16–17; Pfizer CIA at 18–19. As described by Pfizer's declarant, "[t]he Disclosure Logs contain information regarding reports (some of which are made anonymously) by individuals to Pfizer's Compliance Officer (or his designee) regarding potential violations of criminal, civil or administrative laws as required by the CIA. The Disclosure Logs contain summaries of reports made, status of the internal review of the issue(s) raised in the reports, and any corrective actions taken in response." Nowicki Decl. ¶ 32.

The declarants for the defendants focus on the highly confidential nature of the disclosure log summaries, but do not address the key issue of whether this category of withheld documents contains commercial information. *Id.* ("This information is highly confidential"); Weinstein Decl. ¶ 22 ("The Disclosure Log is maintained in a proprietary and highly confidential database."). Again, the Court will not speculate. *See Coastal States Gas Corp.*, 617 F.2d at 870; *Founding Church of Scientology*, 603 F.2d at 949. Without more information about the commercial nature of the information contained in the disclosure log summaries, the Court has insufficient information to evaluate whether these documents are being properly withheld. Consequently, the Court denies summary judgment to the plaintiff and the defendants regarding the challenged category of withheld documents containing the disclosure log summaries.

c. Ineligible Persons Information

Each company is required by their CIA to "ensure that all current Covered Persons[16] are not Ineligible Persons," meaning that they are not "currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs" or have "been convicted of a criminal offense that falls within the

[16] A "Covered Person" is defined in Purdue's CIA to "include[]: all owners, officers, directors and employees [of the company]" and all contractors, not including part time employees or people not involved in the business operations of the company. *See* Purdue CIA at 2–3. The definition in Pfizer's CIA is similar. *See* Pfizer CIA at 2–3.

ambit of 42 U.S.C. § 1320a-7(a), but ha[ve] not yet been excluded, debarred, suspended, or otherwise declared ineligible." Pfizer CIA at 19–20; Purdue CIA at 17–18. The companies are required to include in their Annual Reports two key items of information relating to enforcement of the CIAs provisions regarding Ineligible persons: (1) "any changes to the process by which [the company] fulfills" the Ineligible Persons requirement, and (2) "the name, title, and responsibilities of any person who is determined to be an Ineligible Person." Purdue CIA at 28; Pfizer CIA at 25.

Purdue's declarant does not address this category of withheld documents except to say Purdue's "proposed actions regarding ineligible persons[] all directly relate to Purdue's compliance with legal and regulatory requirements, and are proprietary in nature." Weinstein Decl. ¶ 15. Pfizer's declarant offers a similarly general statement that "[t]his information reflects Pfizer's internal business processes and judgments made to develop and implement the Ineligible Person Management process as well as confidential information related to Pfizer's screening and removal of Ineligible Persons." Nowicki Decl. ¶ 29.

With respect to the first item of information, which requires the defendant-intervenors to notify the OIG of "any changes to the process by which [the company] fulfills the requirements of [the CIA] regarding Ineligible Persons," Pfizer CIA at 25, Purdue CIA at 28, such modifications to internal processes are sufficiently commercial to qualify for Exemption 4 because they involve the process by which the companies make decisions about managing and conducting their business operations. Such information is "instrumental" to conducting business because such individuals must be vetted and, when necessary, removed from the defendant-intervenors' employ to allow the company to continue a significant part of its business with federal health care programs. Pfizer CIA at 20; Purdue CIA at 18–19. Consequently,

information concerning changes to processes regarding the screening or removal of Ineligible Persons amounts to "commercial" information under Exemption 4.[17]

By contrast, the second item of information relating to Ineligible Persons consists only of the "name, title, and responsibilities of any person who is determined to be an Ineligible Person." Pfizer CIA at 25 (Section V.B.11), Purdue CIA at 28 (Section V.B.12). This information is static and does not appear to have anything to do with the ongoing creation or selling of products, nor does this information appear to be "instrumental" to conducting commerce. Indeed, no defendant declarant has provided any information revealing how such information could be "commercial." *Accord Getman*, 450 F.2d at 673 (holding that list of names and addresses of employees are not 'commercial' information"); *Comptel v. F.C.C.*, 910 F. Supp. 2d 100, 116 (D.D.C. 2012) ("The FCC has not met its burden to show that names and contact information should be exempt as confidential commercial or financial information. . . . While the Court assumes corporations can have a commercial interest in the names of certain staff, it is not a certainty that a corporation would have a commercial interest in the names of every one of its employees."). Consequently, the Court grants summary judgment to the plaintiff and orders the release of any documents withheld under Exemption 4 because they contain the "title and responsibilities of any person who is determined to be an Ineligible Person."[18] *See* Pfizer CIA (Section V.B.11); Purdue CIA (Section V.B.12).

d. Investigations Or Legal Proceedings

The CIAs require the companies to, "[w]ithin 30 days after discovery . . . notify OIG, in writing, of any ongoing investigation or legal proceeding . . . conducted or brought by a

[17] The Court must still determine, as discussed in Section III.B.3.b, *infra*, whether these withheld documents are "privileged or confidential" for application of Exemption 4.

[18] The plaintiff has made clear that it is not seeking "names, e-mail addresses, telephone numbers, or signatures of individuals named in withheld documents." Pl.'s Mem. at 2. Any such personally identifiable information may be redacted from released documents.

governmental entity or its agents involving an allegation that [the company] has committed a crime or has engaged in fraudulent activities." Purdue CIA at 19 (Section III.G); *see also* Pfizer CIA at 21 (Section III.G). The "notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding." Purdue CIA at 19 (Section III.G); *see also* Pfizer CIA at 21 (Section III.G). Additionally, the companies are to "provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any." Purdue CIA at 19; *see also* Pfizer CIA at 21.

The reporting requirement for investigatory or legal proceedings consists of three parts: (1) the description of the allegation; (2) the identity of the agency conducting the investigation; and (3) the status of the investigation or proceeding. The defendants' declarants do not expressly address the commercial nature of any part of this category of withheld documents. Instead, Purdue's declarant stresses that "[p]ublic disclosure of this information, which includes non-public legal and/or regulatory actions, such as with a Reportable Event, would certainly have negative commercial consequences for Purdue." Weinstein Decl. ¶ 26. Similarly, Pfizer's declarant states that "release of such information would cause Pfizer competitive harm and could be useful to Pfizer's adversaries in current litigation." Nowicki ¶ 28.

The legal proceedings described in this category of withheld document pertain to allegations of the company's criminal or fraudulent conduct. Although the defendants do not expressly say so, common sense dictates that such allegations about the company itself relate to the conduct of employees and/or policies and practices of management in the operation of the companies' business and thereby implicate the companies' "commercial interests." While the support for this conclusion in the declarations from the defendant and defendant-intervenors is

thin, the definition of the reporting requirement in the CIAs provides sufficient context for the Court to reach this conclusion. Therefore, the first part of the reporting requirement regarding a description of the allegation is "commercial" under Exemption 4.

The other two parts of this reporting requirement, however—the identity of the agency conducting the investigation and the status of the investigation—do not appear to be "commercial," and nothing in the declarations is provided to assist the Court is reaching any other conclusion. The identify of an outside agency conducting an investigation and that investigation's status (e.g., closed, ongoing, active, stayed, dormant, etc.) would not, standing alone, reveal any information about the business operations or other commercial activities of the defendant-intervenors. While the defendant-intervenors' declarants indicate that release of the broad category of information would cause competitive harm or be of some use to "adversaries in current litigation," Nowicki Decl. ¶ 28, the basis for these assertions is unexplained. While the Court appreciates that revealing the existence of an investigation, even if the status is closed, may be embarrassing or harmful to the reputation of a company, the law is well-settled that this potential consequence of a disclosure does not convert the information into "commercial" under Exemption 4. The D.C. Circuit made this point clearly in *United Technologies*. There, defense contractors sought to use Exemption 4 to shield the release of information on the ground that they would suffer competitive harm because "their competitors will use the documents to discredit them in the eyes of current and potential customers" and their "reputation will suffer as a result." *United Technologies*, 601 F.3d at 563. The court bluntly rejected this argument, stating "Exemption 4 does not protect against this species of harm," and further explaining that "[c]alling customers' attention to unfavorable agency evaluations or unfavorable press does not amount to an 'affirmative use of proprietary information by competitors.'" *Id*. at 563–64. In

short, "Exemption 4 does not guard against mere embarrassment in the marketplace or reputational injury." *Id*. at 564; *see also Occidental Petroleum Corp. v. SEC*, 873 F.2d 325, 341 (D.C. Cir. 1989) (holding that a submitter's "right to an exemption, if any, depends upon the competitive significance of whatever information may be contained in the documents, not upon whether its motive is to avoid embarrassing publicity"); *CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1154 (D.C. Cir. 1987) (noting that public embarrassment to a corporation does not warrant withholding material under Exemption 4).

The identities of the agencies conducting the investigations and the status of those investigations are not "commercial" for Exemption 4 purposes. Therefore, the Court grants summary judgment to the plaintiff and orders the release of any documents withheld because they contain the identity of the agency conducting the investigation and the status of the investigation or proceeding.

e. Company Communications with FDA About Off-Label Promotions

The CIAs require each company to provide copies of communications from the FDA that "substantively discuss . . . unlawful or improper promotion of [the company's] products or the misbranding of [the company's] products." Purdue CIA at 20; *see* Pfizer CIA at 22; Nowicki Decl. ¶ 30 (clarifying that this provision of Pfizer's CIA is limited to "unlawful or improper promotion of [the company's] products," and does not include "misbranding"). Although the defendants' declarants say nothing about the commercial nature of these communications, again, the Court may rely on the definition in the CIA to determine that the subject matter of the communications expressly relates to promotion of the companies' products. Since this category of withheld documents pertains to the marketing and sale of the companies' products, the Court finds that these documents are "commercial" within the meaning of Exemption 4.

f. Pfizer's Off-Label Findings And Detailing Sessions

Pfizer, and not Purdue, was required to "provide to OIG a list and explanation of all actively promoted Pfizer products and, if available from third parties, information about the estimated relative usage . . . of those products for off-label purposes." Pfizer CIA at 22. Furthermore, in each Annual Report, "Pfizer shall obtain commercially available non-Pfizer records reflecting the purported content and subject matter of detailing interactions between sales representatives and [health care providers] for the Covered Products." *Id.* After obtaining these third party records, "Pfizer shall review the records . . . and shall identify any instances in which the records appear to indicate that Covered Person may have discussed and/or disseminated information about off-label uses of the Covered Products." *Id.* at 23. "Pfizer shall make findings based on its review . . . and shall take any responsive action it deems necessary." *Id.* Pfizer was required to provide these underlying documents and findings as part of its Annual Report. *Id.*

Pfizer's declarant explains that the details it provides to the OIG about its "Review of Detailing Sessions . . . includes detailed information regarding Pfizer's internal review and monitoring of sales representative activities that are designed to ensure compliance with FDA promotional and other legal requirements." Nowicki Decl. ¶ 33. This declarant further states that this information also describes "the manner in which Pfizer addresses potential violations of Company policies and procedures." *Id.* The description of the subject matter of this category of challenged, withheld documents is sufficiently specific to demonstrate that these documents pertain to sales representative activities, and reflect activities "instrumental" to Pfizer's commercial operations because compliance with FDA regulations is required for Pfizer to sell its products. Therefore, the Court finds that the category of withheld documents regarding Pfizer's off-label findings and detailing sessions are "commercial" for purposes of Exemption Four.

g. Independent Review Organization Reports

The CIAs require each company to engage an IRO to review its transactions, systems, and compliance activities. *See* Purdue CIA at 14; Pfizer CIA at 14. The IROs are required to provide the companies with detailed reports regarding the IRO's findings and, in turn, the companies are required to provide summaries and assessments of changes made as a result of the IRO findings. *See* Purdue CIA at 15; Pfizer CIA at 16–18. Pfizer's declarant explains that the IRO's role "is to make an independent evaluation of Pfizer's 'Promotional and Product Related Functions.'" Nowicki Decl. ¶ 21. In performing this task, the IRO reports contain detailed information about Pfizer's "managed care contracting process," policies and procedures "relating to responses to financial programs" and "policies and procedures relating to responses for medical information requests." Def.'s Mem. at 18. Pfizer's declarant further describes the contents of the IRO reports as containing information "related to Pfizer's internal structure and operations, how the company interacts with [health care providers] and the medical community, and Pfizer's policies governing the selling, detailing, marketing, advertising, promoting and branding of . . . all Pfizer human pharmaceutical products." Nowicki Decl. ¶ 22. Purdue's declarant states that the IRO report contains "an extensive, probing review of Purdue's confidential business systems and policies, as well as selected samples of individual transactions." Weinstein Decl. ¶ 20. These reports contain such information as the identity of customers and the underlying business practices that gave rise to the need for corrective action. *Id.*

This description of the information contained in the IRO reports is sufficiently detailed to leave the Court no doubt that these documents include extensive information about the defendant-intervenors' marketing and sales programs and contracting processes, and, consequently, are commercial under Exemption 4.

h. 2009 Purdue Supplement

The plaintiff challenges the withholding of the 2009 Purdue Supplement, which it describes as the "transmittal memorandum and supplement to Purdue's first annual compliance report." Pl.'s Mem. at 26. According to the plaintiff this "cover memorandum" to OIG was produced only in heavily redacted form. *Id.* The Purdue *Vaughn* Index states that the "withheld portions of the document [under Exemption 4] contain information regarding Purdue's promotional monitoring program and other confidential and proprietary policies and procedures." Purdue *Vaughn* Index No. 22. A promotional monitoring program falls within the scope of commercial information under Exemption 4 because it pertains directly to the methods by which Purdue sells its products.

Yet, the vague reference in the Purdue *Vaughn* Index to "other confidential and proprietary policies" is insufficient to allow the Court to determine whether those portions of the document are commercial under Exemption 4. Purdue *Vaughn* Index No. 22. Thus, to the extent that the 2009 Purdue Supplement pertains to its promotional monitoring program, the Court finds that it is "commercial" within the meaning of Exemption 4. Given the paucity of information provided in the declarations and Purdue *Vaughn* Index about the other portions of the document, however, it is impossible for the Court to determine whether the entire document contains commercial information and whether any non-commercial information can be segregated from the commercial information. Therefore, the Court denies summary judgment to all parties pertaining to the "other confidential and proprietary policies" as to the segregable parts of the 2009 Purdue Supplement.

* * *

In sum, the following categories, or sub-parts of categories, of challenged, withheld documents are not "commercial," and the Court grants summary judgment to the plaintiff with respect the portions of the Annual Reports that require the defendant-intervenors to report on: (1) the "name, title, and responsibilities of any person determined to be an Ineligible Person," pursuant to the Purdue CIA §§ III.F and V.B.12, and the Pfizer CIA §§ III.F and V.B.11; and (2) the identity of the agency conducting, and status of, an investigation or proceeding, pursuant to the Purdue CIA §§ III.G and V.B.13, and the Pfizer CIA §§ III.G and V.B.15.

Due to the insufficiency of the declarations and *Vaughn* indices, the Court is unable to assess for the following categories, or sub-parts of categories, of challenged, withheld documents whether the subject matter is "commercial" for the purpose of Exemption 4: (1) Reportable Event summaries, submitted pursuant to §§ III.H and V.B.9 of the Purdue CIA, and §§ III.H and V.B.12 of the Pfizer CIA; (2) disclosure log summaries, submitted pursuant to the §§ III.E and V.B.10 of the Purdue CIA, and §§ III.E and V.B.14 of the Pfizer CIA ; and (3) references to "other confidential and proprietary policies" in the 2009 Purdue Supplement. The Court will give the defendant and defendant-intervenors the opportunity to supplement their declarations and/or *Vaughn* indices to sustain their burden of showing the commercial nature of these documents or, alternatively, to release them. *See Comptel v. FCC*, No. 06-1718, 2013 WL 2171793, at *7 (D.D.C. May 20, 2013) (after denying summary judgment without prejudice to give agency opportunity to file supplemental information, court reviewed amended declarations and *Vaughn* index, stressing that agency "has the burden to show that the information redacted is commercial or financial, in addition to demonstrating that it was obtained from a person and is privileged or confidential").

The Court has been able to conclude, based upon the context and the CIAs' definitions, in conjunction with the declarations and *Vaughn* indices, that the following categories, or sub-parts of categories, of challenged, withheld documents are "commercial" for the purposes of Exemption 4: (1) changes to the processes by which the companies fulfill the Ineligible Persons requirement in Section III.F of the Purdue and Pfizer CIAs; (2) the description of the allegations subject to investigations or legal proceedings required to be included in the Annual Reports, pursuant to § III.G of the Purdue and Pfizer CIAs; (3) company communications with the FDA regarding off-label promotions required to be included in the Annual Reports, pursuant to § III.I of the Purdue and Pfizer CIAs; (4) Pfizer's off-label findings and detailing sessions required to be included in the Annual Reports, pursuant to §§ III.J and V.B.17 of the Pfizer CIA; (5) IRO reports required to be included in the Annual Reports, pursuant to §§ III.D and V.B.5-8 of the Purdue CIA, and §§ III.D and V.B.6-9 of the Pfizer CIA; and (6) the portions of the 2009 Purdue Supplement addressing Purdue's promotional monitoring program. The Court next examines the sufficiency of the showing that these commercial documents are confidential to warrant application of Exemption 4.

3. *Sufficiency of Showing That Commercial Documents Are Confidential*

A "commercial" document may only be withheld under Exemption 4 if it is "privileged"[19] or "confidential." 5 U.S.C. § 552(b)(4). A two prong test is used to determine

[19] Pfizer argues that all of the challenged documents fall under the "self-evaluation and self-critical reports" privilege for Exemption 4 purposes. Pfizer Mem. at 22. The Court is not persuaded by Pfizer's tortured reading of Circuit precedent. Pfizer cites only a single, unpublished district court case from this Circuit to support its proposition that "courts have long recognized" a self-evaluative privilege. *Id.* (citing *Washington Post Co. v. Dep't of Justice*, Civil Action No. 84-3581, 1987 U.S. Dist. LEXIS 14936, at *21 (D.D.C. Sept. 25, 1987)). As Pfizer points out, that case was reversed on other grounds. *See Wash. Post Co. v. Dep't of Justice*, 863 F.2d 96, 99 (D.C. Cir. 1988). Indeed, in remanding that case for consideration of the applicability of a FOIA exemption other than Exemption 4, the D.C. Circuit court reserved judgment as to whether Exemption 4 encompasses a self-evaluative privilege. *Id.* ("We will decide the exemption (4) question" if "the report [at issue] is not shielded under exemption (7)(B)"). Notably, the D.C. Circuit has rejected the use of the "self-evaluative privilege in the context of private litigation . . . where… the documents in question have been sought by a governmental agency," *FTC v. TRW, Inc.*,

whether information involuntarily submitted to a Federal agency is "confidential" for FOIA purposes. "Commercial or financial matter is 'confidential' for purposes of the exemption if disclosure of the information is likely to have either of the following effects: (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained." *Nat'l Parks and Conserv. Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974) ("*National Parks*"); *see also B.d of Trade v. Commodity Futures Trading Com.*, 627 F.2d 392, 404 (D.C. Cir. 1980). As discussed below, the Court examines the sufficiency of the showing by the defendant and defendant-intervenors that the release of the withheld commercial documents would either "impair the Government's ability to obtain necessary information in the future," *id.*, or "cause substantial harm to the competitive position" of Pfizer or Purdue.[20]

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628 F.2d 207, 210 (D.C. Cir. 1980), and has cautioned that "federal courts should not create evidentiary privileges lightly . . . and we would unlikely fashion a privilege lacking in historical or statutory basis," *First E. Corp. v. Mainwaring*, 21 F.3d 465, 467 n.1 (D.C. Cir. 1994) (internal quotation marks omitted). As this Court noted in *Mahnke v. Washington Metropolitan Area Transit Authority*, the "self-evaluative" privilege is "rarely recognized" and "[c]ourts are 'reluctant to expand [the privilege] beyond cases involving public health or safety.'" 821 F. Supp. 2d 125, 150 n.16 (D.D.C. 2011) (citations omitted) [alterations in the original]. No case from any federal court has been cited by the parties in which the "self-evaluative privilege" was successfully used to justify the withholding of documents under Exemption 4. The Court declines to extend whatever self-evaluative privilege may exist in the civil discovery context to shield from disclosure under Exemption 4 reports involuntarily provided to a government agency and, thus, only considers whether the commercial documents withheld in this case are also confidential.

[20] The bar is lower for withholding confidential information *voluntarily* provided to the Government: voluntarily submitted information need only be "of a kind that would customarily not be released to the public by the person from whom it was obtained" to be withheld as confidential. *Critical Mass*, 975 F.2d at 878. While HHS and Purdue, which joined HHS' arguments, concede that the companies' submissions to OIG were involuntary, Pfizer contends that because it entered into its CIA with HHS voluntarily, the information required by the CIA was also produced voluntarily. *See* Pfizer Mem. at 16–17. Pfizer's argument is contrary to the law of this Circuit. "For purposes of Exemption 4, information provided to the government because it is required for participation in a voluntary government program is treated as a mandatory, as opposed to a voluntary, submission of information." *Judicial Watch, Inc. v. U.S. Dep't of the Treasury*, 796 F. Supp. 2d 13, 35 n.8 (D.D.C. 2011); *see also Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 244 F.3d 144, 149 (D.C. Cir. 2001) (holding that when an agency has "actual legal authority" to compel production of information, such production is not voluntary for the purposes of the FOIA); *Pub. Citizen Health Research Grp. v. F.D.A.*, 964 F. Supp. 413, 414 n.1 (D.D.C. 1997) ("Information is submitted involuntarily, however, if it is supplied pursuant to statute, regulation or some less formal mandate."). Pfizer does not dispute that the documents at issue were "submitted to the OIG in accordance with the terms of the 2004 CIA." Pfizer Mem. 16. As such, the information was submitted involuntarily because it was submitted "pursuant to statute, regulation, or some less formal mandate." *Pub. Health Research Grp.*, 964 F. Supp. at 414 n.1. Therefore, the Court will apply the more stringent confidentiality standard applicable to involuntarily submitted documents recognized in *National Parks* and *Critical Mass*.

a. The Government's Ability to Obtain Necessary Information

The defendant argues that the release of the withheld documents would harm the government's interest in two ways. "First, health care providers currently under CIAs would be reluctant to provide complete information," citing as an example that "providers may hesitate to fully explain the circumstances or submit their full investigative reports if they are concerned that the public may have access to that information [regarding instances of possible noncompliance]." Def.'s Mem. at 26. "Second, the OIG's inability to prevent the disclosure of confidential proprietary information would severely impair [HHS's] ability to negotiate meaningful CIAs in the future." *Id*. Neither argument is persuasive.

First, the Court is skeptical of the defendant's contention that release of the withheld commercial information could jeopardize the government's ability to obtain full and complete reporting as required under the CIAs. The court in *Critical Mass* was similarly skeptical about impairment of the government's ability to obtain information when the submission was required. *Critical Mass*, 975 F.2d at 878 ("because the concessioners [were] required to provide this financial information . . . there is presumably no danger that the public disclosure will impair the ability of the Government to obtain this information in the future") (alteration in original). Instead, the D.C. Circuit explained that the focus is on the risk that disclosure may adversely affect the "continued reliability" or "quality" of the information obtained by the government, not its availability. *Id.*

With respect to the "quality" of the submissions, the government is well-protected by the penalty terms of the CIAs for breaches of the reporting requirements. The CIAs contain extensive monetary and injunctive penalties for violations of the agreement, including exclusion from federal health care programs, the so-called "death penalty." *See* Purdue CIA at 32–38; Pfizer CIA at 30–36. For instance, if Pfizer were to fail "to report a Reportable Event and take

corrective action, as required in Section III.H," Pfizer could be considered in material breach of the agreement. Pfizer CIA at 33 (Section X.D.1.a) "The parties agree that a material breach of the CIA by Pfizer constitutes an independent basis for Pfizer's exclusion from participation in the federal health care programs." *Id.* at 34 (Section X.D.2). Other failures to adhere fully to the CIA can lead to substantial monetary penalties. *See* Pfizer CIA at 31–32 (Section X.A); Purdue CIA at 32–33 (Section X.A). Thus, the defendant has a variety of methods by which to guarantee the continued completeness and accuracy of the reports submitted by these and other companies subject to CIAs.

The defendant's second argument about future trouble negotiating CIAs is similarly unavailing, and largely for the same reason: namely, that the alternative to full compliance with the CIAs is a potentially draconian penalty. CIAs are entered into as part of "the resolution of civil and administrative health care fraud cases." Demske Decl. ¶ 2. The incentive to enter into such an agreement is that "the OIG agrees not to seek an exclusion of that entity from participation in Federal health care programs." *Id.* Exclusion from Federal health care programs is such a severe penalty that it is known in the healthcare industry as "a corporate death sentence." Kesselheim Decl. ¶ 9. It strains credulity to believe that the specter of potential disclosure under the FOIA of certain information required to be submitted to the agency pursuant to a CIA's requirements would lead a pharmaceutical company to choose instead the risk of exclusion from federal drug reimbursement programs. Indeed, "nearly every" Department of Justice investigations into the types of behavior that led to Pfizer and Purdue's original CIAs "has resulted in a settlement with the defendant pharmaceutical manufacturer, with

manufacturers choosing not to risk a finding of guilt at trial and exclusion from engaging in federal health programs." *Id.*[21]

Purdue's declarant seeks to bolster the defendant's impairment argument by stating that "It was critical to Purdue during negotiation of the CIA with OIG that the materials Purdue would submit to OIG would be kept confidential and not subject to disclosure under FOIA." Supplemental Declaration of Bert Weinstein, Vice-President of Corporate Compliance, Purdue Pharma, ("Weinstein Suppl. Decl.") ¶ 2, ECF No. 29-1. This is belied by other language included in the CIA, however, which makes clear that submitted information may be subject to disclosure under the FOIA. While the CIA permits Purdue to "clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act," Purdue CIA at 30, the final determination must be left up to the agency. *See* 5 U.S.C. § 552(a). In any event, merely because it was important to Purdue "that the materials Purdue would submit to OIG" be shielded from disclosure is not the same as saying Purdue would not have signed the CIA without such assurances. Purdue, notably, never makes such an argument, nor does the defendant agency.

[21] The defendant briefly cites two cases for its position that the first prong of the *National Parks* test is met and release of the documents would impair the government's ability to secure CIAs with companies in the future, but neither case is persuasive. The context in *Judicial Watch, Inc. v. Export-Import Bank*, 108 F. Supp. 2d 19 (D.D.C. 2000), differs materially from the instant case. In *Judicial Watch*, the Export-Import Bank established that if disclosure of the withheld records at issue were required, the "Bank's function of providing insurance would be undermined" and its ability "to fulfill its statutory purpose" would be impaired. *Id*. at 29–30. The defendant here nowhere claims that disclosure would have such dire results as impairing its ability to carry out its statutory purpose. The other case cited by the defendant is likewise inapposite. In *Hersh and Hersh v. United States Department of Health and Human Services*, No. C 06-4234, 2008 WL 901539 (N.D. Cal. Mar. 31, 2008), the court deferred to the agency's assertion about impairment of the government interest, as was appropriate since, unlike in the instant case, that assertion was not substantively challenged. *Id.* at *7 ("Plaintiff, moreover, presents no adequate grounds to hold otherwise," noting that the plaintiff's only argument was that certain information submitted under the CIA had been temporarily, inadvertently disclosed and the erroneous belief that the CIA report at issue had been publicly filed with the SEC).

The defendant's concern about its ability to negotiate future CIAs is, at most, minor, since the enticement for companies to enter into CIAs to avoid the "corporate death sentence" will continuing to be compelling. "A minor impairment cannot overcome the disclosure mandate of FOIA." *Wash. Post Co. v. U.S. Dep't of Health and Human Servs.*, 690 F.2d 252, 269 (D.C. Cir. 1982). Therefore, the Court finds that the defendant has not shown how the release of the withheld documents will "impair the Government's ability to obtain necessary information in the future." *National Parks*, 498 F.2d at 770.

b. Competitive Harm

The Court next examines the second prong of the *National Parks* test: whether the agency has sufficiently shown that release of the withheld information is likely to "cause substantial harm to the competitive position of the person from whom the information was obtained." *Id.* at 770; *see also Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d at 1290-91 (D.C. Cir. 1983); *McDonnell Douglas Corp. v. U.S. Dep't of Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004) (party invoking Exemption 4 is not required "to prove disclosure certainly would cause it substantial competitive harm, but only that disclosure would 'likely' do so"). Not all harm to the information provider qualifies as "competitive harm." As noted, the D.C. Circuit has made clear that, "[i]n this inquiry, it is simply irrelevant that" confidential treatment of the documents would avoid disclosure of information "that might be damaging to [the provider's] reputation." *Occidental Petroleum Corp.*, 873 F.2d at 341 (D.C. Cir. 1989). To qualify as "substantial competitive harm," the harm must be "limited to harm flowing from the affirmative use of proprietary information *by competitors*." *Pub. Citizen Health Research Grp.*, 704 F.2d at 1291 & n.30 (emphasis in the original).[22]

[22] The defendant spills a great deal of ink on the argument that "when a company invests time and other resources into developing policies and procedures, among other things, they will face competitive harm if those products are

Based upon the Court's foregoing analysis, the following challenged records are "commercial" and must meet this second prong of the *National Parks* test to be appropriately withheld under Exemption 4: (1) changes to the processes by which the intervenor-defendants fulfill the Ineligible Persons requirement; (2) the description of the allegations subject to investigations or legal proceedings; (3) company communications with the FDA regarding off-label promotions; (4) Pfizer's off-label findings and detailing sessions; (5) IRO reports; and (6) the portions of the 2009 Purdue Supplement addressing Purdue's promotional monitoring program. Each of these categories of commercial documents is examined below to evaluate the sufficiency of the showing that disclosure would cause substantial competitive harm to the defendant-intervenors.

In reviewing the sufficiency of the declarations and *Vaughn* indices, the Court is mindful that merely conclusory statements about competitive harm, even if repeated numerous times, are not sufficient. *See Pub. Citizen Health Research Grp.*, 704 F.2d at 1290-1291 ("Conclusory and generalized allegations of substantial competitive harm, of course, are unacceptable and cannot support an agency's decision to withhold requested documents."); *Occidental*, 873 F.2d at 342 (requiring more than "conclusory statement" regarding substantial competitive harm); *Wash. Post Co.*, 690 F.2d at 269 (D.C. Cir. 1982) ("[T]he government produced no evidence except a conclusory affidavit by the HHS director of personnel policy. Thus, the government has not yet established its Exemption 4 claim."); *Mead Data Cent., Inc. v. U.S. Dep't of Air Force*, 566 F.2d

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released to the public." Def.'s Reply at 15 (alterations in original omitted). The level of resource expenditures may be relevant to evaluating the proprietary nature of information, but it is not necessarily a measure of competitive harm for purposes of Exemption 4. Rather, it is the prospect of the affirmative use of the disclosed information by competitors that makes release of the information competitively harmful. *See Pub. Citizen Health Research Grp.*, 704 F.2d at 1291. The defendant's argument is a virtual non-sequitur in this case, because the primary argument raised by the plaintiff is not about the level of resource expenditures in the creation of the withheld records, but rather that release of these records would not constitute competitive harm because they could not be used affirmatively by the defendant-intervenors' competitors. *See* Pl.'s Reply at 12. Furthermore, to the extent the plaintiff "ignore[d]" the resource expenditure defense to disclosure, as the defendant contends, Def.'s Reply at 15, this does not amount to "concession" since the level of expenditures is irrelevant.

242, 258 (D.C. Cir. 1977) ("An agency cannot meet its statutory burden of justification by conclusory allegations of possible harm."); *Comptel*, 910 F. Supp. 2d at 117 ("[C]onclusory assertions, without any additional description of the contents of the redacted information or reasons for non-disclosure, are insufficient to show that Exemption 4 was appropriately invoked."); *Biles v. U.S. Dep't of Health and Human Servs.*, No. 11-1997, 2013 WL 1154207, at *9 ("[C]onclusory claims of commercial harm . . . are therefore insufficient to establish HHS' burden of proof"). Even with deference given to agency declarations, "deference does not mean blind acceptance." *Mudge Rose Guthrie Alexander & Ferdon v. U.S. Int'l Trade Comm'n*, 846 F.2d 1527, 1532 (D.C. Cir. 1988).

First, to support the contention that disclosure of the changes implemented by the defendant-intervenors for screening and removing Ineligible Persons would cause substantial competitive harm, Pfizer's declarant explains that "[t]his information reflects Pfizer's internal business processes and judgments made to develop and implement the Ineligible Person Management process . . . ." Nowicki Decl. ¶ 29. Purdue's declarant mentions only that "the determination, screening and training of relevant covered persons/vendors, as well as its proposed actions regarding ineligible persons, all directly relate to Purdue's compliance with legal and regulatory requirements, and are proprietary in nature." Weinstein Decl. ¶ 15. These process changes reflect the companies' views of effective ways in which to ferret out Ineligible Persons, in the context of the companies' particular organizational structure and operations. Although the declarations provide only slim support, the Court finds that disclosure of these process changes may risk competitive harm by revealing confidential information about the companies' broader structure and operations in which the changes to Ineligible Persons processes are implemented. *See United Technologies*, 601 F.3d at 564 (finding proprietary manufacturing

and quality control processes were subject to withholding under Exemption 4 since "[o]nce disclosed, competitors could, it appears, use the information to improve their own manufacturing and quality control systems, thus making 'affirmative use of proprietary information' against which Exemption 4 is meant to guard."). Consequently, the Court grants summary judgment to the defendant and defendant-intervenors as to the withholding under Exemption 4 of documents reflecting "changes in process" pertaining to Ineligible Persons.

Second, regarding the likely competitive harm posed by disclosure of documents containing the description of the allegations subject to investigations or legal proceedings, the defendant and defendant-intervenors have not provided a sufficient showing to sustain summary judgment. Pfizer's declarant states only that "the summary information that Pfizer submits to OIG is highly sensitive, confidential information that Pfizer does not publicly release." Nowicki Decl. ¶ 28. This conclusory statement says nothing about how the revelation of these descriptions of allegations, now dating back to at least several years ago, would be used by competitors affirmatively to harm Pfizer. Purdue's declarant does no better by stating "[p]ublic disclosure of this information, which includes non-public legal and/or regulatory actions, such as with a Reportable Event, would certainly have negative commercial consequences for Purdue." Weinstein Decl. ¶ 26. This is a conclusory statement that, again, does nothing to show why or how competitors will be able to use this information affirmatively cause to harm to Purdue. As noted, Exemption Four does not shield embarrassing information or information that may cause reputational harm, but only information that can be affirmatively used by a competitor. *See CNA Fin. Corp. v. Donovan*, 830 F.2d at 1154 & n.158; *Pub. Citizen Health Research Grp.*, 704 F.2d at 1291 n.30. Therefore, the Court denies summary judgment to all parties regarding the

descriptions of allegations contained in the summaries of legal and investigatory inquiries provided by the defendant-intervenors in their Annual Reports.

Third, the defendant-intervenors' communications with the FDA regarding off-label marketing are at least partially non-confidential. Pfizer's declarant makes this clear when he states that "Pfizer's communications with the FDA are *usually* confidential commercial information that Pfizer maintains under strict confidentiality." Nowicki Decl. ¶ 30 (emphasis supplied). This statement implicitly acknowledges that these communications are not *always* strictly confidential, which is further confirmed by the declarant's statement that some communications, such as Warning Letters from the FDA, are publicly available. *Id.* Purdue's declarant says nothing to address this category of records. Neither the *Vaughn* indices nor the declarations provide sufficient specificity for the Court to determine which documents may contain confidential commercial information and which do not. Therefore, summary judgment as to the company communications with the FDA will be denied to all parties.

Fourth, Pfizer's off-label findings and detailing sessions are the murkiest of the withheld records requested by the plaintiff. Pfizer's declarant does little to shed light on what the detailing sessions are, how they are conducted, and from where the records are derived. He merely states that the information "is highly confidential and includes detailed information regarding Pfizer's internal review and monitoring of sales representative activities," but neither Pfizer nor the defendant has explained how Pfizer obtains the underlying documents on which these analyses are based. *See* Nowicki Decl. ¶ 33. Nevertheless, since the off-label findings by Pfizer reflect the company's "findings" about its own sales force' activities, the potential risk of competitive harm from disclosure of what those activities are is plain. Therefore, as to Pfizer's

off-label findings, the Court grants summary judgment to the defendant and defendant-intervenors.

The documents reflecting "detailing sessions" are more difficult, particularly given the lack of information provided to the Court about the precise nature of these documents. The CIA requires Pfizer to obtain "commercially available non-Pfizer records" to conduct its review. Pfizer CIA at 22. If these detailing session documents are commercially available from third parties, it is unclear what the basis is at all for Pfizer's assertion of confidentiality. In any event, the level of specificity provided as to the nature of the detailing session documents is too minimal to demonstrate, as is the agency's burden, that the release of this information would cause competitive harm. Therefore, summary judgment is denied to all parties as to the documents containing detailing sessions.

Fifth, the IRO Reports present "an extensive, probing review of Purdue's confidential business systems and policies, as well as selected samples of individual transactions," Weinstein ¶ 20, and "Pfizer's internal structure and operations, how the company interacts with HCPs and the medical community, and Pfizer's policies governing the selling, detailing, marketing, advertising, promoting and branding of Government Reimbursed Projects, meaning all Pfizer human pharmaceutical products promoted or sold by Pfizer in the United States that are reimbursable by Federal health care programs," Nowicki Decl. ¶ 22. These details make clear that competitive harm would result from their disclosure. For instance, Purdue's declarant states that the reports contain "selected samples of individual transactions . . . which may contain private patient information as well as . . . the identity of Healthcare Professionals who are customers." Weinstein ¶ 20. It is thus obvious that the release of such information would be akin to releasing customer lists which could easily be used affirmatively by competitors to harm

Purdue. Similarly, a competitor could certainly use internal details of the sale and marketing of Pfizer's products against it a number of ways, such as setting prices, competing for ad space, or identifying areas of strength or weakness. Therefore, the Court finds that information pertaining to the IRO Reports, responses, and corrective action taken in response to the IRO Reports were properly withheld under Exemption 4, and summary judgment is granted to the defendant and defendant-intervenors on this category of information.

Finally, Purdue's declarant makes only a single conclusory statement about the potential competitive harm that could be caused by the release of the 2009 Purdue Supplement, stating that the promotional monitoring program "is considered proprietary and highly confidential. Thus, it would be detrimental to Purdue if these documents were publicly disclosed." Weinstein Decl. ¶ 29. These nineteen words provide only slim support for a finding that competitive harm is likely to result from revelation of this promotional monitoring program. Nevertheless, the subject matter plainly relates to core aspects of the company's marketing and sales efforts and, thus, how Purdue conducts those activities in compliance with applicable regulations and laws. Similar to the changes in business processes that the defendant-intervenors use to fulfill the Ineligible Persons requirement, disclosure of how Purdue has continued to perfect its promotional monitoring program could be put to affirmative use by its competitors, thus making it confidential under the terms of Exemption 4. Therefore, summary judgment is granted to the defendant and defendant-intervenors on the withholding of Purdue's promotional monitoring program information contained in the 2009 Purdue Supplement.

* * *

In sum, of the six categories, or sub-parts of categories, found to contain commercial matter, the Court concludes that there is sufficient support for finding that the following withheld documents are also confidential: (1) changes to the processes by which the companies fulfill the Ineligible Persons requirement in § III.F of the Purdue and Pfizer CIAs; (2) Pfizer's off-label findings required to be included in the Annual Reports, pursuant to §§ III.J and V.B.17 of the Pfizer CIA; (3) IRO reports required to be included in the Annual Reports, pursuant to §§ III.D and V.B.5-8 of the Purdue CIA and §§ III.D and V.B.6-9 of the Pfizer CIA; and (4) the portions of the 2009 Purdue Supplement addressing Purdue's promotional monitoring program. Therefore, this information was properly withheld under Exemption 4, and summary judgment is granted to the defendant and defendant-intervenors as to these documents. The declarations and *Vaughn* indices submitted to support the withholding of the remaining commercial documents are insufficient for the Court to assess whether the documents warrant confidential treatment and qualify for withholding under Exemption 4. Thus, summary judgment is denied to all parties with respect to the following documents containing commercial matter: (1) the description of the allegations subject to investigations or legal proceedings required to be included in the Annual Reports, pursuant to § III.G of the Purdue and Pfizer CIAs; (2) company communications with the FDA regarding off-label promotions required to be included in the Annual Reports, pursuant to § III.I of the Purdue and Pfizer CIAs; and (3) Pfizer's detailing sessions required to be included in the Annual Reports, pursuant to §§ III.J and V.B.17 of the Pfizer CIA. As to these documents, the defendant and defendant-intervenors may submit supplemental declarations and/or *Vaughn* indices demonstrating that disclosure of the withheld documents would likely cause competitive harm or, alternatively, release the withheld documents.

Finally, any supplemental support for continued withholding of any of the challenged documents must also address whether any reasonably segregable portions of withheld documents have been released, keeping in mind that an "'agency cannot justify withholding an entire document simply by showing that it contains some exempt material.'" *Hodge v. FBI*, 703 F.3d 575, 582 (D.C. Cir. 2013) (quoting *Stolt-Nielsen Transp. Grp.*, 534 F.3d at 734).

IV. CONCLUSION

The fundamental problem in this case is the lack of detail provided in the defendants' declarations and the *Vaughn* indices. Mere conclusory statements regarding the alleged commercial nature and confidentiality of the records withheld is not sufficient to allow this Court to determine whether the withheld information is properly exempt under FOIA's Exemption 4.

For the reasons explained above, the Motion for Summary Judgment of the defendant and defendant-intervenors is denied in part and granted in part. This motion is DENIED, without prejudice, because the Court has insufficient information to determine if the disputed records are "commercial" within the meaning of Exemption 4 with respect to (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 title and responsibility information of Ineligible Persons required by § V.B.11 of the Pfizer CIA and § V.B.12 of the Purdue CIA; (4) information pertaining to the agency conducting an investigation and the status of that investigation required by § V.B.13 of the Purdue CIA and § V.B.15 of the Pfizer CIA; and (5) reasonably segregable information in the 2009 Purdue Supplement that does not pertain to its promotional monitoring program. The defendant and defendant-intervenors' Motion is also DENIED, without prejudice, because the Court does not have sufficient information to determine if the disputed records are confidential within the

meaning of Exemption 4 with respect to (6) the summaries of legal and investigatory inquiries required by § V.B.13 of the Purdue CIA and § V.B.15 of the Pfizer CIA; (7) company communications with the FDA as required by § V.B.14 of the Purdue CIA and § V.B.16 of the Pfizer CIA; and (8) the "underlying records reflecting the content of detailing sessions between HCPs and Covered persons" as required in § V.B.17 of the Pfizer CIA.

The Motion for Summary Judgment of the defendant and defendant-intervenors is GRANTED with respect to the following records, which the Court finds were properly withheld under Exemption 4 as commercial and confidential: (1) the records reflecting "changes in process" of the monitoring and removal of Ineligible Persons required by § V.B.11 of the Purdue CIA and § V.B.10 of the Pfizer CIA; (2) the Off-Label Findings and summary of responsive action taken by Pfizer required by § V.B.17 of the Pfizer CIA; (3) the IRO reports required by §§ V.B.5–8 of the Purdue CIA and §§ V.B.6–9 of the Pfizer CIA; and (4) the portions of the 2009 Purdue Supplement pertaining to its promotional monitoring program.

The plaintiff's Cross-Motion for Summary Judgment is granted in part and denied in part. The Cross-Motion is GRANTED as to the inadequacy of the defendant's search for responsive records regarding the Pfizer Section V.B.6 documents; and as to the following records, which the Court finds were not properly withheld under Exemption 4 and must be released to the plaintiff: (1) the titles and responsibilities of Ineligible Persons removed required by § V.B.12 of the Purdue CIA and § V.B.11 of the Pfizer CIA; and (2) the identity of the investigatory agency and status of any investigations required by § V.B.13 of the Purdue CIA and § V.B.15 of the Pfizer CIA. In all other respects, the plaintiff's Cross-Motion for Summary Judgment is DENIED, without prejudice.

For the remaining records at issue, the parties are directed to meet and confer and, by November 8, 2013, provide the Court with (1) a status report that sets forth a list of the records that remain in dispute, in light of this Memorandum Opinion, and that identifies each such disputed record by a Bates number, or other unique identifier, and by citation to the particular page(s) of the *Vaughn* index where the disputed record is described; and (2) a proposed briefing schedule for any further proceedings in this matter, including deadlines for the submission of any renewed dispositive motions, supplementary *Vaughn* indices, and/or supplementary declarations.

An appropriate Order accompanies this decision.

Date: October 4, 2013

Digitally signed by Beryl A. Howell
DN: cn=Beryl A. Howell, o=District Court for the District of Columbia, ou=District Court Judge, email=howell_chambers@dcd.uscourts.gov, c=US
Date: 2013.10.04 14:38:01 -04'00'

BERYL A. HOWELL
United States District Judge