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., Defendant-Intervenors.	Civil Action No. 11-1681 (BAH) Judge Beryl A. Howell

MEMORANDUM OPINION

The plaintiff, Public Citizen, brought this suit under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, seeking certain records filed by the defendant-intervenors, Pfizer Inc. ("Pfizer") and Purdue Pharma L.P. ("Purdue"), in compliance with the companies' "Corporate Integrity Agreements" ("CIAs")[1] with the Office of the Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS"). *See Public Citizen v. U.S. Dep't of Health & Human Servs.* (*Public Citizen I*), 975 F. Supp. 2d 81, 88–89 (D.D.C. 2013). The defendant and defendant-intervenors objected to the release of these records, claiming they were exempt from disclosure under the FOIA's Exemption 4, which applies to "trade secrets and

[1] The CIAs are part of "settlement agreements . . . with companies seeking to resolve civil and administrative health care fraud cases and avoid costly exclusion from participation in Federal health care programs." *See Public Citizen v. U.S. Dep't of Health & Human Servs.* (*Public Citizen I*), 975 F. Supp. 2d 81, 88 (D.D.C. 2013). "In return for these benefits, under the CIA[s], the companies must agree to enhanced compliance measures, subject to auditing by an outside independent party and monitoring by the OIG." *Id.*

commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). After this Court denied in part and granted in part the parties' initial cross-motions for summary judgment, the parties submitted revised *Vaughn*[2] indices and supplemental declarations in support of renewed motions for summary judgment. Pending before the Court are HHS' Renewed Motion for Summary Judgment ("Def.'s 2d Mot."), ECF No. 51; Pfizer's Renewed Motion for Summary Judgment ("Pfizer's 2d Mot."), ECF No. 47; Purdue's Renewed Motion for Summary Judgment ("Purdue's 2d Mot."), ECF No. 50; and the plaintiff's Renewed Motion for Summary Judgment ("Pl.'s 2d Mot."), ECF No. 53. For the reasons set forth below, the defendant and defendant-intervenors' motions are granted and the plaintiff's motion is denied.

I. BACKGROUND

The facts underlying this action have been explained in the Court's prior Memorandum Opinion and need not be repeated in detail here. *See Public Citizen I*, 975 F. Supp. 2d at 89–93. For the purposes of the instant motions, only a brief summary of the facts and the procedural history is necessary to provide context for the documents still at issue in this litigation.

A. *Public Citizen I* and Subsequent Procedural History

In 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 Pharm L.P.,' and 'by Pfizer, Inc. pursuant to the May 2004 Corporate Integrity Agreement between OIG and Pfizer.'" *Id.* at 90–91. These reports were submitted by the defendant-intervenors to the HHS OIG "as part of the companies' compliance with settlement agreements arising from the companies' illegal off-label promotion of drugs

[2] A *Vaughn* index is a document that correlates all withholdings with specific FOIA exemptions and the agency's specific nondisclosure justifications. *Vaughn v. Rosen*, 484 F.2d 820, 827 (D.C. Cir. 1973).

reimbursed by federal health care programs." *Id.* at 88. HHS "withheld the bulk of the requested records on grounds that they contain confidential, commercial information exempt from disclosure under FOIA Exemption 4." *Id.* at 89.

In the parties' initial summary judgment motions, eight categories of documents were in dispute, and the plaintiff challenged the defendant's search for responsive records as to a ninth set of documents. *See Public Citizen I*, 975 F. Supp. 2d at 91–92. The Court granted summary judgment to the plaintiff on two subsets of records in dispute, namely, documents pertaining to "the titles and responsibilities of Ineligible Persons removed [as] required by § V.B.12 of the Purdue CIA and § V.B.11 of the Pfizer CIA;" and "the identity of the investigatory agency and status of any investigations required [to be disclosed] by § V.B.13 of the Purdue CIA and § V.B.15 of the Pfizer CIA." *Id.* at 119. The Court also found that "the defendant's search for responsive records regarding the Pfizer [§] V.B.6 documents," was inadequate, *id.* at 119, and allowed the defendant to "either supplement its declarations to address the factual questions raised by the plaintiff [in *Public Citizen I*] or perform an additional search to locate the missing records," *id.* at 98.[3]

The Court granted summary judgment to the defendants as to four categories of disputed records, namely:

> (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;[4] (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

[3] Pfizer was required by § V.B.6 of its CIA to provide responses to required Independent Review Organization ("IRO") reports and recommendations pertaining to certain Pfizer programs. *See Public Citizen I*, 975 F. Supp. 2d at 92, 92 n.9, 119. The plaintiff challenged the adequacy of the defendant's search for records responsive to this portion of the plaintiff's original FOIA request because the redacted documents released by the defendant indicated that Pfizer had filed supplemental follow-up documents, as required by the CIA, that were not included in the defendant's release of records or reflected on Pfizer's *Vaughn* Index. *See id.* at 95.

[4] This category of records is unique to Pfizer, as Purdue's CIA did not have a similar requirement. *See Public Citizen I*, 975 F. Supp. 2d at 107–08. The content of these records is explained in greater detail in Part III.B, *infra.*

> portions of the 2009 Purdue Supplement pertaining to its promotional monitoring program." *Id*. at 118–19.
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> Remaining at issue after *Public Citizen I* were six categories of records, specifically:
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> (1) the Reportable Events summaries required by § V.B.9 of the Purdue CIA and § V.B.12 of the Pfizer CIA; (2) the Disclosure Log summaries required by § V.B.10 of the Purdue CIA and § V.B.14 of the Pfizer CIA; (3) the summaries of legal and investigatory inquiries required by § V.B.13 of the Purdue CIA and § V.B.15 of the Pfizer CIA; (4) reasonably segregable portions of the 2009 Purdue Supplement that do not pertain to Purdue's promotional monitoring program; (5) company communications with the FDA required by § V.B.14 of the Purdue CIA and § V.B.16 of the Pfizer CIA; and (6) the "underlying records reflecting the content of detailing sessions between HCPs and Covered persons" as required by § V.B.17 of the Pfizer CIA. Order at 2, ECF No. 35.

Following *Public Citizen I*, the plaintiff moved for reconsideration, arguing that the declaration of Dr. Kevin Rodondi (the "Rodondi Declaration") created issues of material fact sufficient to deny summary judgment to the defendants as to three sets of records. *See* Pl.'s Mot. Part. Reconsideration ("Pl.'s Mot. Rec.") at 1, ECF No. 37. The plaintiff also complained that the Court "overlooked [the plaintiff's] argument that records revealing suspected or confirmed illegal activity cannot, as a matter of law, be 'confidential' for the purpose" of the FOIA. *Id.* Finally, the plaintiff sought clarification as to one record ruled upon in *Public Citizen I*, namely, a June 18, 2009 supplement to Purdue's First Annual Report required by its CIA. *See* Mem. & Order at 10, ECF No. 44.

In denying the Motion for Reconsideration, the Court found the plaintiff's arguments as to the Rodondi Declaration utterly without merit. *See id.* at 5–8. First, the plaintiff was in error as to whether the declaration was considered by the Court in ruling on the plaintiff's Motion for Summary Judgment. *See id.* at 5 ("The plaintiff's underlying premise is incorrect, since the Court read and evaluated the declaration in preparing its Memorandum Opinion . . ."). Second, in reviewing the contents of the Rodondi Declaration, the Court noted that "the declaration provides nothing but qualified statements that are insufficient to raise a genuine issue of material

fact." *Id.* The Court further noted that although it saw no need to cite explicitly to the Rodondi Declaration in *Public Citizen I*, "[r]eferences to the declaration were woven throughout the plaintiff's briefing, to which the Court responded in detail." *Id.*

As for the plaintiff's argument that the Court "overlooked" the plaintiff's argument that records revealing illegal activity could not, as a matter of law, be confidential within the meaning of Exemption 4, the Court pointed out that the plaintiff had failed to make that argument in any of its voluminous summary judgment briefs or accompanying declarations and exhibits. *Id.* at 8. Instead, the plaintiff had argued vociferously and unpersuasively that records regarding suspected or confirmed illegal activity could not, as a matter of law, be "commercial" within the meaning of Exemption 4, and the Court addressed that argument extensively. *See Public Citizen I*, 975 F. Supp. 2d at 101–03. Even if the plaintiff's new argument had been raised, the Court found the argument was implicitly rejected by the Court's finding that "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." *Id.* at 10.

Finally, the Court addressed the plaintiff's request for "clarification" as to which record the Court was referring by the short title the "2009 Purdue Supplement." The Court had fully described the document in *Public Citizen I* as "Purdue's supplement, dated June 18, 2009, to its first Annual Report, which was submitted on September 25, 2008" and even cited the plaintiff's exhibit, which was a redacted copy of the same record at issue. *See Public Citizen I*, 975 F. Supp. 2d at 92, 92 n.10. Nevertheless, the Court attached a copy of the document about which the plaintiff was confused to its Order on the plaintiff's motion for reconsideration. *See* Mem. & Order Appendix, ECF No. 44-1.

B. The Remaining Documents In Dispute

In its Order in *Public Citizen I*, the Court required the parties jointly to file a status report that, *inter alia*, "sets forth a list of the records remaining in dispute . . . and identifying 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." Order at 3. This requirement was a direct response to the vague, generalized, and inadequate statements made by the parties in their first round of summary judgment briefing regarding what records were in dispute. Indeed, in *Public Citizen I*, the Court admonished the parties that 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." 975 F. Supp. 2d at 93.[5]

Prior to filing the list of remaining disputed documents, the defendant released "some documents for which this Court had denied all parties' earlier motions for summary judgment," removing those documents from dispute.[6] Pl.'s Mem. Supp. Pl.'s 2d Mot. ("Pl.'s 2d Mem.") at 2, ECF No. 53. The parties timely filed the list of the remaining disputed records, *see generally* Status of Records Remaining in Dispute ("Rec. Status"), ECF No. 46, and renewed their cross-motions for summary judgment. In the subsequent renewed round of summary judgment

[5] One of the remaining categories of disputed records, namely, the actions taken regarding Ineligible Persons, provides an example of this lack of clarity. None of the parties identified precisely the section or sections of the defendant-intervenors' CIAs that required submission of the disputed records and, instead, directed the Court to pages of the CIAs, each of which listed multiple types of submissions the defendant-intervenors were required to make as part of their Annual Reports. Due to the generalized page references made by the parties, the Court did not address a subset of records required for submission under one clause of one section of the CIAs. The plaintiff did not raise this omission in its Motion for Reconsideration, either. *See generally* Pl.'s Mot. Rec.

[6] The defendant and defendant-intervenors maintain that their voluntary release of certain responsive documents "should not be construed as a concession or waiver of any kind." Status of Records Remaining in Dispute ("Rec. Status") at 3 n.5, ECF No. 46.

briefing,[7] the defendant "introduced new evidence to support the adequacy of its search for the missing Pfizer responses to and corrective action plans based on IRO reports," in other words, the Pfizer § V.B.6 documents. *See* Pl.'s 2d Mem. at 2. The new information regarding the "missing" Pfizer responses is contained in the Second Declaration of Robin R. Brooks, the FOIA Officer for the HHS OIG ("2d Brooks Decl."), ECF No. 51-1. The defendant's declarant clearly and succinctly explains the links between the records listed in the original Pfizer *Vaughn* Index, ECF No. 18, the exemptions applied, and the presence or absence of any additional responsive records pertaining to the "missing Pfizer responses." *See* 2d Brooks Decl. ¶¶ 5–18. On the basis of this new evidence, the plaintiff "is now satisfied that the missing Pfizer documents were either included in records accounted for in the first Pfizer *Vaughn* index . . . or were never submitted to HHS." *See* Pl.'s 2d Mem. at 2. Thus, the plaintiff is no longer challenging the adequacy of the defendant's search for responsive documents. *See id.* Consequently, the defendant and defendant-intervenors are granted summary judgment as moot regarding (1) the allegedly missing Pfizer documents required to be submitted pursuant to § V.B.6 of the Pfizer CIA and (2) those documents previously in dispute but now either no longer in dispute or released voluntarily by the defendant.[8]

In light of the confusion stemming from deficiencies in the initial round of summary judgment briefing, the voluntary release of certain records by the defendant and defendant-

[7] In lieu of filing a detailed opposition to the plaintiff's Renewed Motion for Summary Judgment, the defendant has adopted the "factual and legal arguments" made by the defendant-intervenors, since the adequacy of the defendant's search for the allegedly missing Pfizer § V.B.6 documents is no longer contested. *See* Def.'s Opp'n Pl.'s 2d Mot. & Def.'s Reply Supp. Def.'s 2d Mot. ("Def.'s Opp'n") at 1, ECF No. 60.

[8] The documents previously listed as in dispute on the initial Joint Status Report but no longer in dispute are: Pfizer Bates Nos. OIG 000123–000124; OIG 000126; OIG 000128; OIG 000129–000131; OIG 000137–000138; OIG 000139; OIG 000140; OIG 000141; OIG 001921–1923; OIG 001925; OIG 001946–001947; OIG 001949; OIG 001951; OIG 001953; OIG 003827–003829; OIG 003831; OIG 003846–003847; OIG 003849; OIG 003851; OIG 003853; OIG 005967–005969; OIG 005971; OIG 005985–005986; OIG 005988; OIG 005990; OIG 005992; OIG 007971–007975; OIG 007991–007992; OIG 007994; OIG 007996; OIG 007998; Purdue Bates Nos. OIG 000430–000436; OIG 000473–000500; OIG 001082–001088. *See* Rec. Status at 3–4; Parties' Update to Joint List of Records Remaining in Dispute/2d Supplemental Purdue *Vaughn* Index ("Suppl. Rec. Status") Appendix B at B-1, ECF No. 64.

intervenors, and the plaintiff's decision to cease pursuing other records, the Court ordered the parties to file a Supplemental Joint Status Report identifying the specific records the plaintiff no longer disputes were properly withheld and the records that remain in dispute.[9] *See* Minute Order, August 12, 2014; Parties' Update to Joint List of Records Remaining in Dispute/2d Supplemental Purdue *Vaughn* Index ("Suppl. Rec. Status"), ECF No. 64.

> The records that remain at issue thus fall into four categories:
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> (1) Reportable Event summaries required by § V.B.12 of the Pfizer [CIA] and § V.B.9 of the Purdue CIA;
> (2) Disclosure Log summaries required by § V.B.14 of the Pfizer CIA and § V.B.10 of the Purdue CIA;
> (3) information regarding actions taken in response to screening and removal obligations for Ineligible Persons required by § V.B.11 of the Pfizer CIA and § V.B.12 of the Purdue CIA; and
> (4) Pfizer documents reflecting the content of detailing sessions that reveal off-label promotion required by § V.B.17 of the Pfizer CIA.[10]

Pl.'s 2d Mot. at 1. Of these four categories, categories one and two, referring to Reportable Event summaries and Disclosure Log summaries, respectively, involve both defendant-intervenors. *See id.* Purdue challenges whether the third category, regarding actions taken toward Ineligible Persons, pertains to it at all. *See* Part III.C *infra*; *see also* Third Decl. of Julie A. Murray, Counsel for Plaintiff ("3d Murray Decl.") Attachs. A–B (reproducing redacted documents already released by the defendant pertaining to Purdue's Ineligible Persons information). The fourth category regarding the "content of detailing sessions" applies to Pfizer only.

[9] Indeed, defendant-intervenor Purdue recognized the confusion and apparently "requested that HHS file a revised Supplemental Vaughn Index incorporating the two additional documents Plaintiff has put at issue here," Purdue's Reply Supp. Purdue's 2d. Mot ("Purdue's 2d Reply") at 6 n.4, ECF No. 58, though no such supplemental *Vaughn* index was filed.

[10] Pfizer and Purdue's CIAs were filed by the defendant along with its first Motion for Summary Judgment, ECF No. 22. *See* Decl. of Edward Nowicki, Pfizer Vice President & Assistant General Counsel, Deputy Compliance Officer – Global Programs ("1st Nowicki Decl.") Ex. 3, ECF No. 22-1 (reproducing Pfizer CIA); Def.'s 1st Mot. Summ. J. ("Def.'s 1st Mot.") Ex. 6, ECF No. 22-2 (reproducing Purdue CIA).

Relevant to the instant motions, in *Public Citizen I* the Court found that (1) insufficient information was provided by the parties to determine whether the Reportable Event summaries[11] and the Disclosure Log summaries[12] were commercial in nature, 975 F. Supp. 2d at 118; (2) insufficient information was provided by the parties to determine whether the "detailing sessions" documents referred to in § V.B.17 of the Pfizer CIA were "confidential" in nature, *id.*; and (3) the Court did not rule on whether information regarding "the actions taken by [the defendant-intervenors] in response to the screening and removal obligations set forth in" their CIAs regarding Ineligible Persons[13] were properly withheld, *id.*

II. LEGAL STANDARD

A. Summary Judgment In FOIA Cases

"[T]he vast majority of FOIA cases can be resolved on summary judgment." *Brayton v. Office of the U.S. Trade Rep.*, 641 F.3d 521, 527 (D.C. Cir. 2011). When an agency's response to a FOIA request is to withhold responsive records, either in whole or in part, the agency "bears the burden of proving the applicability of claimed exemptions." *Am. Civil Liberties Union v. U.S. Dep't of Def.*, 628 F.3d 612, 619 (D.C. Cir. 2011). The government may sustain its burden of establishing that requested records were appropriately withheld through the submission of

[11] "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.'" *Public Citizen I*, 975 F. Supp. 2d at 92 n.5 (citation omitted).

[12] "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.' 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.'" *Public Citizen I*, 975 F. Supp. 2d at 92 n.6 (internal citations omitted).

[13] "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.'" *Public Citizen I*, 975 F. Supp. 2d at 92 n. 7.

declarations detailing the reason that a FOIA exemption applies, along with an index, as necessary, describing the materials withheld. *See, e.g.*, *id.* at 619. "If an agency's affidavit describes the justifications for withholding the information with specific detail, demonstrates that the information withheld logically falls within the claimed exemption, and is not contradicted by contrary evidence in the record or by evidence of the agency's bad faith, then summary judgment is warranted on the basis of the affidavit alone." *Id.*

B. FOIA's Exemption 4

The dispute over whether the remaining documents at issue may be withheld as exempt under the FOIA's Exemption 4 rests on whether those documents are "commercial" and "confidential." *See Jurewicz v. U.S. Dep't of Agric.*, 741 F.3d 1326, 1331 (D.C. Cir. 2014). The Court reviewed extensively the precedent surrounding these terms in *Public Citizen I*, 975 F. Supp. 2d at 99–103, 110–15, but a brief review of the FOIA's Exemption 4 and the key terms "commercial" and "confidential" is helpful in resolving the instant motions. Records must be both "commercial" and "confidential" in order for them to be exempt from disclosure under Exemption 4.[14] Neither term is defined in the FOIA, but the D.C. Circuit has "consistently held that [this] term . . . in [Exemption 4] should be given [its] ordinary meaning[]." *Pub. Citizen Health Research Grp. v. U.S. Food & Drug Admin.*, 704 F.2d 1280, 1290 (D.C. Cir. 1983). "[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 26, 38 (D.C. Cir. 2002) (internal quotation marks and citation omitted), or are records in which the provider has "a

[14] Exemption 4 also exempts documents that reveal "trade secrets" and "financial" information. *See* 5 U.S.C. § 552(b)(4). The defendant and the defendant-intervenors do not assert that the documents remaining in dispute fall into either of those categories. *See generally*, Def.'s Mem. Supp. Def.'s 2d Mot. ("Def.'s 2d Mem."), ECF No. 51; Pfizer's Mem. Supp. Pfizer's 2d Mot. ("Pfizer's 2d Mem."), ECF No. 47-1; Purdue's Mem. Supp. Purdue's 2d Mot. ("Purdue's 2d Mem."), ECF No. 50. There is no dispute that all of the documents came from a "person," as required under Exemption 4, leaving only the "commercial" and "confidential" prongs of the analysis in dispute. *See Public Citizen I*, 975 F. Supp. 2d at 98.

commercial interest." *Baker & Hostetler LLP v. U.S. Dep't of Commerce*, 473 F.3d 312, 319 (D.C. Cir. 2006).

In addition to being "commercial," for Exemption 4 to apply, the records must also be "privileged[15] or confidential." *See* 5 U.S.C. § 552(b)(4); *Jurewicz*, 741 F.3d at 1331. A two prong test is used to determine whether information involuntarily submitted to a Federal agency is "confidential" for FOIA purposes: whether release of the records would (1) impair the Government's ability to obtain necessary information in the future; or (2) 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*"); *accord Jurewicz v. U.S. Dep't of Agric.*, 741 F.3d 1326, 1331 (D.C. Cir. 2014). Releasing the documents involuntarily submitted documents in dispute in this matter has already been found not to "impair the Government's ability to obtain necessary information in the future." *See Public Citizen I*, 975 F. Supp. 2d at 111–13. Thus, only the second prong of the *National Parks* test remains at issue in the instant matter. *Id*. "Substantial competitive harm" is "limited to harm flowing from the affirmative use of proprietary information *by competitors*." *Pub. Citizen Health Research Grp.*, 704 F.2d at 1291, 1291 n.30 (emphasis in the original); *see Jurewicz*, 741 F.3d at 1331 (same).

III. DISCUSSION

As noted, the plaintiff continues to contest the withholding of only four categories of responsive records. The parties' arguments regarding the Reportable Event summaries and the Disclosure Log summaries generally overlap and are addressed together in Part III.A *infra*. The

[15] Although Pfizer pressed the argument that all of the documents submitted pursuant to the CIAs were subject to the "self-evaluation and self-critical reports" privilege, this Court rejected that argument in *Public Citizen I*, 975 F. Supp. 2d at 111 n.19, and Pfizer does not reassert it here. *See generally* Pfizer's 2d Mem.

documents relating to the Pfizer "detailing sessions"[16] are addressed in Part III.B *infra*, and the documents pertaining to the actions taken by the defendant-intervenors in response to screening for Ineligible Persons are addressed in Part III.C *infra*.

A. Reportable Event Summaries And Disclosure Log Summaries

In the cross-motions for summary judgment that were resolved in *Public Citizen I*, the parties failed to provide sufficient information to determine whether the summaries of the defendant-intervenors' Reportable Events and Disclosure Logs were "commercial" within the meaning of Exemption 4, rendering any discussion of whether these documents were "confidential" premature. *See Public Citizen I*, 975 F. Supp. 2d at 103–04. The parties have remedied the deficiencies here, as explained below.

1. *The Reportable Event Summaries And Disclosure Log Summaries Are "Commercial"*

The plaintiff offers no arguments as to why the Reportable Event summaries and Disclosure Log summaries should not be considered "commercial" within the meaning of Exemption 4. *See generally* Pl.'s 2d Mem. Consequently, the defendant-intervenors' arguments as to the commercial nature of the documents may be accepted as conceded. *See Jones v. Horne*, 634 F.3d 588, 603 (D.C. Cir. 2011) (upholding District Court's granting of defendant's motion to dismiss when plaintiff failed to respond to motion); *United States v. Kellogg Brown & Root Servs., Inc.*, 856 F. Supp. 2d 176, 185 (D.D.C. 2012) (holding argument in dispositive motion left unaddressed by opposing party as conceded); *Buggs v. Powell*, 293 F. Supp. 2d 135, 141 (D.D.C. 2003) (same). Nevertheless, the Court briefly summarizes the defendant-intervenors'

[16] "'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. Pfizer was required to make findings based on this review and take any corrective action necessary. The findings and corrective actions were required to be submitted to the OIG. Purdue's CIA did not contain this requirement.'" *Public Citizen I*, 975 F. Supp. 2d at 92 n.8 (internal citations omitted).

rationale as it also helps illuminate the basis for the defendant-intervenors' arguments that the disputed records are "confidential."

Purdue's declarant avers that "[b]y their very nature, these Reportable Event Summaries and Disclosure Log Summaries describe and directly relate to Purdue's business transactions and therefore deal with commercial matters." Suppl. Decl. of Bert Weinstein, Purdue Vice President, Corporate Compliance ("1st Suppl. Weinstein Decl.") ¶ 4, ECF No. 50-2. This is because the "Reportable Event Summaries describe in detail basic business operations and techniques at Purdue, in particular Purdue's internal training exercises and the conduct of individuals engaged in promotional activities involving Purdue products." *Id.* ¶ 5. Likewise, Pfizer's declarant states that "[a]ll 'Reportable Event' letters and summaries relate to Pfizer's sales and marketing activities, such as its speaker programs, detailing sessions, and sampling plans." 2d Decl. of Edward Nowicki, Pfizer Vice President and Asst. General Counsel, Chief Compliance Counsel—Global Programs, R&D/Medical & PGS ("2d Nowicki Decl.") ¶ 15, ECF No. 47-2.

Such activities are "instrumental" to defendant-intervenors' methods for selling their products. A company has a clear commercial interest in its "basic business operations and techniques," 1st Suppl. Weinstein Decl. ¶ 5, and its "sales and marketing activities," 2d Nowicki Decl. ¶15. Thus, Purdue and Pfizer have shown adequately that the Reportable Event summaries are "commercial" within the meaning of Exemption 4.

As for the Disclosure Log summaries, the defendant-intervenors' declarants make similarly adequate proffers as to what is contained in the summaries to illustrate why they are appropriately considered "commercial." For instance, Purdue's declarant states that "[t]he Disclosure Log Summaries . . . constitute 'commercial' information in that they identify and describe interactions with prescribers, consumers, and other customers of Purdue's various

healthcare products, all vital business functions for Purdue." 1st Suppl. Weinstein Decl. ¶ 6. Moreover, "the Disclosure Log Summaries include details of identification and techniques related to Purdue's product promotion, its Code of Business Ethics, and compliance with industry guidelines in general." *Id.* ¶ 7. Pfizer's declarant similarly avers that its Disclosure Log summaries contain information "about how Pfizer compensates and disciplines its employees," 2d Nowicki Decl. ¶ 39, and "details about internal investigations of the matters reported, which demonstrates how Pfizer conducts its compliance program," *id.* ¶ 38, along with activities such as "promotional statements, call planning activities, sample distribution, travel and expense, and other interactions between sales representatives (or other Pfizer employees) and doctors, health care providers, and customers," *id.* ¶ 35.

Both declarants make clear that the information contained within the Disclosure Log Summaries is sufficiently "instrumental" to the companies' operations to qualify as "commercial" within the meaning of Exemption 4. Both declarants state that the documents in question contain information about interactions between the companies' salespeople and customers, how the companies promote their products, and the way the companies implement their compliance programs. *See* 1st Suppl. Weinstein Decl. ¶¶ 6–7; 2d Nowicki Decl. ¶¶ 35–39. Consequently, the Disclosure Log summaries are "commercial" information.

2. *The Reportable Event Summaries And Disclosure Log Summaries Are "Confidential"*

The parties use the bulk of their briefing to address whether the Reportable Event and Disclosure Log summaries are "confidential," i.e., whether the release of such documents would cause "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). Purdue and

Pfizer's declarants make a strong case as to why the information contained in these documents could be used to cause substantial commercial harm.

For instance, Pfizer's declarant describes how a competitor could use the Reportable Event summaries to "learn how Pfizer promotes its products through its marketing programs," and "its related compliance controls around these programs," which would allow that competitor to "copy Pfizer's approach." 2d Nowicki Decl. ¶ 26. Similarly, Purdue's declarant explains that "Purdue has made a significant investment of time and monies over the course of the CIA to interpret the requirements of a CIA and to operationalize its requirements within its own processes and practices." 2d Suppl. Decl. of Bert Weinstein, Purdue Vice President, Corporate Compliance ("2d Suppl. Weinstein Decl.") ¶ 5, ECF No. 58-1. The declarant goes on to state that "[t]he details . . . would have substantial commercial value to Purdue's competitors, whether or not they are under a CIA, as evidence of emerging practices within the industry and the types of conduct where other companies have drawn the lines, without the competitor having to make the same investment to determine what might or might not constitute illegal practices." *Id.*

The plaintiff responds to these declarations, and the declarations pertaining to the other two disputed categories of records, by rehashing an argument already rejected in *Public Citizen I* and the denial of the plaintiff's motion for reconsideration: that, because some of the information contained in the records at issue may pertain to illegal activity, the records cannot be withheld pursuant to Exemption 4. The plaintiff's arguments on this score continue to reflect a fundamental misunderstanding of the purpose behind the FOIA's Exemption 4.

As noted in *Public Citizen I*, "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." 975 F. Supp. 2d at 102. Whether

records potentially exempt from disclosure under Exemption 4 may lead to possible legal conclusions about the lawfulness of the activities described therein, has little bearing on whether the activities described are "commercial" or "confidential." Rather, the applicability of Exemption 4 rests on what information can be gleaned from the disputed records about the company's commercial enterprises and whether that information can be used affirmatively by the company's competitors. *See Jurewicz*, 741 F.3d at 1331. Even if the activities described in such records pertain to what may be deemed illegal conduct, the context of and facts about the activity revealed in the records may retain their commercial character, in terms of revealing closely held information about the company's operations and structure that would be valuable to competitors. Thus, the Court, again, rejects the plaintiff's argument that when disputed records reflect facts that may lead to the conclusion that an unlawful act occurred, those records are stripped of eligibility for Exemption 4 withholding.

The plaintiff's argument that there is no "competitive market for information about suspected or confirmed unlawful policies and practices," Pl.'s 2d Mem. at 4, is predicated on an overly simplistic view of the concerns and practices of competitors in a highly regulated industry such as pharmaceuticals. As an example, the plaintiff argues that "the operations described in Reportable Event summaries are in part going to be those a reasonable person would consider a probable violation of criminal, civil, or administrative laws." Pl.'s 2d Mem. at 6. The plaintiff conclusorily states that "[a]ll companies are aware of their legal obligations and the steps they must take to comply." *Id.* While the plaintiff's argument may be true of industries that operate with few regulatory constraints, the pharmaceutical industry operates under a unique set of restraints, not the least of which being that the companies are prohibited by law from selling all of their goods directly to consumers. *See Christopher v. SmithKline Beecham Corp.*, 635 F.3d

383, 396 (9th Cir. 2011) (remarking that pharmaceutical industry is "heavily regulated" and that "pharmaceutical manufacturers . . . have structured their 90,000-person sales force and their marketing tactics to accommodate this unique environment.").

In the context of this "unique environment," *id.*, Purdue's declarant explains the precise way in which Purdue's competitors could use information pertaining to its compliance policies:

> The analysis and application of the relevant law consumes significant legal and compliance resources for a pharmaceutical company like Purdue. Purdue relies in part on external legal, consulting, and other resources for benchmarking its own activities against others in the industry and to assist it in making decisions in circumstances where the line between lawfulness and unlawfulness is not clearly drawn. 2d Suppl. Weinstein Decl. ¶ 4.

The information contained in the Reportable Event and Disclosure Log summaries, according to the declarants, provides competitors with two valuable pieces of information: what Pfizer and Purdue have determined is a legally and, presumably, profitable, compliant manner of operating and what these companies have determined is illegal, particularly where "the line between lawfulness and unlawfulness is not clearly drawn." *See id*. As Pfizer's declarant explains, "Pfizer's Disclosure Program is one aspect of [its] compliance program," and its release would cause Pfizer to "lose its competitive advantage if a competitor obtained details of Pfizer's program at little or no cost." 2d Nowicki Decl. ¶ 43. In addition to the "substantial time and money," *id.*, the defendant-intervenors invest in their compliance programs, the activities described in the summaries and the reactions taken in response to them also represent a savings in exposure to risk. *See id.* ¶ 4 (noting that "mitigating risk through [its] compliance program gives [Pfizer] a competitive advantage").[17] Contrary to the plaintiff's assertions, the declarants

[17] Pfizer's declarant states that the release of the compensation and discipline information in these records could also be used by a competitor to poach disgruntled employees away from Pfizer. *See* 2d Nowicki Decl. ¶¶ 39–40; Pfizer's 2d Mem. at 14. This potential for competitive harm is unsupported and speculative, but it is unnecessary to determine the ultimate accuracy of this contention, since the defendant-intervenors have provided ample evidence otherwise to meet their burden in justifying withholding the disputed records under Exemption 4.

have successfully demonstrated the value to competitors contained in the Disclosure Logs and Reportable Event Summaries: they are, in a sense, a free roadmap as to what works in pharmaceutical marketing without violating the legal framework of regulatory enforcement and laws that govern the industry, and what activities to avoid, and release of this roadmap would allow competitors to avoid incurring the experiential or monitoring costs Pfizer and Purdue did in gaining the information.

The defendant-intervenors' internal treatment of these records bears out this conclusion. Pfizer and Purdue's declarants state that their companies maintain tight internal controls on these records and only a few individuals have access to them. *See* 1st Suppl. Weinstein Decl. ¶ 9 ("Purdue diligently ensures that information such as that contained in the Reportable Event Summaries and Disclosure Log Summaries is maintained securely and not disseminated beyond those within the company who need access."); 2d Nowicki Decl. ¶ 41 ("Pfizer . . . maintains the confidentiality of the Disclosure Log even within the Company inasmuch as revealing the content of the information could cause a chilling effect and would undermine its compliance program"). These internal controls are not ultimately dispositive as to whether the disputed records are "confidential" within the meaning of Exemption 4, but they do corroborate the defendant-intervenors' assertions that their release could result in competitive harm, notwithstanding the plaintiff's arguments that a loss of anonymity and internal confidentiality controls would have no effect on—or could potentially increase reporting of—allegedly unlawful activity. *See, e.g.*, Pl.'s Reply Supp. Pl.'s 2d Mot. ("Pl.'s 2d Reply") at 4–6, ECF No. 62.

The plaintiffs' other contentions regarding the confidentiality of the summaries are on more sound footing, but they are ultimately not enough to overcome the obvious competitive harm that would result from the release of the summaries as described above. The plaintiff

correctly points out that merely because the defendant-intervenors "marked [the Reportable Event summaries] as 'FOIA confidential' and 'the government obligated itself in good faith not to disclose documents or information received pursuant to the CIA,'" Pfizer's Mem. Supp. Pfizer's 2d Mot. ("Pfizer's 2d Mem.") at 8, ECF No. 47-1 (quoting *Hersh & Hersh v. U.S. Dep't of Health and Human Servs.*, No. 06-4234, 2008 WL 901539, at *7 (N.D. Cal. March 31, 2008)), does not mean these documents were properly withheld under the FOIA. The Court has already considered and rejected these bases for withholding. *See Public Citizen I*, 975 F. Supp. 2d at 90; *id.* at 90 n.3; *id.* at 113.

Similarly, the plaintiff is correct that the alleged "chilling effect" that disclosure of these documents might have on the defendant-intervenors' employees' willingness to come forward with possible violations does not meet the definition of "competitive harm" for the purposes of Exemption 4. *See* Pl.'s 2d Mem. at 7–8. Since the cognizable competitive harm under Exemption 4 is limited to that which "flow[s] 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), it is highly unlikely that any internal chilling of potential whistleblowers employed by Pfizer or Purdue could be used affirmatively by their competitors to wreak substantial harm.

* * *

While the plaintiff is correct to discount the merits of several of the defendant-intervenors' arguments regarding the competitive harm posed by the release of the Disclosure Log summaries and the Reportable Event summaries, the plaintiff is unable to overcome the substantial competitive advantage to be gained by the defendant-intervenors' competitors to be able to learn from Pfizer and Purdue's mistakes at little or no cost in capital or exposure to risk. Since the defendant-intervenors have shown there is no material fact in dispute regarding the

commercial and confidential nature of the Reportable Event summaries and Disclosure Log summaries, the Court finds that these two sets of documents are exempt from disclosure under the FOIA's Exemption 4.[18]

B. Detailing Sessions

The Court in *Public Citizen I* already determined that the "'underlying records reflecting the content of the detailing sessions between [Health Care Providers] and Covered persons' as required in § V.B.17 of the Pfizer CIA" were "commercial" within the meaning of Exemption 4. *Public Citizen I*, 975 F. Supp. 2d at 118.[19] Thus, the parties' dispute over this set of records relates only to whether the information contained in the "detailing sessions" is "confidential." Pfizer's declarants adequately explain why these records are confidential.

First, Pfizer's declarant states that "'[d]etailing sessions' are sales presentations, either by face-to-face meetings or through electronic, interactive media, by Pfizer's employees (usually sales representatives) to health care providers." Decl. of Bill Nealon, Pfizer Lead, Business Analytics & Insights CD/BD Pain/Neuroscience/Rare Diseases ("Nealon Decl.") ¶ 3, ECF No. 47-4. They "are intended to educate health care providers about Pfizer's products, including giving details about their potential use, the conditions for which they can be prescribed, side-effects, and to answer any questions." *Id.* They are primarily "marketing" sessions, and "Pfizer . . . regularly assess[es whether] detailing sessions are [effective] in educating health care providers and promoting Pfizer's products." *Id.* ¶ 5.

To assess these sessions' effectiveness, Pfizer "hire[s] a market research firm to survey health care providers," asking the provider "to answer questions that solicit 'verbatim' recall of

[18] This ruling covers the documents with the following Bates Number ranges (all of which begin with the prefix OIG-): Pfizer Documents 000088–000101; 001887–001893; 003752–003759; 005885–005891; 007911–007915; 000112–000120; 001906–001919; 003772–003825; 005904–005965; Purdue Documents 000019–000020; 000398–000414; 000518–000520; 001060–001076. *See* Suppl. Rec. Status Appendix A at A-1 to A-4, ECF No. 64.
[19] "Purdue's CIA did not contain this requirement." *Public Citizen I*, 975 F. Supp. 2d at 92 n.8.

the detailing session." *Id.* ¶¶ 6–7. These surveys are costly[20] and "tend[] to capture a provider's major recollections—e.g. a disease or treatment option—that the provider retained in the mind after the detailing session." *Id.* ¶ 8. These "verbatims" were "intended as a business tool [and] it was hoped that verbatims could be carefully reviewed for suggestions of possible improper promotion." 2d Nowicki Decl. ¶ 55. Moreover, despite the fact that this information is now several years old, Pfizer notes that "[m]arketing strategies used a few years ago (even on products Pfizer no longer owns) inform marketing strategies Pfizer uses today to market these and other Pfizer products." Decl. of Laura Chenoweth, Pfizer Senior Vice President and Assoc. General Counsel, Chief Counsel for Global Established Pharma business ("Chenoweth Decl."), ¶ 9, ECF No. 47-3.

Verbatims are not, despite their name, a record of "the actual conversation of a detailing session—instead it captures a health care provider's subsequent recollection and dominant impressions." 2d Nowicki Decl. ¶ 56. As a result, "one cannot ascertain from a verbatim whether actual improper promotion occurred." *Id.* Instead, verbatims "may only suggest a possibility of improper promotion," *id.* ¶ 57, which must then be "followed up and investigated to determine whether there is any direct and substantial evidence of improper promotion," *id.* ¶ 58.

Pfizer offers three reasons why this information is "confidential" within the meaning of Exemption 4, or, in other words, how its competitors could use the information contained in the verbatims against it: (1) "Pfizer pays a substantial fee for the verbatims;" (2) the content of the verbatims reflects precisely targeted customers' recall of the company's marketing approach; and (3) "Pfizer is contractually bound to keep the [information] confidential." *See* Pfizer's 2d Mem.

[20] In 2013, Pfizer spent "a total of $200,000 [on] . . . verbatim surveys for compliance purposes." Nealon Decl. ¶ 10.

at 18–19.[21] The first and second justifications are sufficient to show that the verbatims are "confidential" within the meaning of Exemption 4. As Pfizer's declarant explains:

> If a competitor could get a verbatim at essentially no cost, Pfizer would be put at a competitive disadvantage. Such a competitor could use the verbatim to understand the strengths and weaknesses of Pfizer's marketing strategies at little cost to itself, information Pfizer paid to acquire. A competitor could then copy marketing techniques that are working or exploit weaknesses in Pfizer's marketing efforts with its own marketing or promotion efforts. Nealon Decl. ¶ 12.

As this detailed explanation indicates, a competitor could use the content of the verbatims affirmatively to wreak competitive harm on Pfizer by acquiring records that, according to Pfizer and undisputed by the plaintiff, show what is and is not working in companies' marketing from the perspective of its customers. *See id*. This kind of harm was contemplated by the D.C. Circuit in *Worthington Compressors, Inc. v. Costle*, 662 F.2d 45, 48 (D.C. Cir. 1981). In that case, one manufacturer of air compressors sought another manufacturer's "production verification and quality control reports" that were submitted to the Environmental Protection Agency. *Id.* The manufacturer whose reports were being requested filed a reverse-FOIA action to prevent their disclosure, claiming the reports were protected by Exemption 4. *Id.* at 49. In applying the *National Parks* test, the D.C. Circuit noted that when commercial information "is freely or cheaply available from other sources . . . it can hardly be called confidential and agency

[21] Pfizer also rather disingenuously asserts that because the "records reflecting the content of the detailing sessions" do not, in and of themselves, show improper promotion efforts, they do not "directly address, discuss, or identify off-label promotion." Pfizer's 2d Mem. at 18. Therefore, according to Pfizer, since the plaintiff is only seeking records that "relate to off-label promotion," Pl.'s 2d Mem. at 14, and the content of the detailing sessions can only trigger an investigation into the possibility of off-label promotion, these records fall outside the plaintiff's request and should not be released since they are non-responsive to the plaintiff's request, *see* Pfizer's 2d Mem. at 18. The plaintiff's initial FOIA request sought complete copies of "all annual reports submitted to [HHS] OIG by Pfizer, Inc. pursuant to the May 2004 Corporate Integrity Agreement between OIG and Pfizer." Decl. of Robin R. Brooks, FOIA Officer, HHS OIG, Apr. 6, 2012 ("1st Brooks Decl.") Ex. A (FOIA Request from Public Citizen, November 12, 2009) at 1, ECF No. 22-1. Thus, the records are clearly responsive to the initial request, since no party disputes the records were "submitted to OIG by Pfizer" pursuant to its CIA. The plaintiff's subsequent limitation of the documents in dispute to "Pfizer documents reflecting the content of detailing sessions that reveal off-label promotion *required by § V.B.17 of the Pfizer CIA*," Pl.'s 2d Mot. at 1 (emphasis added), still encompasses all detailing session content submitted as part of Pfizer's obligation to the defendant, regardless of whether the content itself actually "reveal[s] off-label promotion," *id.*

disclosure is unlikely to cause competitive harm." *Id.* at 51. Nevertheless, when "competitors can acquire the information only at considerable cost, agency disclosure may well benefit the competitors at the expense of the submitter." *Id.*

The D.C. Circuit's holding is directly applicable here. Pfizer obtains these verbatims at considerable cost, *see* Nealon Decl. ¶ 10, and is then required to turn over portions of them to comply with its CIA, *see* Pfizer CIA § V.B.17. The information itself is valuable to a competitor, since it would reveal "marketing techniques that are working," for Pfizer and allow the competitor to "exploit weaknesses in Pfizer's marketing efforts with its own marketing or promotion efforts," Nealon Decl. ¶12. This is a classic example of the competitive harm with which the *Worthington* court was concerned, since "competition in business turns on the relative costs and opportunities faced by members of the same industry" and "there is a potential windfall for competitors to whom valuable information is released under FOIA." *Worthington Compressors, Inc.*, 662 F.2d at 51.

The plaintiff's arguments to the contrary are unavailing. While the plaintiff is correct that the information in the verbatims is known by both the health care provider who was surveyed and the market research firm, Pl.'s 2d Reply at 13, it is not "freely or cheaply available from [those] sources," *Worthington Compressors, Inc.*, 662 F.2d at 51. A competitor wishing to obtain this information would, absent its release through the FOIA, have to pay a market research firm to conduct a similar survey, incurring the same expenses Pfizer incurred in the first instance. A competitor's ability to obtain the information at virtually no cost would cause competitive harm to Pfizer, since it could be used affirmatively by those competitors to challenge

Pfizer's place in the market and exploit any vulnerability revealed through the verbatims' content.[22]

Consequently, Pfizer has shown the "'underlying records reflecting the content of the detailing sessions between [Health Care Providers] and Covered persons' as required in § V.B.17 of the Pfizer CIA" are confidential under Exemption 4 and that it is entitled to summary judgment on this set of documents.[23]

C. Ineligible Person Responses

The defendant-intervenors' CIAs required them to institute a "screening program" to identify and exclude "Ineligible Persons" from any involvement with Federal health care programs. *See Public Citizen I*, 975 F. Supp. 2d at 104–05. The defendant-intervenors also were required to notify the defendant of "'any changes to the process by which [the company] fulfills' the Ineligible Persons requirement," and provide the "name, title, and responsibilities of any person who is determined to be an Ineligible Person." *Id.* at 105 (internal citations omitted; alteration in original). The plaintiff has made clear in this round of summary judgment briefing that a third category of information is also required to be reported regarding Ineligible Persons: "[T]he actions taken by [the company] in response to the CIA's Ineligible Person screening and removal obligations." Pfizer's 2d Mem. at 2.

In *Public Citizen I*, the Court found that the information pertaining to "any changes to the process" of Ineligible Person screening was both commercial and confidential, and awarded summary judgment to the defendant and defendant-intervenors. *See Public Citizen I*, 975 F.

[22] The parties dispute whether the actual contract between Pfizer and its market research firm must be submitted to prove, pursuant to the best evidence rule, whether Pfizer is required to keep the verbatims confidential. *See* Pl.'s 2d Mem. at 14–15; Pfizer's Opp'n Pl.'s 2d Mot. ("Pfizer's 2d Opp'n") at 11–12, ECF No. 57; Pl.'s 2d Reply at 14. Since the information at issue is confidential under the *Worthington Compressors, Inc.* rationale, resolution of this dispute is unnecessary.

[23] This ruling applies to the following documents, as identified by their Bates Range numbers (all of which begin with the prefix OIG-):000132–000136; 001927; 001932–001944; 003833; 003838–003844; 005973; 005978–005983; 007979; 007984–007989. *See* Suppl. Rec. Status A-2 to A-3.

Supp. 2d at 115. On the other hand, the Court awarded summary judgment to the plaintiff on the "title and responsibilities of any person who is determined to be an Ineligible Person," since the information in question was not commercial. *See id.* at 105 ("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."). At issue now is whether the third category of information, the actions the companies took in response to the discovery of Ineligible Person(s) ("Responsive Action(s)"), is commercial and confidential.

For substantially the same reasons that the Court found information pertaining to the changes in process the companies used to screen for Ineligible Persons was protected by Exemption 4, this Responsive Action information is similarly protected. First, just as the information about changes in process "involve[d] the process by which the companies make decisions about managing and conducting their business operations," *Public Citizen I*, 975 F. Supp. 2d at 105, so too is the process used by the companies if and when they discover such a person. *See* 2d Nowicki Decl. ¶ 52 ("Disclosure would also reveal how Pfizer implements any changes it makes to the process of identifying and removing Ineligible Persons."). In the same vein, revealing the actions a company took in response to the discovery of an Ineligible Person would "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." *Public Citizen I*, 975 F. Supp. 2d at 115. It is this revelation that could easily lead to substantial competitive harm, as Pfizer's declarant points out. *See* 2d Nowicki Decl. ¶ 54 ("If details about Pfizer's screening system were made public, a competitor could copy Pfizer's system and adopt it for its own use . . . . thus obtain[ing] the benefit of Pfizer's investment without having to incur the cost itself.").

The plaintiff's arguments to the contrary are unpersuasive. The plaintiff again oversimplifies the compliance environment in which pharmaceutical manufacturers work and the value of a robust compliance program to them. According to the plaintiff, "[t]he CIA already describes in great detail the process that Pfizer must use to identify Ineligible Persons and the corrective actions that the company must take." Pl.'s 2d Mem. at 13. While this is true, it is equally true that each company "has made a significant investment of time and monies over the course of the CIA to interpret the requirements of a CIA and to operationalize its requirements within its own processes and practices." 2d Suppl. Weinstein Decl. ¶ 5; *see also* 2d Nowicki Decl. ¶ 54 ("If details about Pfizer's screening system were made public, a competitor could copy Pfizer's system and adopt it for its own use. The competitor would thus obtain the benefit of Pfizer's investment without having to incur the cost itself."). The difference between the bare-bones requirements in the CIAs and the actual operational methods used by the defendant-intervenors' is, according to both companies' declarants, significant and tailored to the individual companies' use. *See id.*[24] There is, therefore, little doubt that a competitor could make use of the information to be gleaned about the defendant-intervenors' compliance programs from the reports of actions taken in response to the discovery of an Ineligible Person as well as the information to be gleaned about the companies' business practices and corporate structures.

The Court finds that the information required to be disclosed to HHS regarding actions taken by the defendant-intervenors in response to the discovery of Ineligible Persons is

[24] The plaintiff's argument that this customization would render such information worthless to the defendant-intervenors' competitors, *see* Pl.'s 2d Mem. at 13; Pl.'s 2d Reply at 12, is equally unpersuasive. The plaintiff relies in part on the declaration this Court noted was of little or no value due to its qualified statements and generally vague nature, *see* Mem. & Order at 5–8 (noting the Rodondi Declaration was rife with qualified "observations" including that "defendant-intervenors' ineligible screening policies 'are likely similar [to] the same actions and processes taken by competing companies'"), and otherwise merely asserts that there is no "competitive market" for information in Pfizer and Purdue's processes that is not contained in their respective CIAs, *see* Pl.'s 2d Reply at 12. This argument is belied by the importance the companies place on their compliance programs, *see* 2d Nowicki Decl. ¶¶ 4–5, 8–11; 2d Suppl. Weinstein Decl. ¶ 4, and the general importance all companies place on best practices in corporate governance and structure.

commercial and confidential,[25] and the defendant-intervenors and defendant are entitled to summary judgment as to this category of documents.[26]

D. Segregability

The Court expressly instructed the defendant and defendant-intervenors regarding segregability in *Public Citizen I*, 975 F. Supp. 2d at 118, stating that "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." The defendant-intervenors nonetheless failed to include in their supplemental declarations any discussion of segregable portions of the documents at issue. *See generally* 2d Nowicki Decl.; 1st Suppl. Weinstein Decl.; 2d Suppl. Weinstein Decl. In reviewing the supplemental *Vaughn* indices, however, the Court is satisfied that any reasonably segregable portions of the records at issue have already been released.

The supplemental *Vaughn* indices reveal that very few documents were withheld in full. *See generally* Pfizer Suppl. *Vaughn* Index, ECF No. 48; Purdue Suppl. *Vaughn* Index, ECF No. 49. Those documents in dispute that were withheld in full are Purdue's two Disclosure Log summaries, Bates Nos. OIG-000398-000414 and OIG-001060-001076; Pfizer's Disclosure Log summary, Bates Nos. OIG-000112-000120; and Pfizer's "Records Reflecting Content of Detailing Sessions," Bates Nos. OIG-000132-000136, OIG-001932-001944, OIG-003838-003849, OIG-003842-003844, OIG-005978-005983, and OIG-007984-007989. Considering the nature of these documents, it is reasonable to surmise that these documents do not contain any

[25] Since this information is exempt from disclosure under Exemption 4, it is unnecessary for the Court to resolve whether Purdue's actions taken in regard to an Ineligible Person *not* discovered by the company's screening process are covered by the plaintiff's request. *See* Pl.'s 2d. Mem. at 11–12.

[26] The documents covered by this ruling are identified by the following Bates Numbers (each of which bears the prefix OIG-); Pfizer Documents 001878–001880; 001882–001885; 003737–003738; 003740–003750; 005883; 007909; Purdue Documents 000023; 0000523. *See* Suppl. Rec. Status at A-1 to A-2, A-4.

reasonable segregable information, since the Disclosure Log summaries and the "verbatims" are entirely exempt from disclosure under Exemption 4. *See supra* Parts III.B and III.C. The Court is therefore satisfied, based on its review of the declarations and the supplemental *Vaughn* indices that all reasonably segregable, non-exempt material has been released by the defendant and the defendant-intervenors.

IV. CONCLUSION

For the foregoing reasons, since there are no disputed issues of material fact remaining, the defendant and defendant-intervenors' renewed motions for summary judgment are granted and the plaintiff's renewed motion for summary judgment is denied.

An appropriate Order accompanies this Memorandum Opinion.

Date: September 5, 2014

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: 2014.09.05 17:47:24 -04'00'

BERYL A. HOWELL
United States District Judge