IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

REPLY IN SUPPORT OF
PLAINTIFF'S RENEWED MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION AND SUMMARY OF ARGUMENT

In their oppositions to Public Citizen's renewed motion for summary judgment, defendants advance a hodgepodge of arguments to contend that the records remaining at issue—Reportable Event summaries, Disclosure Log summaries, documents regarding company actions taken in response to screening and removal obligations for Ineligible Persons, and Pfizer documents reflecting the content of detailing sessions that reveal potential off-label promotion—are exempt from disclosure under Freedom of Information Act (FOIA) Exemption 4. The defendants have failed, however, to meet their burden of demonstrating that these records are "confidential," as required for Exemption 4 to apply. Accordingly, this Court should grant Public Citizen's renewed motion for summary judgment; deny the renewed motions for summary judgment by defendants Department of Health and Human Services (HHS), Pfizer, and Purdue; and order HHS to produce the requested records.

ARGUMENT

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

Under the terms of their Corporate Integrity Agreements (CIAs), Pfizer and Purdue were obligated to provide annually to HHS's Office of Inspector General (OIG) a summary of Reportable Events—defined, with minimal variation, as reports involving a matter "that a reasonable person would consider a probable violation of criminal, civil, or administrative laws" that apply to a federal health care program or to certain Food and Drug Administration (FDA) requirements. Doc. 22-1, Pfizer CIA at 21; Doc. 22-2, Purdue CIA at 19-20. Those Reportable Event summaries were required to identify the underlying events and the status of any corrective or preventative action that the companies took. Pfizer CIA at 25-26; Purdue CIA at 28. Pfizer and Purdue were also obligated to maintain a disclosure program for internal whistleblowers who

believed that company activities with respect to federal health care programs or FDA requirements potentially violated "criminal, civil, or administrative law[s]." Pfizer CIA at 18; Purdue CIA at 16. The companies were then required to conduct an internal review of "sufficiently specific" whistleblower disclosures and—in their annual reports to OIG—to provide Disclosure Log summaries. Pfizer CIA at 19, 26; Purdue CIA at 17, 28.

As explained in Public Citizen's renewed motion for summary judgment, the defendants have failed to demonstrate that release of the Reportable Event summaries and Disclosure Log summaries would likely cause them substantial competitive harm, as required for the documents to be confidential under Exemption 4. Among other things, the companies have not shown that there is a competitive market for information contained in Reportable Event summaries and Disclosure Log summaries, that is, information about non-compliance with the law or techniques that end up in a whistleblower report. Pl.'s 2d S.J. Mem. at 6, 8-9. Although Pfizer and Purdue raise numerous arguments in response, all of them lack merit.

A. Pfizer and Purdue primarily contend that the Reportable Event summaries and Disclosure Log summaries are confidential because the summaries reveal lawful business and promotion strategies alongside probable violations of those strategies, and that the two types of information are inextricably intertwined. *See* Pfizer Opp. at 3, 7; Purdue Opp. at 3. The problem with the companies' argument is two-fold. First, the companies are wrong to assume that disclosure of lawful business or marketing strategies will necessarily cause substantial competitive harm. Accordingly, Purdue misses the point by relying on several paragraphs from the supplemental declaration of Mr. Weinstein that address why the Reportable Event summaries and Disclosure Log summaries are commercial. *See* Purdue Opp. at 3-4 (quoting and citing to

Doc. 50-2, Weinstein Supp. Decl. ¶¶ 4-5, 7). This evidence does not support the conclusion that the release of this information will likely cause Purdue substantial competitive harm.

Second, even if *some* information in the summaries reflects lawful business or promotion strategies and the release of this information could cause substantial competitive harm, the defendants have not demonstrated that *all* information withheld from the summaries falls into this category or that any such information is not segregable from information about unlawful activities that gave rise to the reportable event or disclosure. *See*, *e.g.*, Doc. 47-2, 2d Nowicki Decl. ¶¶ 12-47.

B. Pfizer argues that Exemption 4 applies because the conduct at the center of Reportable Event summaries and Disclosure Log summaries may not even constitute a probable legal violation. Pfizer Opp. at 3. 7. Specifically, with respect to Reportable Event summaries, Pfizer contends that it included in the summaries incidents that do not necessarily rise to the level of a Reportable Event and information about probable violations of Pfizer's internal policies and procedures, not just violations of federal law or regulations. Pfizer Opp. at 3 (citing Doc. 22-1, Nowicki Decl. ¶ 26; Doc. 47-1, 2d Nowicki Decl. ¶ 19). Pfizer's assertions in this regard are at odds with Pfizer's CIA, which limits Reportable Event summaries, in relevant part, to those matters "that a reasonable person would consider a probable violation of criminal, civil, or administrative laws." *See* Pfizer CIA at 21. In any event, Pfizer's declarations and its *Vaughn* index confirm that the Reportable Event summaries contain various types of information required by the CIA and, as noted above, the CIA requires reports of matters that a reasonable person would believe to be a probable legal violation.

Likewise, Pfizer argues that the Disclosure Log summaries may reveal information that is only potentially, not probably, illegal. But even assuming Pfizer's assertion is correct, the

company has not demonstrated that there is a competitive market for techniques that are legally questionable, as opposed to legally objectionable because they likely violate the law. *See* Pl.'s 2d S.J. Mem. at 8-9.

C. Pfizer also contends that the Reportable Event summaries and Disclosure Log summaries are confidential, and thus covered by Exemption 4, because they reflect "findings" regarding, respectively, Pfizer's sales force activities and whistleblower reports. Pfizer Opp. at 4, 7. In Pfizer's view, these "findings" are analogous to the findings regarding off-label promotion that this Court held exempt in its earlier opinion. *Id.* However, simply stating that the summaries reveal "findings"—and comparing the conclusions to findings on a separate issue—cannot stand in for actual evidence that there is a competitive market for the kind of findings that appear in the summaries. Companies make "findings" all the time, including findings based on their business activities, and Pfizer cannot seriously contend that all such "findings" are categorically protected from disclosure under Exemption 4.

D. Pfizer's next argument is that Reportable Event summaries are confidential because their disclosure would allow competitors to copy Pfizer's compliance program. Pfizer Opp. at 4. Pfizer relies for this contention on Dr. Kevin Rodondi's statement that companies highly customize compliance programs; the company thus suggests that the release of information about Pfizer's customization of its compliance program would cause the company competitive harm. *Id.* at 4-5. However, Pfizer has plucked Dr. Rodondi's statement out of context. As a full reading of the declaration makes clear, Dr. Rodondi stated that compliance programs are customized due to the specific needs of a pharmaceutical company, including its organization, its products, and the level of risk with which it is comfortable. Rodondi Decl. ¶ 11. Those factors necessarily will vary from company to company. Dr. Rodondi also explained that

"regular exchanges of information, policies, procedures and recommended programs on compliance are discussed in public forums at professional meetings throughout the year," so information about compliance programs is already well-known. *Id.* ¶ 10. Most important, Dr. Rodondi specifically addressed release of information contained in Reportable Event summaries. He stated that "investigative results or actions taken as a result of" Reportable Events would "not provide any meaningful or actionable information that a competitor would use to alter its sales tactics." *Id.* ¶ 14. Thus, far from supporting Pfizer's contention, Dr. Rodondi's testimony refutes it.

E. In a reprise of its motion for summary judgment, Pfizer contends that the Reportable Event summaries and Disclosure Log summaries are confidential because their disclosure might discourage employees from making reports about unlawful activity. *See* Pfizer Opp. at 5, 7. Pfizer's argument, however, falls short of demonstrating that competitors will affirmatively use the information to Pfizer's disadvantage, as this Court's earlier opinion—relying in part on *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983)—required. Although Pfizer contends that *Public Citizen Health Research Group* merely stated that affirmative use of information by competitors is a sufficient, but not necessary, condition of demonstrating a likelihood of substantial competitive harm under Exemption 4, Pfizer Opp. at 5, Pfizer's new legal theory is precluded by this Court's previous interpretation of *Public Citizen Health Research Group*. *See* Mem. Op. at 46 (concluding that "*only* information that can be affirmatively used by a competitor" can be shielded by Exemption 4 (emphasis added) (citing, inter alia, *Public Citizen Health Research Group*)). As a result, even assuming employees might react to disclosure by reporting incidents less frequently, that dynamic would

not support a finding that disclosure of the summaries would cause Pfizer substantial competitive harm.

Perhaps recognizing this weakness in its argument, Pfizer suggests in passing that its competitors might emphasize publicly "that Pfizer cannot guarantee anonymity" to its employees due to disclosures of Reportable Event summaries. Pfizer Opp. at 6. However, Public Citizen does not seek the names of individuals involved in the summaries. Moreover, Pfizer's speculation falls short of showing the kind of affirmative use of information by competitors that Exemption 4 requires. As this Court's earlier opinion recognized, "'[c]alling customers' attention to unfavorable agency evaluations or unfavorable press'" would not "'amount to an affirmative use of proprietary information by competitors.'" Mem. Op. at 32 (quoting *United Tech. Corp. v. DOD*, 601 F.3d 557, 563-64 (D.C. Cir. 2010)). In the same way, even if Pfizer's competitors were to call attention to the disclosure of anonymized Reportable Event summaries, that kind of negative attention is not cognizable for the purpose of Exemption 4.

Pfizer's contention fails in any event because it rests on the assumption that employees will be less likely to report if summaries are released to the public, even if the summaries do not contain employee names. *See* Pfizer Opp. at 8-9. Dr. Kesselheim's expert opinion to the contrary at least creates a dispute over this issue that precludes summary judgment. *See* Pl.'s 2d S.J. Mem. at 9 (discussing Kesselheim Decl. ¶¶ 18-19). Although Pfizer suggests that employees participating in its internal reporting program might be more easily dissuaded from reporting than the qui tam whistleblowers described in one of Dr. Kesselheim's studies, Pfizer has provided no evidence to support that suggestion. Moreover, one might actually expect that employees using an internal reporting program would be *more* likely to report if the summaries that Public Citizen seeks are made public because the employees know there is some measure of

public or government oversight to act as a bulwark against employer retaliation efforts related to an employee's perhaps unwelcome report of company wrongdoing.

F. For its part, Purdue contends that this Court already addressed Public Citizen's contention that the Reportable Event summaries and Disclosure Log summaries are not confidential when this Court held that information regarding confirmed or suspected illegal activity could—as a matter of law—fall within Exemption 4's scope. *See* Purdue Opp. at 3. Public Citizen is not, however, seeking "another bite at the apple" in this regard, as Purdue contends. *Id.* Rather, as Public Citizen explained in its renewed motion for summary judgment, even assuming that information regarding suspected or confirmed illegal activity could be confidential as a matter of law, the companies do not explain why a competitor would seek to copy the particular illegal activities disclosed in the summaries, nor do they demonstrate that there is actual competition for information about non-compliance with the law in this case. Pl.'s 2d S.J. Mot. at 6, 8-9. In other words, even if some information about confirmed or suspected illegal activity could fall within Exemption 4's scope as a legal matter, the defendants have not met their evidentiary burden of showing that Exemption 4 applies to these particular documents.

G. Purdue also contends that it would suffer substantial competitive harm from release of the Reportable Event summaries and Disclosure Log summaries because the information would reveal where Purdue draws the line in distinguishing between legal and illegal conduct. Purdue Opp. at 4-5. Purdue asserts that other companies could use this information in "benchmarking" their own behavior without "having to make the same investment to determine what might or might not constitute illegal practices." *Id.* at 5. But even if Exemption 4 could cover competitive harm related to information about wrongdoing in some circumstances, here, the market to which Purdue points—a market in information about abiding by the law—is one

that is separate from Purdue's actual business: the sale of pharmaceuticals. Moreover, the Reportable Event summaries and Disclosure Log summaries are not exercises in sophisticated legal analysis; they do not necessarily show where Purdue's advisors, consultants, and attorneys draw the legal line. Reportable Event summaries, for example, are based on what a "reasonable person" would believe to be a probable violation of law. Pfizer CIA at 21; Purdue CIA at 19-20.[1]

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

The CIAs required Pfizer and Purdue to screen certain individuals to determine whether they were "Ineligible Persons," defined as individuals (1) who were "excluded, debarred, suspended, or otherwise ineligible to participate" in federal health care, procurement, or nonprocurement programs, or (2) who had been convicted of crimes for which mandatory exclusion was required but who had not yet been excluded. Pfizer CIA at 19-20; Purdue CIA at 17-18. In addition, Pfizer and Purdue were required to remove Ineligible Persons from all involvement with the federal health care programs in which the companies engaged and to ensure that no federal funds were used to compensate the individuals. Pfizer CIA at 20; Purdue CIA at 19.

A. As Public Citizen emphasized in its renewed motion for summary judgment, this Court has not yet addressed whether actions taken by the companies in line with their screening and removal obligations must be disclosed. *See* Pl.'s 2d S.J. Mem. at 11. Although Pfizer agrees that this category of records remains at issue, *see* Pfizer Opp. at 1, Purdue contends that this Court already granted summary judgment to Purdue for such records, *see* Purdue Opp. at 6.

[1] Pfizer also argues that it is "not irrelevant" to the analysis of whether the summaries are confidential that Pfizer marked the information as "FOIA Confidential." Pfizer Opp. at 6. Public Citizen fully addressed this argument in its renewed motion for summary judgment. *See* Pl.'s 2d S.J. Mem. at 7.

Purdue's records in this category are listed as entries 4 and 27 in the first Purdue *Vaughn* index, Doc. 19, but are not accounted for in the supplemental Purdue *Vaughn* index, Doc. 49. Specifically, Purdue contends that *Vaughn* entries 4 and 27 are covered by the Court's summary judgment award with respect to "'records reflecting changes in process of the monitoring and removal of Ineligible Persons required by § V.B.11 of the Purdue CIA.'" Purdue Opp. at 5-6 (quoting Mem. Op. at 52).

Purdue's argument fails under the plain terms of its CIA and the redacted versions of *Vaughn* entries 4 and 27 available to Public Citizen. "[T]he actions taken by Purdue in response to [its] screening and removal obligations" are required to be reported pursuant to § V.B.12 of the Purdue CIA, not § V.B.11, for which the Court awarded summary judgment to defendants. Purdue CIA at 28. Moreover, the redacted versions of entries 4 and 27, which Public Citizen submitted into evidence, are labeled "Section V.B.12 – Ineligible Persons," which further confirms that this Court's order granting summary judgment with respect to information reported under § V.B.11 of Purdue's CIA does not cover these documents. *See* Doc. 53-1, 3d Murray Decl. ¶¶ 2-3 & Attach. A, B.

B. Although it is undisputed that whole paragraphs have been redacted from *Vaughn* entries 4 and 27, Purdue remarkably contends that "there is no information to disclose" with respect to the company's actions in fulfilling its screening and removal obligations. Purdue Opp. at 7. Purdue's contention, though far from clear, appears to be that all of the redacted information in entries 4 and 27 pertains to Purdue's former Chief Legal Officer and that the officer—although concededly an Ineligible Person, *see* Doc. 58-1, 2d Weinstein Supp. Decl. ¶ 6—was not identified as such through the CIA screening process. As a result, argues Purdue, the redacted information does not pertain to "Purdue's actions in response to the screening and removal

obligations set forth in [its] CIA," and need not be released. Purdue Opp. at 8 (internal quotation marks omitted).

Purdue's argument should be rejected. As an initial matter, neither the initial *Vaughn* entries for documents 4 and 27, nor Purdue's declarant, indicated that all redacted information from these documents pertains to Purdue's Chief Legal Officer. *See generally* Doc. 19, Purdue *Vaughn* Index, Entries 4, 27; Doc. 58-1, 2d Weinstein Supp. Decl. And the supplemental Purdue *Vaughn* index does not even account for these documents, much less narrow their scope to information regarding Purdue's Chief Legal Officer. *See* Doc. 49, Supp. Purdue *Vaughn* Index. Although Public Citizen noted in its renewed motion for summary judgment that "the location of one of the redactions specifically suggests that some of the withheld information relates to the company's actions with regard to Purdue's former Chief Legal Officer," Pl.'s 2d S.J. Mem. at 12, it has no reason to believe that *all* of the redacted information falls into that category. *See generally* Doc. 54-1, 3d Murray Decl., Attach. A, B (showing several paragraphs redacted in full or in part in the two documents, only one of which includes a paragraph regarding Purdue's Chief Legal Officer).

Moreover, even assuming that all redacted information from entries 4 and 27 pertains to Purdue's Chief Legal Officer, it is undisputed that this individual was an Ineligible Person—regardless how he was identified—and that the information appears in a document that falls within the scope of records sought by Public Citizen. *See* Doc. 19, First Purdue *Vaughn* Index, Entry 4 (stating that document contains information "regarding privileged communications to the OIG related to Purdue's *proposed actions regarding ineligible persons*" (emphasis added)); *see also id.*, Entry 27 (same). Such information unquestionably appears in documents that Purdue submitted to purport to comply with its obligations under § V.B.12 of its CIA. *See* Doc. 54-1, 3d

Murray Decl., Attach. A, B. And it clearly falls within the scope of information sought by Public Citizen. *See* Pl.'s 2d S.J. Mem. at 11 (identifying as still at issue "information about actions taken by the companies in line with their legally-mandated screening and removal obligations"). Accordingly, additional information from Purdue about actions taken to comply with its screening and removal obligations can be released.

C. On the merits, Pfizer and Purdue compare actions taken to fulfill the companies' screening and removal obligations with changes to the process of screening and removing Ineligible Persons, Purdue Opp. at 6; Pfizer Opp. at 9-10, the latter of which this Court has held are protected from disclosure under Exemption 4, *see* Mem. Op. at 50. However, to support its argument, Purdue quotes from a portion of this Court's decision explaining why changes to the screening and removal process are commercial, not why they are confidential. *See* Purdue Opp. at 6 (quoting Mem. Op. at 29). Purdue thus marshals a wholly irrelevant portion of this Court's decision in support of its argument.

For its part, Pfizer contends that actions taken to screen and remove Ineligible Persons are analogous to changes to the process for screening and removal because both may "'reveal[] confidential information about the companies' broader structure and operations.'" Pfizer Opp. at 10 (quoting Mem. Op. at 45). But as Public Citizen has explained, *see* Pl.'s 2d S.J. Mem. at 13, the contours of the actions that Pfizer must take to comply with its screening and removal obligations are clearly identified in its CIA. Pfizer's contrary contention that its "CIA only provides definitions and general requirements that 'Pfizer shall screen' and 'Pfizer shall implement a policy'" distorts the company's CIA. Pfizer Opp. at 10 (quoting Pfizer CIA at 19-20). As is clear from Pfizer's actual CIA, the document is far more specific with respect to the agency's screening and removal obligations. It addresses, for example, which employees must be

screened, how quickly and frequently the screening must occur, the lists against which Pfizer must screen employees, the necessary length of removal, and Pfizer's obligations with respect to employees facing pending charges for certain criminal offenses. *See* Pfizer CIA at 19-20. Moreover, even if some aspects of the screening and removal process are not specifically mandated by Pfizer's CIA, Pfizer has not demonstrated that there is a competitive market for such information, but instead simply emphasizes that Pfizer spends time and money to develop its screening process. *See* Doc. 47-2, 2d Nowicki Decl. ¶¶ 48-54. *Compare* Rodondi Decl. ¶ 22 (making clear that processes for screening and removal of ineligible persons "are widely known and each company tailors its program to its unique circumstances and based on its own assessment of compliance and risk management" and that, as a result, it would be unlikely that release of this information would benefit Pfizer's competitors in selling their products). As a result, this Court's earlier decision awarding summary judgment to defendants on changes in the screening and removal process does not preclude awarding summary judgment to Public Citizen regarding actions taken by the companies to comply with their screening and removal obligations.

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

Pfizer's CIA required the company to obtain commercially available non-Pfizer records that reflect the content and subject matter of "detailing interactions." Pfizer CIA at 22. Based on those records, Pfizer was then required to identify and make findings regarding instances in which it appeared that Pfizer sales representatives discussed or disseminated information for off-label uses for certain Pfizer drugs. *Id.* at 23. In its annual reports, Pfizer was obligated to provide OIG with those findings and the underlying records to support them. *Id.* at 26.

Records reflecting the actual content of detailing sessions and references to those records for which findings were made (identified as Pfizer *Vaughn* entries 15B, 46, 48, 84, 86, 120, 122, 155, and 157) remain at issue. As Public Citizen explained in its renewed motion for summary judgment, the information contained in these records is not proprietary to Pfizer, but rather is based on information from health care providers visited by a Pfizer representative. Pl.'s 2d S.J. Mem. at 15. Public Citizen also disputed Pfizer's contention that it was contractually bound not to disclose the records by pointing out that Pfizer had failed to introduce the best evidence of such an obligation: the original contract. *Id.* at 14-15. Under Federal Rule of Evidence 1002, "[a]n original writing . . . is required in order to prove its content unless the[] rules [of evidence] or a federal statute provides otherwise."

In its opposition, Pfizer now contends that the records reflecting off-label promotion during detailing sessions are exempt from disclosure because their release would reveal Pfizer's "findings" in investigating off-label promotion, for which this Court has already granted summary judgment to defendants. Pfizer Opp. at 11 (citing Mem. Op. at 47-48). However, release of the underlying records would indicate only that Pfizer made a finding based on the records, not what the specific finding was.

Pfizer also challenges Public Citizen's assertion that the information in the withheld records is not proprietary to Pfizer by emphasizing that Pfizer must pay a fee to view the information. *Id.* at 12. Pfizer's argument in this regard misses the point. Regardless whether the record is available to Pfizer only for a fee, the information that it contains—that is, the memorialization of a marketing discussion between a health care provider and a Pfizer representative—is not proprietary to Pfizer. Rather, the information is shared with and by health care providers and conveyed to a market research firm. And defendants have never argued that

Exemption 4 applies based on potential competitive harm to a market research firm selling the records, as opposed to Pfizer itself.

In addition, Pfizer contends that it has no obligation—despite Federal Rule of Evidence 1002—to introduce the "best evidence" of its contractual obligation not to disclose records reflecting the content of detailing sessions. *Id.* In Pfizer's view, its "affidavit sets out that the contractual obligation [not to disclose the records] exists and that is all that is required" under Federal Rule of Civil Procedure 56 at summary judgment. *Id.* Pfizer's argument is at odds with Rule 56 and this Court's case law. The 2010 Advisory Committee Notes to Federal Rule of Civil Procedure 56 make clear that "materials referred to in an affidavit or declaration" at summary judgment "must be placed in the record." Moreover, this Court has applied the "best evidence" rule on summary judgment. *See Buruca v. Dist. of Columbia*, 902 F. Supp. 2d 75, 82 (D.D.C. 2012) (holding that affidavit's description of video footage was inadmissible at summary judgment because the video footage was the best evidence of its content). Accordingly, this Court should not consider on summary judgment Pfizer's assertions regarding its contractual obligations with respect to the records reflecting off-label promotion during detailing sessions.

CONCLUSION

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

Respectfully submitted,

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