IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, plaintiff Public Citizen hereby moves for summary judgment in this case brought under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, on the ground that there is no genuine issue of disputed material fact and that plaintiff is entitled to judgment as a matter of law. Of the records responsive to its FOIA request, Plaintiff seeks (1) Pfizer and Purdue Reportable Event summaries; (2) Pfizer and Purdue Disclosure Log summaries; (3) Pfizer and Purdue records involving the screening and removal of Ineligible Persons; (4) Pfizer and Purdue summaries of government investigations or legal proceedings; (5) Pfizer and Purdue communications with the Food and Drug Administration (FDA); (6) Pfizer and Purdue portions of IRO reports identified in Plaintiff's Memorandum in Support of Summary Judgment and the company's responses and corrective

action plans as to those portions; (7) Purdue's cover memorandum for a supplement to its first annual report; and (8) records involving Pfizer's off-label findings and responses to those findings, portions of the off-label review of detailing sessions for specific drugs for which the portions reveal off-label promotion, and underlying detailing session records that reveal off-label promotion identified in the off-label findings.

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

Plaintiff also moves this Court to order HHS to conduct an additional search for Pfizer responses and corrective action plans related to its IRO reports, which were not specifically identified in defendant's initial search.

In support of this motion and in opposition to defendant's and defendant-intervenors' motions for summary judgment, plaintiff submits the accompanying Memorandum in Support of Plaintiff's Motion for Summary Judgment and Opposition to Defendant's and Defendant-Intervenors' Motions for Summary Judgment; Plaintiff's Statement of Genuine Issues and Response to Defendant's Statement of Material Facts as to Which There Is No Genuine Issue; Plaintiff's Statement of Material Facts as to Which There Is No Genuine Issue; the Declaration of Sidney Wolfe; the Declaration of Aaron Kesselheim; the Declaration of Julie Murray; the Declaration of Kevin Rodondi; and a proposed order.

Respectfully submitted,

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May 31, 2012

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

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INTRODUCTION

Plaintiff Public Citizen brought this Freedom of Information Act (FOIA) case to seek annual compliance reports that two pharmaceutical manufacturers submitted to the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS). These compliance reports were required under "Corporate Integrity Agreements" (CIAs) that the companies—Pfizer, Inc. and Purdue Pharma L.P.—made with OIG after resolving claims that the companies engaged in illegal, off-label drug promotion for products reimbursed by federal health care programs. The annual reports reveal information about whether the companies subsequently complied with federal laws that protect the public fisc and public health and about OIG's response to such compliance or non-compliance. The reports thus contain critical information for the public to assess whether the CIAs are effective at deterring or discovering fraud in federal health care programs.

HHS has refused to produce the bulk of the annual compliance reports. It claims that the reports contain confidential, commercial information exempt from disclosure under FOIA Exemption 4, 5 U.S.C. § 552(b)(4), because disclosure will either cause substantial competitive harm to the drug companies or impair the government's ability to obtain necessary information from these companies in the future. HHS also contends that portions of the records contain private, personal information exempt from disclosure under FOIA Exemption 6, *id.* § 552(b)(6).

As discussed below, HHS has not met its burden of showing that Exemption 4 applies to the withheld records. Many of the documents reveal only suspected or confirmed unlawful conduct, which does not constitute "commercial" information. Moreover, HHS has not demonstrated that disclosure of the records sought by Public Citizen is likely to cause substantial competitive harm to the drug companies. Nor has HHS demonstrated that disclosure will impair its ability to obtain necessary information in the future, or that the asserted impairment would

outweigh the substantial public interest in disclosure. Pfizer's separate argument that its documents are privileged and thus exempt from disclosure under Exemption 4 is wrong; regardless of whether Pfizer's documents would qualify for any "self-critical analysis" privilege in the discovery context, FOIA Exemption 4 does not incorporate this little-accepted privilege.

In addition, HHS has not met its burden of demonstrating that FOIA Exemption 6 applies to the records sought here. Public Citizen does not seek names, e-mail addresses, telephone numbers, or signatures of individuals named in the withheld documents. Anonymous individuals have only a de minimis privacy interest in other information pertaining to them, such as job titles and descriptions. The strong public interest in disclosure outweighs any privacy interest.

Accordingly, this Court should grant Public Citizen's motion for summary judgment; deny the motions for summary judgment by HHS, Pfizer, and Purdue; and order HHS to produce the requested records. In addition, because HHS failed to produce certain Pfizer documents that are known to exist and are responsive to Public Citizen's request, this Court should order the agency to conduct an additional search.

BACKGROUND

In 2009, Public Citizen submitted a FOIA request to OIG, seeking (1) a copy of all annual reports submitted to OIG by Purdue pursuant to a May 2007 Corporate Integrity Agreement between OIG and Purdue, and (2) a copy of all annual reports submitted to OIG by Pfizer pursuant to a May 2004 Corporate Integrity Agreement between OIG and Pfizer. *See* Wolfe Decl. ¶ 3, attached as Exh. 1. The following sections describe the regulatory scheme that gave rise to Public Citizen's interest in the requested documents, the CIAs pursuant to which Pfizer and Purdue submitted the annual compliance reports sought in this litigation, and the administrative proceedings that preceded this lawsuit.

I. The Regulatory Framework

The Food, Drug, and Cosmetic Act (FDCA) requires a drug manufacturer to submit to the Food and Drug Administration (FDA), in advance of marketing a new product, a "new drug application" (NDA) demonstrating substantial evidence that the drug is safe for use under the conditions prescribed in its labeling. 21 U.S.C. §§ 321(p); 355(a), (b), (d). The law prohibits marketing a drug for any use not approved by the FDA. For drugs already approved for one use, a manufacturer must submit a supplemental NDA demonstrating the drug's safety and effectiveness for any additional use before labeling or promoting the drug for that new use. *See* 21 C.F.R. § 314.70. In addition, the FDCA requires a manufacturer to ensure that its drug is not "misbranded," meaning, among other things, that a drug's labeling must contain "adequate directions for use." 21 U.S.C. § 352(f). In this way, the regulatory scheme is crafted to provide an objective assessment of safety and effectiveness for each approved use for which the manufacturer intends to promote its product and to ensure adequate labeling for that use.

Although drug manufacturers cannot legally promote products for uses not within a drug's approved labeling, physicians can legally prescribe drugs for so-called off-label uses. *See* Kesselheim Decl. ¶ 8, attached as Exh. 2; *see also, e.g.*, John N. Joseph, et al., *Enforcement Related to Off-Label Marketing and Use of Drugs and Devices: Where Have We Been and Where Are We Going?*, 2 J. Health & Life Sci. L. 73, 82 (2009). Therefore, manufacturers have often engaged in illegal, off-label promotion, which influences physicians' prescribing patterns. Kesselheim Decl. ¶ 8. Off-label use, when not based on reliable evidence of effectiveness, "exposes patients to risk of serious adverse effects," leading to documented, harmful outcomes. *Id.*

To combat this public health threat, the Department of Justice (DOJ) has pursued criminal charges against drug manufacturers under the FDCA and civil claims under the False Claims Act (FCA), 31 U.S.C. § 3729(a)(1)(A), among other statutes. Under the FDCA, a drug manufacturer commits a federal crime when it sells or distributes, with the intent to defraud or mislead someone, a misbranded drug or a drug for a use not approved by the FDA. *See* 21 U.S.C. §§ 331(a), (d); 333(a)(2). A pharmaceutical manufacturer is subject to civil liability under the FCA if it causes other entities, such as pharmacies, to "present . . . false or fraudulent claims for payment" to federal health care programs, including claims for off-label uses caused by illegal, off-label promotion. 31 U.S.C. § 3729(a)(1)(A); *see also* Joseph, *Enforcement Related to Off-Label Marketing*, 2 J. Health & Life Sci. L. at 83.

Against a corporate entity, both the FDCA criminal provisions and the civil False Claims Act provisions allow the imposition of fines. But these fines, although sometimes substantial, "are consistently dwarfed by the revenues that the manufacturers earn[] on the product," leading some to characterize the fines as a "cost of doing business." Kesselheim Decl. ¶ 10 (internal quotation marks omitted). Likely more powerful than fines is the collateral consequence for a company convicted of crimes relating to off-label promotion: Congress has provided for mandatory "exclusion" from all federal health care programs, such as Medicaid and Medicare, for any entity convicted of a felony relating to health care fraud. *See* 42 U.S.C. § 1320a-7(a). An entity convicted of a similar misdemeanor is subject to permissive exclusion. *Id.* § 1320a-7(b), (c)(3)(D).

In practice, exclusion means that federal health care programs will not reimburse the cost of any drugs produced by an "excluded" manufacturer. Federal health care programs "together account for a substantial fraction of drug reimbursement." Kesselheim Decl. ¶ 9. For example,

by 2006, the federal government was Pfizer's "largest customer, accounting for approximately 45% of U.S. sales." Murray Decl. ¶ 2, Attach. A, attached as Exh. 3. Some have thus called exclusion a "corporate death sentence." Kesselheim Decl. ¶ 9 (internal quotation marks omitted).

II. Global Settlements Involving Pharmaceutical Manufacturers and the Rise of Corporate Integrity Agreements

Hesitant to risk exclusion, pharmaceutical manufacturers facing charges brought by DOJ nearly always enter into global settlement agreements with the federal government to resolve civil and/or criminal investigations relating to off-label promotion. *Id.* ¶ 9. Those agreements often follow a familiar pattern: Many include (1) a resolution of criminal allegations through a criminal plea or a deferred prosecution agreement entered into by a drug manufacturer's subsidiary or related company, (2) a civil settlement resolving claims under federal and state false-claims statutes, and (3) a Corporate Integrity Agreement, or CIA, between OIG and the drug manufacturer to deter or discover future off-label promotion and other illegal activity on federal health care programs. *See, e.g.*, Joseph, *Enforcement Related to Off-Label Marketing*, 2 J. Health & Life Sci. L. at 84-97 (describing numerous cases).

A CIA usually lasts five years and imposes a series of compliance obligations on drug companies, including the submission of annual reports to OIG on the status of the company's compliance activities. Murray Decl. ¶ 3, Attach. B. Drug companies "agree to the obligations [in the CIAs], and in exchange, OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other [f]ederal health care programs." *Id.*

OIG's heavy reliance on CIAs to fulfill the agency's oversight function is troubling. "In theory, CIAs help the government deter and detect pharmaceutical manufacturers' illegal activity, such as off-label promotion of drugs or kickbacks to health care providers." Wolfe

Decl. ¶ 11. But "in practice, it is unclear whether CIAs are an effective tool for deterrence or detection." *Id.*; *see also* Kesselheim Decl. ¶ 11 (describing need for clarity with regard to which CIA features are effective or ineffective). As is relevant to this case, for example, Pfizer has entered into "three serial Corporate Integrity Agreements with OIG for conduct engaged in by Pfizer's own employees or the employees of companies that Pfizer acquired." Wolfe Decl. ¶ 11.[1]

III. The CIAs at Issue in This Case

Purdue and Pfizer, the Defendant-Intervenors in this case, entered into CIAs with OIG under circumstances similar to those described in Part II.

A. Background of Purdue's 2007 CIA with OIG

The federal government pursued Purdue and one of its affiliates, Purdue Frederick Co., based on allegations that the companies fraudulently misbranded the drug OxyContin and submitted false claims to the federal government. *See* Civil Settlement Agreement, Attach. D to Plea Agreement, at 2, *United States v. Purdue Frederick Co., Inc.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007). OxyContin is a form of oxycodone that has an abuse potential similar to morphine. Agreed Statement of Facts ¶ 2, *Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007). Between 1996 and 2001, the period of the unlawful conduct, oxycodone-related

[1] Pfizer's most recent settlement, resolved in 2009, relates to, among other things, the company's alleged off-label promotion and sale of four drugs—(1) Bextra, (2) Geodon, (3) Zyvox, and (4) Lyrica—between 2001 and 2008. Civil Settlement Agreement, Attach. to Plea Agreement, at 36-38, *United States v. Pharmacia & Upjohn Co., Inc.*, No. 1:09-cr-10258 (D. Mass. Sept. 2, 2009). As part of that settlement, Pfizer agreed to enter a new CIA with OIG in exchange for HHS's agreement not to seek to exclude Pfizer from federal health care programs. *Id.* at 40, 43-44. The United States also agreed not to criminally prosecute Pfizer for its activities related to the four drugs on the condition that Pfizer fulfill its obligations under a civil settlement agreement and that Pharmacia & Upjohn Company, a Pfizer subsidiary, plead guilty to felony misbranding of Bextra. Side Letter Agreement at 1-2, *Pharmacia & Upjohn Co.*, No. 1:09-cr-10258 (D. Mass. Sept. 15, 2009).

deaths increased 400 percent, while annual prescriptions for OxyContin rose from 300,000 to almost 6 million. Wolfe Decl. ¶ 6.

In 2007, Purdue and Purdue Frederick struck a three-part deal with the federal government. First, the government filed a criminal information against Purdue Frederick, which pleaded guilty to felony misbranding related to fraudulent marketing and promotion of OxyContin. *United States v. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, 571 (W.D. Va. 2007). The company admitted that its sales representatives had fraudulently "marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other paid medication." Agreed Statement of Facts ¶ 20, *Purdue Frederick Co.*, No. 1:07-cr-00029. Second, both companies entered a simultaneous civil settlement agreement to resolve, among other things, the related federal false-claims allegations. *See* Civil Settlement Agreement, *Purdue Frederick Co.*, No. 1:07-cr-00029. Under that civil agreement, Purdue Frederick was excluded from federal health care programs for twenty-five years; Purdue Pharma admitted no wrongdoing and thus escaped exclusion. *Id.* at 5, 9. Both companies agreed to pay civil fines. *Id.* at 3. Third, as a condition of the civil settlement, Purdue entered into a CIA with OIG. *Id.* at 5.

B. Background of Pfizer's 2004 CIA with OIG

Under similar circumstances, the federal government pursued Pfizer based on the off-label promotion of the drug Neurontin by a Pfizer subsidiary, Warner-Lambert Company LLC. *See generally* Information, *United States v. Warner-Lambert Co. LLC*, No. 1:04-cr-10159 (D. Mass. May 13, 2004).[2] Warner-Lambert was alleged to have, among other things, "[p]romoted

[2] Plaintiff cites the Criminal Information because Warner-Lambert later agreed that all facts in the Information were true. *See* Plea Agreement, *Warner-Lambert Co. LLC*, No. 1:04-cr-10159 (D. Mass. May 13, 2004).

Neurontin for use as a sole drug in the treatment of epileptic seizures, even though FDA had rejected the monotherapy indication" and "[u]sed sham consultants' meetings and sham independent medical education to promote Neurontin for off-label uses." Joseph, *Enforcement Related to Off-Label Marketing*, 2 J. Health & Life Sci. L. at 96.

Pfizer and Warner-Lambert resolved those claims in 2004 as part of a three-part settlement. Warner-Lambert pleaded guilty to two felonies under the FDCA related to its off-label promotion of Neurontin, agreeing to pay a criminal fine. *See* Plea Agreement, at 1-2, *Warner-Lambert Co. LLC*, No. 1:04-cr-10159 (D. Mass. May 13, 2004). It also agreed to pay civil fines to settle civil false claims allegations. *See* News Release, DOJ, Warner-Lambert to Pay $430 Million to Resolve Criminal and Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), *available at* http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm. Finally, as an "integral" piece of the settlement, Pfizer agreed to "amend[]" and "expan[d]" an existing 2002 CIA that it had with OIG unrelated to the Neurontin marketing. Sentencing Mem. of the United States at 3, *Warner-Lambert Co. LLC*, No. 1:04-cr-10159 (D. Mass. June 2, 2004).

IV. The Terms of the Pfizer and Purdue Corporate Integrity Agreements

The Pfizer and Purdue CIAs gave rise to the annual reports that Public Citizen requested in its FOIA request to OIG. Each CIA had a term of five years, with Pfizer's CIA beginning in 2004 and Purdue's in 2007. Pfizer CIA, Doc. 22-1 at 50; Purdue CIA, Doc. 22-2 at 19. As is customary, each CIA required the companies to maintain a comprehensive compliance program and to submit annual compliance reports. *See* Pfizer CIA, Doc. 22-1 at 72; Purdue CIA, Doc. 22-2 at 45. The following sections describe the minimum elements of the CIA-mandated

compliance program and the corresponding portions of the annual reports sought by Public Citizen.[3]

A. Elements of the Compliance Program and Corresponding Portions of Annual Reports Sought by Public Citizen

1. "Reportable Events." Pfizer and Purdue were required to tell OIG about so-called "Reportable Events," defined, with minimal variation between the two CIAs, as a report involving a matter "that a reasonable person would consider a probable violation of criminal, civil, or administrative laws" that apply to a federal health care program or to certain FDA requirements. Pfizer CIA, Doc. 22-1 at 69; Purdue CIA, Doc. 22-2 at 37-38. In their annual reports, the companies were then obligated to provide a summary of Reportable Events identified during the reporting period and the status of any corrective or preventative action. Pfizer CIA, Doc. 22-1 at 73-74; Purdue CIA, Doc. 22-2 at 46.

2. Disclosure program. Under the CIAs, Pfizer and Purdue were obligated to maintain a disclosure program for internal whistleblowers who believed that company activities violated criminal, civil, or administrative laws relating to federal health care programs or FDA requirements. Pfizer CIA, Doc. 22-1 at 66; Purdue CIA, Doc. 22-2 at 34. The CIAs mandated that the disclosure program provide a mechanism for "anonymous communications for which appropriate confidentiality [would] be maintained." Pfizer CIA, Doc. 22-1 at 67; Purdue CIA, Doc. 22-2 at 34 (same). The companies were required to conduct an internal review of "sufficiently specific" whistleblower disclosures. Pfizer CIA, Doc. 22-1 at 67; Purdue CIA, Doc. 22-2 at 35 (same).

[3] After reviewing the *Vaughn* Indexes submitted by HHS, Public Citizen has decided not to seek all documents withheld by HHS. Public Citizen seeks only those categories of documents identified in this brief.

In their annual reports, Pfizer and Purdue were required to provide a summary of disclosures in the "Disclosure Log" that related to federal health care programs or FDA requirements. Pfizer CIA, Doc. 22-1 at 73-74; Purdue CIA, Doc. 22-2 at 46.

3. Screening and removal of "Ineligible Persons." The CIAs required Pfizer and Purdue to screen certain individuals—including some officers, employees, and applicants—to determine whether those individuals were "Ineligible Persons." Pfizer CIA, Doc. 22-1 at 68; Purdue CIA, Doc. 22-2 at 36.[4] "Ineligible Persons" were defined as individuals (1) who were "excluded, debarred, suspended, or otherwise ineligible to participate" in federal health care, procurement, or nonprocurement programs, or (2) who had been convicted of crimes for which mandatory exclusion was required but had not yet been excluded. *See* Pfizer CIA, Doc. 22-1 at 67 (referring to crimes covered by 42 U.S.C. § 1320a-7(a)); Purdue CIA, Doc. 22-2 at 35 (same). If the screening revealed that an individual was an "Ineligible Person," Pfizer and Purdue were required to remove that person from all involvement with the federal health care programs in which the companies engaged and to ensure that no federal funds were used to compensate the person. Pfizer CIA, Doc. 22-1 at 68; Purdue CIA, Doc. 22-2 at 37.[5]

The CIAs required Pfizer and Purdue to screen for Ineligible Persons by, among other activities, referring to two, publicly available lists on government websites that identify individuals ineligible to participate in federal health care, procurement, and nonprocurement programs. Pfizer CIA, Doc. 22-1 at 68; Purdue CIA, Doc. 22-2 at 36. Those lists include,

[4] The scope of individuals required to be screened differs slightly between the Pfizer and Purdue CIAs. *Compare* Pfizer CIA, Doc. 22-1 at 68, *with* Purdue CIA, Doc. 22-2 at 36.

[5] Ineligible Persons who are excluded from federal health care programs may not work on such programs without violating the terms of their exclusion, and drug companies—even those not subject to CIAs—face civil fines for hiring Ineligible Persons to work on such programs. *See* OIG, The Effect of Exclusion from Participation in Federal Health Care Programs, Special Advisory Bulletin (Sept. 1999), *available at* http://oig.hhs.gov/exclusions/effects_of_exclusion.asp.

among other things, the names of individuals and the terms of their exclusion. *See* HHS-OIG, List of Excluded Individuals / Entities Search, http://exclusions.oig.hhs.gov (last visited May 16, 2012); General Services Administration, Excluded Parties List System, http://epls.arnet.gov (last visited May 16, 2012).

In their annual reports, Pfizer and Purdue were obligated to provide OIG with any changes to the process by which they fulfilled the requirement to screen for and remove Ineligible Persons; the name, title, and responsibilities of any person identified as an Ineligible Person; and the actions taken by the company in line with its screening and removal obligations. Pfizer CIA, Doc. 22-1 at 73-74; Purdue CIA, Doc. 22-2 at 46.

4. Investigations or legal proceedings. The CIAs required the companies to notify OIG soon after discovering any government investigations or legal proceedings based on allegations that the companies had committed a crime or engaged in fraud. Pfizer CIA, Doc. 22-1 at 69; Purdue CIA, Doc. 22-2 at 37 (same). Pfizer's CIA, but not Purdue's, limited reportable investigations or legal proceedings to those based in the United States. Moreover, the companies were required to advise OIG of the findings or results of proceedings or investigations upon resolution. Pfizer CIA, Doc. 22-1 at 69; Purdue CIA, Doc. 22-2 at 37.

As part of their annual reports, Pfizer and Purdue were obligated to provide a summary of any ongoing investigations or legal proceedings required to be reported under the CIAs, including a description of the allegation, the identity of the investigating or prosecuting agency, and the status of the investigation or legal proceeding. Pfizer CIA, Doc. 22-1 at 73-74; Purdue CIA, Doc. 22-2 at 46.

5. Company communications with FDA about off-label promotion. Pfizer and Purdue were required to report to OIG certain written communications that the companies had

with FDA about unlawful, off-label promotion and the results or findings of those interactions with FDA. Pfizer CIA, Doc. 22-1 at 70; Purdue CIA, Doc. 22-2 at 38. Specifically, Pfizer had an obligation to report communications related to its "promotion, discussion, or dissemination of information about off-label uses" for its drug products. Pfizer CIA, Doc. 22-1 at 70. In substantially similar language, Purdue's CIA required the company to report contacts that "substantively discuss[ed]" unlawful promotion or misbranding of drugs by Purdue or certain individuals working for it. Purdue CIA, Doc. 22-2 at 38.

In their annual reports, Pfizer and Purdue were obligated to provide a summary of any ongoing communication with the FDA required to be reported under the CIA. Pfizer CIA, Doc. 22-1 at 73-74; Purdue CIA, Doc. 22-2 at 46.

6. Pfizer's off-label findings and detailing sessions. Pfizer's CIA required the company to obtain commercially available non-Pfizer records that reflected the content and subject matter of "detailing interactions," Pfizer CIA, Doc. 22-1 at 70, which are basically interactions in which pharmaceutical sales representatives give doctors and other health care providers details about certain drugs and their uses. Pfizer was required to identify, based on those records, instances in which it appeared that Pfizer sales representatives discussed or disseminated information for off-label uses for certain Pfizer drugs selected by OIG. *Id.* at 71. The company was then obligated to make findings with respect to these instances of off-label dissemination or discussion of information and to take corrective action where necessary. *Id.*

In its annual reports, Pfizer was obligated to provide OIG with any findings that its sales representatives engaged in off-label promotion, dissemination, or discussion of certain drugs with health care providers, and the underlying records to support those findings. Pfizer CIA, Doc. 22-1 at 74.

7. Independent Review Organization reports,. The CIAs obligated Pfizer and Purdue to hire an Independent Review Organization (IRO), such as an auditing or consulting company, to perform reviews of certain company policies, practices, systems, and processes. Pfizer CIA, Doc. 22-1 at 62; Purdue CIA, Doc. 22-2 at 32.[6] The IROs, in turn, were charged with producing reports for each of the specific reviews required in the CIAs. Pfizer CIA, Doc. 22-1 at 65; Purdue CIA, Doc. 22-2 at 33. As part of their annual reports, Pfizer and Purdue were required to submit all reports prepared by an IRO for the company and the company's response and corrective action plans related to any issues raised in the IRO reports. Pfizer CIA, Doc. 22-1 at 73-74; Purdue CIA, Doc. 22-2 at 46.

B. Penalties for Non-Compliance with the CIAs

The Pfizer and Purdue CIAs provided for stipulated penalties, in nearly all instances accrued on a daily basis, for non-compliance with CIA obligations. *See* Pfizer CIA, Doc. 22-1 at 79-80; Purdue CIA, Doc. 22-2 at 50-51. The CIAs also made clear that if the companies materially breached the agreements, OIG could exclude the companies from all federal health care programs and other federal procurement and non-procurement programs. Pfizer CIA, Doc. 22-1 at 81-82; Purdue CIA, Doc. 22-2 at 53-54. The CIAs defined a "material breach" to include a failure to report a Reportable Event and take correction action; a failure to hire or use an IRO, or a "repeated or flagrant violation" of any CIA obligations. Pfizer CIA, Doc. 22-1 at 81-82; Purdue CIA, Doc. 22-2 at 53.

[6] Specifically, Pfizer's IRO was required to address and analyze (1) "Pfizer's systems, processes, policies, and practices relating to the Medicaid Rebate Program"; (2) "Pfizer's systems, policies and practices with regard to managed care contracting"; and (3) "Pfizer's systems processes, policies, and practices relating to sales, marketing, and product services activities." Pfizer CIA, Doc. 22-1 at 62. Purdue's IRO was required to perform a "Promotional and Product Services Engagement" review, consisting of a system review component and a transactions review component. Purdue CIA, Doc. 22-2 at 32.

C. Public Disclosure of Information Submitted Under the CIAs

The Pfizer and Purdue CIAs specifically contemplated in two sections that information submitted pursuant to the CIAs might be subject to disclosure under FOIA. The first section, titled "Designation of Information," provided in full:

> [The company] shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore *potentially exempt* from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. [The company] *shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.*

Pfizer CIA, Doc. 22-1 at 76 (emphasis added); Purdue CIA, Doc. 22-2 at 48 (same). Another section in each CIA titled "Disclosures" provided that OIG would "make a reasonable effort to notify [each company]" before releasing information in response to a FOIA request if the company had designated the information "as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules." Pfizer CIA, Doc. 22-1 at 78; Purdue CIA, Doc. 22-2 at 50.[7] Provisions like these are common in CIAs between OIG and drug manufacturers. *See* Murray Decl. ¶ 4, Attach. C.

V. OIG's Response to Public Citizen's FOIA Request

In response to Public Citizen's FOIA request, OIG released 84 pages of Purdue's annual compliance reports with redactions and withheld 1,093 pages in full. Wolfe Decl. ¶ 3. It also released 4,216 pages of Pfizer's annual compliance reports with redactions and withheld 5,216

[7] The remainder of the "Disclosures" provisions varied slightly between the Pfizer and Purdue CIAs. *Compare* Pfizer CIA, Doc. 22-1 at 78, *with* Purdue CIA, Doc. 22-2 at 50.

pages in full. *Id.*[8] OIG asserted that the withheld records were protected from disclosure under FOIA Exemptions 4 and 6.

Public Citizen administratively appealed OIG's determinations. *Id.* ¶ 4. OIG affirmed the denial of Public Citizen's request with respect to the Purdue records. *Id.* OIG did not respond to Public Citizen's appeal with respect to the Pfizer records. *Id.* On September 16, 2011, Public Citizen filed this lawsuit against HHS. Pfizer and Purdue subsequently intervened as defendants.

STANDARD OF REVIEW

Summary judgment is appropriate when no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. FOIA's "strong presumption in favor of disclosure places the burden on the agency to justify the withholding of any requested documents." *U.S. Dep't of State v. Ray*, 502 U.S. 164, 173 (1991). If the government cannot "carry its burden of convincing the court that one of the statutory exemptions appl[ies]," the requested records must be released to the plaintiff. *Goldberg v. U.S. Dep't of State*, 818 F.2d 71, 76 (D.C. Cir. 1987).

ARGUMENT

I. Exemption 4 Does Not Apply to Any Records Sought by Public Citizen.

FOIA Exemption 4 protects from public disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). HHS and the companies argue that the withheld records are both "commercial" and "confidential," and thus exempt from disclosure. *See* HHS Mem. in Supp. of Mot. Summ. J.

[8] Where helpful, Public Citizen submits excerpts of these documents as exhibits to the Murray Declaration. The documents thus far released by OIG are also available in full on Public Citizen's website, http://www.citizen.org/PCvHHS-Pfizer-Purdue-Corp-Integrity-Agreements.

(HHS SJ Mem.), Doc. 22 at 32-33; Purdue Joinder in HHS Mot. for Summ. J., Doc. 24 at 2; Pfizer Mem. in Supp. of Mot. for Summ. J. (Pfizer SJ Mem.), Doc. 23-1 at 15-16.[9] Pfizer also argues that its materials are "privileged" under the so-called "self-critical analysis" privilege, and thus fall within the scope of Exemption 4 even if they are not deemed "confidential." Pfizer SJ Mem. at 22-23.

HHS and the companies have not met their burden of demonstrating that the withheld documents are exempt from disclosure under FOIA Exemption 4. First, many of the records at issue in this case reflect suspected or confirmed illegal conduct on the part of the companies or their workers. This information is not "commercial."

Second, the records sought by Public Citizen are not confidential. The declarations submitted by HHS fail to describe "the justifications for nondisclosure with reasonably specific detail," *Military Audit Project v. Casey*, 656 F.2d 724, 738 (D.C. Cir. 1981), instead relying repeatedly on general and conclusory statements to assert that the withheld information is confidential. Contrary to HHS's vague assertions of harm, the documents sought are not confidential because disclosure is neither likely to result in substantial competitive harm to Pfizer or Purdue, nor to impair OIG's ability to obtain necessary information in the future from companies subject to CIAs.

Third, Pfizer's assertion that its documents are "privileged," and thus exempt from disclosure under FOIA Exemption 4 on alternative grounds, is meritless. Whatever the scope of

[9] In its motion for summary judgment, HHS asserts in a footnote that the withheld documents constitute trade secrets, but that such protection is coextensive with Exemption 4's coverage in this case for confidential, commercial information. HHS SJ Mem. at 32. Because HHS does not assert any separate argument for trade secret protection, Public Citizen does not address the issue here.

the novel "self-critical analysis" privilege in the discovery context, it does not apply in FOIA cases.

A. Records Reflecting Illegal Conduct Do Not Constitute "Commercial" Information.

The term "commercial," as used in Exemption 4, must be given its "ordinary meaning[]." *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983). "[N]ot every bit of information submitted to the government by a commercial entity qualifies for protection under Exemption 4." *Id.* Instead, information is "commercial" if "it serves a commercial function or is of a commercial nature." *Nat'l Ass'n of Home Builders v. Norton*, 309 F.3d 26, 38 (D.C. Cir. 2002) (internal quotation marks omitted).

HHS and the companies assert that all of the withheld information is "commercial" in nature. *See* HHS SJ Mem. at 32-33; Pfizer SJ Mem. at 21-22. Many of the records sought by Public Citizen, however—such as Disclosure Log summaries; Reportable Event summaries; correspondence with the FDA about illegal, off-label promotion; lists without names of Ineligible Persons unlawfully employed by the companies to work on federal health care programs; and Pfizer's findings of off-label promotion in detailing sessions—consist of information about suspected or confirmed illegal conduct by the companies or their employees and the companies' corrective action, if any, to comply with applicable laws, regulations, and program requirements. Information about a company's violation of laws and regulations is not commercial in nature. Congress adopted FOIA's nine exclusive exemptions, including Exemption 4, because it "'realized that *legitimate* governmental and private interests could be harmed by release of certain types of information.'" *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 872 (D.C. Cir. 1992) (en banc) (quoting *FBI v. Abramson*, 456 U.S. 615, 621 (1982)) (emphasis added). Companies like Pfizer or Purdue may have an

interest in keeping unlawful conduct secret, but that interest is not a *legitimate* interest protected by Exemption 4.

B. The Records Sought by Public Citizen Are Not Confidential.

Not only are many of the records sought by Public Citizen not "commercial" in nature, they are not "confidential" within the meaning of Exemption 4. As discussed below, Pfizer's and Purdue's submissions to OIG were required by the terms of the CIAs and were thus involuntary. As a consequence, the test set forth in *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974), to determine the confidentiality of involuntarily submitted records applies. HHS and the companies have not met their burden under the *National Parks* test. In contrast, Public Citizen's declarations make clear that the records sought are not confidential.

1. Pfizer and Purdue involuntarily submitted annual reports to OIG, so the *National Parks* standard for confidential information applies.

Under what is known in this Circuit as the *National Parks* standard, information that a company submits *involuntarily* to the government is confidential only if disclosure is "likely either '(1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.'" *Critical Mass*, 975 F.2d at 878 (quoting *Nat'l Parks*, 498 F.2d at 770). In contrast, to determine whether voluntarily submitted records are confidential, courts ask only whether the records are "'of a kind that the provider would not customarily make available to the public.'" *Baker & Hostetler LLP v. U.S. Dep't of Commerce*, 473 F.3d 312, 320 (D.C. Cir. 2006) (quoting *Critical Mass*, 975 F.2d at 872). Voluntarily submitted records thus receive a greater level of protection from disclosure under FOIA than involuntary submissions.

HHS and Purdue concede that the submissions pursuant to the CIAs in this case were required (with the exception of two Pfizer documents that Public Citizen no longer pursues).[10] HHS SJ Mem. at 34; *see also* Purdue Joinder at 2. But Pfizer argues that it voluntarily submitted all annual reports to OIG and that the reports are therefore exempt from disclosure so long as Pfizer does not customarily release them to the public. Pfizer SJ Mem. at 22-23. Specifically, Pfizer contends that "[b]ecause the arrangement between Pfizer and OIG, under which Pfizer submitted the documents to the government, was entered into voluntarily, the information is, in turn, voluntarily submitted." *Id.*

Pfizer cites no legal authority for this remarkable proposition, and for good reason. "Whether supplied pursuant to statute, regulation, or some less formal mandate," disclosure of material to the government is involuntary where it is a "mandatory condition" on a right provided to the submitter of information. *Nat'l Parks*, 498 F.2d at 770. In contrast, "if an agency has no authority to enforce an information request, submissions are not mandatory." *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 244 F.3d 144, 150 (D.C. Cir. 2001).

For example, in *National Parks*, the D.C. Circuit determined that park concessioners involuntarily provided to the government information regarding audits of the concessioners' books and other financial information. In so doing, it emphasized that the disclosure of those records to the Park Service was "a mandatory condition of the concessioners' right to operate in national parks." *Id.*; *see also Pub. Citizen Health Research Grp. v. FDA*, 964 F. Supp. 413, 414 n.1 (D.D.C. 1997) (holding that a company involuntarily submitted a drug protocol because submission "was necessary in order to obtain FDA approval" of the drug).

[10] Those two documents are listed as entries 74 and 111 in Pfizer's *Vaughn* index. *See Vaughn* Index of Withheld Pfizer Inc. Docs., Doc. 18 at 41, 63; HHS SJ Mem. at 34 n.10.

Like the concessioners in *National Parks*, who agreed to submit information to the government as a condition of doing business in the parks, Pfizer elected to enter into a CIA as a condition of its continued ability to do business with federal health care programs. Pfizer's submission of annual reports to OIG was a mandatory condition on Pfizer's ability to enter into a CIA, for which an annual reporting requirement is a standard term. Murray Decl. ¶ 3, Attach. B. In exchange, Pfizer was assured that OIG would not seek to exclude the company from participation in federal health care programs.

Moreover, consistent with *Center for Auto Safety*, OIG had legal authority to require the annual reports. By the CIA's own terms, OIG could have imposed a monetary penalty of $1,000 for each day that Pfizer failed to comply with its annual report obligations. Pfizer CIA, Doc. 22-1 at 80. The CIA also permitted OIG to treat a "repeated or flagrant violation" of the annual report obligation as a material breach of the agreement and to seek Pfizer's exclusion as a consequence. *Id.* at 82.

In sum, Pfizer's submission of annual reports to OIG was involuntary, and the two-prong *National Parks* test applies to determine whether the records are confidential.

2. The records sought by Public Citizen would not cause substantial competitive harm to Pfizer or Purdue.

HHS and the companies argue in sweeping strokes that release of the withheld records would cause substantial competitive harm to Pfizer and Purdue (and, to a limited extent, PriceWaterhouseCoopers (PcW), which served as Purdue's IRO and produced that company's withheld IRO reports). As discussed below, HHS has not met its burden of demonstrating the likelihood of such harm with respect to the categories of documents sought by Public Citizen.

Under the *National Parks* prong relating to competitive harm, the government must demonstrate "[a]ctual competition and the likelihood of substantial competitive injury" to show

that Exemption 4 applies. *Gulf & W. Indus., Inc. v. United States*, 615 F.2d 527, 530 (D.C. Cir. 1979). The government must provide more than general and conclusory statements to demonstrate competitive harm. "[C]ourts in this Circuit routinely reject Exemption 4 arguments that are grounded in generalizations." *In Def. of Animals v. Nat'l Inst. of Health*, 543 F. Supp. 2d 70, 79 (D.D.C. 2008) (collecting cases); *see also, e.g., Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 906 (D.C. Cir. 1999); *Gov't Accountability Project v. Dep't of Health & Human Servs.*, 691 F. Supp. 2d 170, 179 (D.D.C. 2010).

To be cognizable under Exemption 4, a competitive injury must "flow[] from the affirmative use of proprietary information by competitors," *CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1154 (D.C. Cir. 1987) (internal quotation marks omitted), not, for example, from "customer or employee disgruntlement," *Pub. Citizen Health Research Grp.*, 704 F.2d at 1291 n.30. Moreover, Exemption 4 does not "guard against mere embarrassment in the marketplace or reputational injury." *United Techs. Corp. v. Dep't of Def.*, 601 F.3d 557, 564 (D.C. Cir. 2010). It does not extend, for example, to "the embarrassing publicity attendant upon public revelations concerning . . . illegal or unethical payments to government officials or violations of civil rights, environmental or safety laws." *Pub. Citizen Health Research Grp.*, 704 F.2d at 1291 n.30; *see also United Techs. Corp.*, 601 F.3d at 563-64 (holding that a competitor's attempt to "[c]all customers' attention to unfavorable agency evaluations or unfavorable press does not amount to an affirmative use of proprietary information by competitors" (internal quotation marks omitted)).

Relying on vague and conclusory assertions of harm, HHS and the companies have not met their burden to demonstrate that release of the records sought by Public Citizen is likely to cause the companies substantial competitive harm. In contrast, Public Citizen has produced

specific and detailed evidence showing that disclosure would not cause substantial competitive harm to Pfizer and Purdue.

Reportable Events. HHS asserts that the release of Reportable Event summaries would cause Pfizer and Purdue "significant competitive injury," HHS SJ Mem. at 45, or "commercial injury," *id.* at 49. But neither HHS's brief not the underlying declarations explains how competitors could use this information about suspected or confirmed unlawful conduct at all. *See* Nowicki Decl. ¶ 26, Doc. 22-1 at 44-45; Weinstein Decl. ¶ 25, Doc. 22-2 at 9-10. In fact, Reportable Event summaries would "not provide any meaningful or actionable information that a competitor would use to alter its sales tactics" or its "approach to the market to more effectively sell" or "position its products." Rodondi Decl. ¶ 14, attached as Exh. 4. "It is also unlikely that access to this information would prompt a shift in an overarching sales and marketing strategy because the focus is typically on differences in effectiveness and safety of competing products." *Id.* Although "some sales tactics might be included in the requested reports, the reports are unlikely to provide any meaningful insights that are not routinely obtained through customers sharing information about competitors; from intelligence gleaned at local, regional and national trade shows and clinical meetings; or from employees changing jobs to work for a competitor." *Id.* The age of the requested records also "makes the information less relevant as strategies and tactics are constantly evolving to address changes in the marketplace." *Id.*

Disclosure Log summaries. HHS argues that release of Disclosure Log summaries would cause "significant competitive harm to Pfizer" and, with respect to both companies, would have a chilling effect on internal whistleblower reports. HHS SJ Mem. at 46, 48. As an initial matter, whether public release of Disclosure Log summaries would have a chilling effect on whistleblowers is not a relevant consideration with respect to the competitive harm analysis.

Competitive injury must "flow[] from the affirmative use of proprietary information *by competitors*." *CNA Fin. Corp.*, 830 F.2d at 1154 (emphasis added). Moreover, HHS fails to explain how competitors could affirmatively use Disclosure Log summaries to cause Pfizer or Purdue substantial competitive harm.

The disclosure of Disclosure Log summaries would not cause Pfizer or Purdue substantial competitive harm because this kind of information, especially in light of its age, "would not be materially useful to a competitor to better position its products or to create a competitive advantage in the marketplace, particularly if names and personally identifiable information in the logs are redacted." Rodondi Decl. ¶ 25. Although "[i]ncidents reflected in the disclosure logs may include sales and marketing tactics that might violate applicable laws and regulations, . . . competitors are equally required to be in compliance with these laws and regulations." *Id.* "Having knowledge of Pfizer's compliance or non-compliance does not provide any meaningful information useful to competitors to position their products in the marketplace." *Id.*

Screening and removal of "Ineligible Persons." HHS asserts that release of information about Pfizer's Ineligible Person Management process, the names of Ineligible Persons on Pfizer's payroll, and actions taken by Pfizer to screen and remove Ineligible Persons would "reflect Pfizer's internal business processes and judgments made to develop and implement the Ineligible Person Management process as well as confidential information related to Pfizer's screening and removal of Ineligible Persons." HHS SJ Mem. at 46 (citing Nowicki Decl.). With respect to Purdue, HHS addresses documents relating to "Ineligible Persons" only as part of policies or practices that HHS has withheld that it says "directly relate to Purdue's compliance with legal and regulatory requirements." *Id.* at 41 (citing Weinstein Decl. at ¶ 15). Notably

missing from HHS's papers, however, is an explanation as to how release of these documents could cause substantial competitive harm to the companies.

Some of the information relating to Ineligible Persons is already publicly available, so it plainly is not confidential. For example, the CIAs describe in detail the process that Pfizer and Purdue must use to identify Ineligible Persons, and the corrective actions that the companies must take. Yet HHS did not provide any substantive information on Ineligible Persons. *See* Murray Decl. ¶ 5, Attach. D. In addition, as discussed above in Part IV.A.3 of the Background, the names of currently Ineligible Persons are available through government websites, which the CIAs direct the companies to use as a tool for screening Ineligible Persons.

In any event, Public Citizen has produced evidence that release of this information would not cause Pfizer or Purdue substantial competitive harm. As described in more detail in the Rodondi declaration, "[t]he process used by the company to screen for ineligible persons or the company's actions taken to comply with its obligations to screen and remove ineligible persons are likely similar [to] the same actions and processes taken by competing companies to comply with the various rules and regulations governing the pharmaceutical industry." Rodondi Decl. ¶ 22. "It is unlikely that a competitor would attempt to duplicate Pfizer and Purdue processes on these matters because these processes are widely known and each company tailors its program to its unique circumstances and based on its own assessment of compliance and risk management." *Id.*

Ongoing investigations or legal proceedings. HHS relies on the Nowicki and Weinstein declarations to assert that disclosure of government investigations and legal proceedings ongoing at the time of the annual reports would "cause Pfizer competitive harm," "could be useful to Pfizer's adversaries in current litigation," and would be "likely to have negative commercial

consequences for Purdue." HHS SJ Mem. at 45, 49. But the creation of a disadvantage in litigation is not covered by Exemption 4, which extends only to the affirmative use of proprietary information by competitors. *See Badhwar v. U.S. Dep't of the Air Force*, 622 F. Supp. 1364, 1377 (D.D.C. 1985) (holding that a company's "fear of litigation" was insufficient to establish competitive harm), *aff'd in part and rev'd in part on other grounds*, 829 F.2d 182 (D.C. Cir. 1987). And beyond the Nowicki declaration's reference to litigation, HHS presents nothing more than general and conclusory statements about competitive harm.

Moreover, some information in this category cannot be confidential because it should already be public through requisite company reports to shareholders. *See* Rodondi Decl. ¶¶ 17, 19; *CNA Fin. Corp.*, 830 F.2d at 1154. In any event, release of this information would not cause Pfizer and Purdue substantial competitive harm. It is unlikely "that a competitor would use information about a legal proceeding or ongoing government investigation regarding an alleged crime or fraudulent activity by Pfizer or Purdue to more effectively compete, to better position its products in the marketplace, or to create a competitive advantage." Rodondi Decl. ¶ 19. "Information about ongoing government investigations or legal proceedings is not typically materially useful to a competitor to create a competitive advantage in the marketplace." *Id.* "While it is possible that a competitor might try to use this information to paint Pfizer or Purdue in a bad light, negative tactics are not typically well received in the market nor are they very successful in creating a substantial competitive advantage [versus] differentiating competing products based on safety and efficacy." *Id.*

Company communications with the FDA about off-label promotion. HHS fails to demonstrate that the communications with the FDA about actual or potential unlawful drug promotion would cause substantial competitive harm. Instead HHS offers nothing beyond a

conclusory statement that release of this information would cause Pfizer substantial competitive harm. *See* HHS SJ Mem. at 46 (citing Nowicki Decl. ¶ 30).

In reality, communications with the FDA, which "substantively discuss[] misbranding or unlawful promotion by Purdue, or information on the promotion, discussion or dissemination of information about off-label uses of Pfizer products, [are] unlikely to provide information to a competitor that would cause substantial competitive harm." Rodondi Decl. ¶ 39. Instead, "[t]his information is more relevant to Purdue or Pfizer's compliance with applicable laws and regulations, not commercially sensitive information regarding the products' appropriate use or lawful promotion." *Id.*

Purdue's follow-up memorandum and supplement to its first annual report. HHS also withheld a transmittal memorandum and supplement to Purdue's first annual compliance report. *Vaughn* Index of Withheld Purdue Pharma L.P. Docs. (Purdue *Vaughn* Index), Doc. 19, Entry 22. Based on a review of the Purdue *Vaughn* Index and the redacted records falling within this category that were released to Public Citizen, the first memorandum and supplement appear to consist of a letter from Purdue to OIG that updates Purdue's previous annual report "with information that ha[d] recently come to the attention of the Company." Murray Decl. ¶ 6, Attach. E; *see also* Purdue *Vaughn* Index, Entry 22. HHS redacted from that letter *all* further explanation regarding what Purdue failed to submit in its annual report and the reasons for this oversight. *See* Murray Decl. ¶ 6, Attach. E. HHS also withheld the supplement, which—based on the last page of the otherwise withheld document—appears to be a training document. *Id.* Public Citizen does not seek access to this training module but does seek access to Purdue's cover memorandum to OIG.

HHS and the Weinstein Declaration assert, without more, that Purdue's cover memorandum cannot be released to the public because it is "proprietary and highly confidential" and would "be detrimental to Purdue" if disclosed. HHS SJ Mem. at 50 (citing Weinstein Decl. ¶ 29). This kind of general and conclusory statement falls short of the specificity necessary for the government to meet its burden under Exemption 4.

Pfizer's off-label findings and underlying records. HHS withheld records about detailing sessions between health care providers and covered persons working for Pfizer, including records reflecting the content of detailing sessions; reviews of detailing sessions for (1) Lipitor, (2) Viagra, (3) Zoloft, (4) Geodon, (5) Lyrica, and (6) Zyvox; and the findings of these reviews, including Pfizer's response to these findings. *See* Pfizer *Vaughn* Index, Entries 46, 48-53, 84, 86-91, 120, 122-127, 155, 157-162.

HHS asserts that information relating to the off-label findings "includes Pfizer's review methodology, contents of the detailing sessions, and limitations of the audits, analysis, and actions taken by Pfizer following the review sessions." HHS SJ Mem. at 47 (citing Nowicki Decl. ¶ 33). But both HHS and the Nowicki declaration fail to explain how competitors could use this information to cause injury to Pfizer's competitive position. *See id.* HHS's general and conclusory statement falls short of meeting its burden.

Public Citizen seeks only the disclosure of (1) off-label findings and Pfizer's response to these findings; (2) portions of the review of detailing sessions for specific drugs where the portions reveal off-label promotion; and (3) to the extent segregable, underlying detailing session records that reveal off-label promotion identified in the off-label findings. Public Citizen does not seek content of detailing sessions that reflect legal, on-label promotion. The release of this narrow category of information documenting illegal behavior is "unlikely to cause substantial

competitive harm to Pfizer." Rodondi Decl. ¶ 44. "The off-label uses of pharmaceuticals are generally known through experiences and case studies presented in the scientific literature and at professional meetings." *Id.* "While the withheld information may reveal whether Pfizer was engaged in marketing its products for off-label uses, or how the company responded if these practices were uncovered, these records would not provide any meaningful information for a competitor to better position its products [versus] a Pfizer product." *Id.* After all, off-label promotion by a drug manufacturer is illegal. Moreover, "information about how any pharmaceutical company engaged in discussions of off-label use, and about how a company manages compliance with applicable standards, is well described through laws, regulations and government guidelines provided to the industry . . . ." *Id.* And the age of the requested records makes them less relevant, as does the fact that "two of the drugs, Lipitor and Geodon, have now gone off patent and are generically available." *Id.*

IRO reports and the companies' responses / corrective action plans. HHS withheld the IRO reports, including certain attached letters (*see* Pfizer *Vaughn* Index, Entries 64, 100; Murray Decl. ¶ 7, Attach. F), the companies' responses to the reports, and even the name of Pfizer's IRO.[11] Public Citizen seeks only specific portions of the reports that fall into six general areas: (1) findings and recommendations by the IRO on the company's systems, policies, procedures, and practices;[12] (2) the IRO's assessment of the company's compliance with its policies and procedures;[13] (3) the IRO's assessment of corrective actions taken by the company;[14] (4) the

[11] Public Citizen does not seek the methodology of the IRO reports, including the type and order of the testing used by the IROs, unless such methodology is already publicly available, e.g., through the terms of the CIAs themselves.

[12] *See* Pfizer CIA, Attach. A, §§ I.A.2.c., I.B.4.b.2.; *id.*, Attach. C, § II.B.g.; Purdue CIA, App'x B, §§ III.B.2.l-o.

[13] *See* Pfizer CIA, Attach. A, §§ I.B.2.b.2, I.B.4.b.3-5; *id.*, Attach. C, §§ III.C.2.b.i-iii., III.C.2.c-d.; Purdue CIA, App'x B, §§ III.B.2.d., III.B.2.f-g. III.B.2.j.

IRO's determination of the root cause analysis of material errors of the company or the company's non-compliance with its policies and procedures;[15] (5) the IRO's assessment with the company's compliance with the CIA,[16] and (6) the IRO's description of the company's systems, policies, procedures, and practices.[17]

As an initial matter, HHS's assertion of competitive harm with respect to this information is wholly inadequate. For example, the Pfizer *Vaughn* Index, which addresses individual "tabs" of the withheld IRO Reports, simply uses the same boilerplate language for each tab, making no distinction with respect to the specific contents of each tab. *See, e.g.*, Pfizer Vaughn Index, Entries 22-29, 60-63.

In any event, release of the limited category of information concerning IRO reports sought by Public Citizen would not cause substantial competitive harm to Pfizer or Purdue. Information "regarding Pfizer's and Purdue's compliance program, policies, procedures, systems and business judgment required to maintain compliance and reflected in the IRO reports is unlikely to cause substantial competitive harm to Pfizer or Purdue, as this information will have many similarities to the compliance programs of other companies." Rodondi Decl. ¶ 35. "This information will not provide actionable information that will allow a competitor to more effectively sell its products in the marketplace or better position its products versus Pfizer or Purdue products." *Id.*

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[14] *See* Pfizer CIA, Attach. A, §§ I.B.2.b.3., I.B.4.b.3.; Pfizer CIA, Attach. C, §§ II.B.e., II.B.h., III.C.2.b.iv., III.C.2.c.; Purdue CIA, App'x B, §§ II.B.6., III.B.2.e., III.B.2.k.

[15] *See* Pfizer CIA, Attach. A, §§ I.B.3., I.B.4.b.4.; *id.*, Attach. C, §§ III.A.3 (last paragraph of section), III.D.2.d.

[16] *See* Purdue CIA, App'x B, §§ III.B.2.c., III.B.2.i.

[17] *See* Purdue CIA, App'x B, § II.B.5.

Moreover, release of the information sought by Public Citizen will not cause substantial competitive harm to PriceWaterhouseCoopers because "[m]any of the methods used to develop the findings and reports are described in both the Pfizer and Purdue CIAs, and information about the design, development and monitoring of compliance programs is discussed in public forums and professional meetings throughout the year." *Id.* ¶ 36.

3. Disclosure of records sought by Public Citizen will not impair HHS's ability to obtain necessary information in the future.

HHS also cannot meet its burden of showing that the withheld records are confidential under Exemption 4 by using the alternative prong of the *National Parks* test. Disclosure of the withheld records is not likely to "impair the Government's ability to obtain necessary information in the future." *Critical Mass*, 975 F.2d at 878 (quoting *Nat'l Parks*, 498 F.2d at 770).

"[W]hen dealing with a FOIA request for information the provider is required to supply, the governmental impact inquiry will focus on the possible effect of disclosure on its quality." *Id.* "A minor impairment cannot overcome the disclosure mandate of FOIA. Rather, the question must be whether the impairment is significant enough to justify withholding the information." *Wash. Post Co. v. Dep't of Health & Human Servs.*, 690 F.2d 252, 269 (D.C. Cir. 1982) (*Wash. Post I*). If disclosure would result in some impairment, the "inquiry necessarily involves a rough balancing of the extent of impairment and the importance of the information against the public interest in disclosure." *Id.*

HHS asserts that "health care providers currently under CIAs would be reluctant to provide complete information" if the withheld information were disclosed. HHS SJ Mem. at 50 (citing Demske Decl. ¶ 5). It also argues that "OIG's inability to prevent the disclosure of confidential proprietary information would severely impair [its] ability to negotiate meaningful

CIAs in the future." *Id.* (citing Demske Decl. ¶ 5). HHS's first argument is based on a faulty premise; its second argument is irrelevant as a matter of law. In any event, as discussed below, Public Citizen has introduced evidence countering HHS's summary judgment evidence in this regard. It has also demonstrated that the public interest in disclosure outweighs any non-minor government impairment.

First, HHS's argument with regard to impairment runs aground because it fails to account for companies' expectations at the time CIAs are created with respect to public disclosure. HHS predicts that companies subject to CIAs "may hesitate to fully explain the circumstances or submit their full investigative reports if they are concerned that the public may have access to that information" and that such companies might not provide disclosure logs "beyond the bare minimum necessary." HHS SJ Mem. at 50 (quoting Demske Decl. ¶ 5). But this argument assumes that companies, upon entering CIAs, are unaware that their information could be disclosed to the public. To the contrary, provisions in the CIAs signed by Pfizer, Purdue, and many other companies subject to CIAs make clear that records submitted to OIG are subject to disclosure under FOIA unless exempt. *See* Pfizer CIA, Doc. 22-1 at 76, 78; Purdue CIA, Doc. 22-2 at 48, 50; Murray Decl. ¶ 4, Attach. C. In other words, release to Public Citizen in this case should not change settled expectations.

Pfizer, which joins in HHS's argument, claims that its CIA with OIG contained a "FOIA exclusion" clause, suggesting that the government guaranteed Pfizer confidential treatment of submitted information. Pfizer SJ Mem. at 26. Pfizer's statement is inaccurate. *See* Pfizer CIA, Doc. 22-1 at 76, 78. In addition, it is belied by a letter that OIG sent to Pfizer in 2003. In that letter, which referred to Pfizer's submissions under its 2002 CIA, OIG warned Pfizer that if its "CIA materials [we]re requested under FOIA, such materials m[ight] not be fully exempt."

Murray Decl. ¶ 8, Attach. G. OIG also told Pfizer that it "should not assume that all of Pfizer's reports and other documents," even those bearing a "FOIA exempt" marking, "[would] be exempt from a FOIA request." *Id.*

Second, HHS mistakenly argues that its ability to negotiate future CIAs is a relevant consideration in determining whether disclosure will impair its ability to get necessary information in the future. That theory was rejected in *Washington Post Co. v. U.S. Department of Health and Human Services*, 865 F.2d 320 (D.C. Cir. 1989) (*Wash. Post II*), which involved the disclosure of federal peer review consultants' past employment and financial interests. In that case, the government submitted survey data of consultants to argue that "qualified individuals might forego participation in the peer review process altogether if their listing of financial interests were made publicly available." *Id.* at 323. According to the D.C. Circuit, "the district court correctly recognized that this information was irrelevant to the question of 'impairment'—that is, to whether those scientists who *do* become involved with NCI committees will narrowly construe the financial disclosure requests." *Id.*

In other words, the relevant inquiry in this circuit with respect to obtaining necessary information is whether people who participate in a program, such as CIA oversight, will disclose necessary information to the government in the future if they know that it will be released. That inquiry does not incorporate whether those individuals might reconsider their participation in the first place. The government and Pfizer's reliance on an unpublished, out-of-Circuit case, *see* HHS SJ Mem. at 51 (citing *Hersh & Hersh v. Dep't of Health & Human Servs.*, No. 06-4234, 2008 WL 901539 (N.D. Cal. Mar. 31, 2008)); Pfizer SJ Mem. at 28 (citing same), is unavailing.

Third, in any event, on the facts, there is little risk that disclosure under FOIA will lead companies to stop providing information required by a CIA or to enter into CIAs. Kesselheim

Decl. ¶¶ 13, 16. As a penalty for not submitting information required by the CIA, companies could be excluded from federal health programs and face additional fines. *Id.* Likewise, CIAs are generally explicit with regard to reporting requirements and the timing of reports. *Id.* ¶ 14. As a result, the "bare minimum" material under a CIA should provide sufficient documentation about companies' compliance behavior to facilitate monitoring. *Id.*

Moreover, even if OIG's ability to *negotiate* future CIAs were a relevant consideration here, HHS provides nothing more than general and conclusory predictions to support its theory. *See* HHS SJ Mem. at 50. In reality, companies have a strong incentive to negotiate CIAs to ensure their continued ability to participate in federal health care programs. *See* Murray Decl. ¶ 3, Attach. B. Moreover, multiple factors "promot[e] advantageous settlements for the government," including "the strength and reliability of the evidence supporting [a] case [against a drug manufacturer] and the impropriety of the behavior at issue." Kesselheim Decl. ¶ 16. Given the government's advantage in settlements that involve CIAs, "there is little risk these factors w[ill] be outweighed by the possibility that some CIA-mandated compliance information might one day be publicly available through a FOIA request." *Id.*

Fourth, if HHS could establish impairment cognizable under *National Parks*, the substantial benefit to the public from disclosure would outweigh that impairment. Although the D.C. Circuit has rejected a public-interest balancing to assess Exemption 4's competitive harm prong, *see Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d at 904, in evaluating government impairment, the Court is still "required to conduct [a] rough balancing of the extent of impairment and the importance of the information against the public interest in disclosure," *Wash. Post II*, 865 F.2d at 326.

The public has a strong interest in knowing whether CIAs are effective at identifying corporate fraud and other wrongdoing and deterring future unlawful conduct that affects federal health care programs. *See* Kesselheim Decl. ¶ 21; Wolfe Decl. ¶ 14. The records sought by Public Citizen will reveal whether the government's oversight has been successful in ending illegal marketing, or whether company practices have just become more subtle under OIG's scrutiny. Kesselheim Decl. ¶ 21. Independent analysis of the withheld materials could also help the public determine whether the government needs additional investigatory or oversight tools. *Id.*

C. Pfizer Errs by Asserting a "Self-Critical Analysis" Privilege Under FOIA.

Pfizer alone argues that its submissions to OIG, in addition to being "confidential," are also "privileged" under a so-called "self-critical analysis" privilege, and thus protected by Exemption 4 on alternative grounds. Pfizer SJ Mem. at 28. Pfizer's reliance on the self-critical analysis privilege is misplaced.

It is far from clear that the "self-critical analysis" privilege, which is intended to "encourage confidential self-analysis and self-criticism," *First E. Corp. v. Mainwaring*, 21 F.3d 465, 467 (D.C. Cir. 1994) (internal quotation marks omitted), would apply to Pfizer's documents in the discovery context. In *Federal Trade Commission v. TRW, Inc.*, for example, the D.C. Circuit held that the privilege did not apply to records subpoenaed by a government agency, and it stated that the "privilege at the most remain[ed] largely undefined and ha[d] not generally been recognized." 628 F.2d 207, 210 (D.C. Cir. 1980) (internal quotation marks omitted). More than a decade later, in *First E. Corp.*, the D.C. Circuit again expressed skepticism of the privilege, stating that one had been recognized only in the areas of public health or public safety, and then only in limited cases. 21 F.3d at 467 n.1.

Moreover, discovery rules "provide only rough analogies" for whether information is "privileged" for FOIA purposes. *Wash. Post I*, 690 F.2d at 268. FOIA incorporates "generally recognized civil discovery protections," protecting only information that is "routinely protected" in discovery. *Burka v. Dep't of Health & Human Servs.*, 87 F.3d 508, 516 (D.C. Cir. 1996). "[A] particular [discovery] privilege should be incorporated only after careful consideration of the language and legislative history of Exemption 4, its relationship to other exemptions, and the general disclosure mandate of FOIA." *Wash. Post Co. I*, 690 F.2d at 268. Not only is the "self-critical" analysis privilege not generally recognized, it appears to have lost favor in the past two decades. *See Dowling v. Am. Haw. Cruises, Inc.*, 971 F.2d 423, 426 (9th Cir. 1992) (collecting cases and stating that "[t]he Supreme Court and the circuit courts have neither definitively denied the existence of [the self-critical analysis] privilege, nor accepted it and defined its scope"); *Martin v. Potomac Elec. Power Co.*, No. 86-0603, 1990 WL 158787 (D.D.C. May 25, 1990) (stating that "[f]ederal district courts are moving away from earlier decisions embracing the privilege").

Thus, whatever the privilege's scope in discovery, it does not fill the bill for FOIA incorporation. Pfizer asserts to the contrary that "[c]ourts have long recognized" such an application of the privilege under FOIA Exemption 4. Pfizer SJ Mem. at 28. But it relies for that proposition on a single, unpublished opinion that is twenty-five-years old. *See id.* (citing *Wash. Post Co. v. Dep't of Justice*, No. 84-3581, 1987 U.S. Dist. LEXIS 14936, at *21 (D.D.C. Sept. 25, 1987), *rev'd in part on other grounds*, 863 F.2d 96, 99 (D.C. Cir. 1988)). Notably, in that same case on appeal, the D.C. Circuit avoided deciding the question whether information is exempt under Exemption 4 if subject to a privilege for self-evaluation reports. *See* 863 F.2d at 99. It called the question "less precedent-bound" than the one on which the court ultimately

resolved the case. *Id.* Pfizer's documents are thus not privileged for the purpose of FOIA Exemption 4.

II. FOIA Exemption 6 Does Not Apply.

HHS asserts that FOIA Exemption 6 protects from disclosure all information related to Ineligible Persons identified in the annual reports. HHS SJ Mem. at 52; *see also* Pfizer SJ Mem. at 30. Public Citizen does not seek the names, phone numbers, signatures, or e-mail addresses of any individuals not already disclosed by HHS. Public Citizen does seek, however, job titles, job descriptions, and personnel action taken by Pfizer and Purdue with respect to individuals identified in the annual reports as, for example, Ineligible Persons or persons engaged in Reportable Events. Exemption 6 does not apply to this narrow category of information.

For Exemption 6 to apply, "disclosure [must] compromise a substantial, as opposed to a de minimis, privacy interest. If no significant privacy interest is implicated[,] . . . FOIA demands disclosure." *Multi AG Media LLC v. Dep't of Agric.*, 515 F.3d 1224, 1229 (D.C. Cir. 2008) (quoting *Nat'l Ass'n of Retired Fed. Employees v. Horner*, 879 F.2d 873, 874 (D.C. Cir. 1989)). In this case, after names are removed, the individuals named in the annual reports have at most a de minimis privacy interest in the remaining information. *See Ray*, 502 U.S. at 175-76 (stating that even disclosure of migrants' "highly personal information regarding marital and employment status, children, living conditions and attempts to enter the United States" would constitute "only a *de minimis* invasion of privacy when the identities of the [individuals] are unknown"). FOIA Exemption 6 thus does not protect the information sought here.

Even if this Court found that individuals named in the requested records had more than a de minimis privacy expectation after their names were redacted, that finding would "not conclude the inquiry; it [would] only move[] it along to the point where we [could] 'address the

question whether the public interest in disclosure outweighs the individual privacy concerns.'" *Multi AG Media*, 515 F.3d at 1230 (quoting *Nat'l Ass'n of Home Builders*, 309 F.3d at 35). "Because the basic purpose of [FOIA] . . . focuses on the citizens' right to be informed about what their government is up to, information that sheds light on an agency's performance of its statutory duties is in the public interest." *Id*. at 1231 (alterations in original) (internal quotation marks omitted).

There is a strong public interest in releasing the job titles, job descriptions, and corrective actions taken by Pfizer and Purdue with respect to individuals engaged in wrongdoing. For example, under the terms of their CIAs, both Pfizer and Purdue were expressly precluded from hiring Ineligible Persons to participate in federal health care program activities. Moreover, an excluded individual engaged in federal health care programs is in violation of his exclusion, and a company that knowingly employs him is subject to civil fines. Release of the withheld information would inform the public about OIG's oversight of Pfizer and Purdue, that is, whether the companies took the actions required by their CIAs and applicable federal law and, if they did not, whether OIG responded to protect the public interest in preventing fraud and other wrongdoing in federal health care programs.

Accordingly, the public interest outweighs any privacy interest in job titles, job descriptions, and corrective company actions, divorced from the names of individuals. Exemption 6 therefore does not apply.

III. HHS Failed to Conduct an Adequate Search.

HHS asserts that it conducted an adequate search for records responsive to Public Citizen's FOIA request. HHS SJ Mem. at 31. But in records released to Public Citizen, Pfizer indicates that it intended to provide to OIG, under separate cover and at a later date, responses to

the IRO reports and any applicable corrective action plans. *See* Murray Decl. ¶ 9, Attach. H. The Pfizer IRO responses and corrective actions plans were required portions of the annual reports. *See* Pfizer CIA, Doc. 22-1 at 73. However, they are not clearly identified in the *Vaughn* Index of withheld Pfizer documents, nor has HHS produced these documents. Based on the description of the search in the declaration of Robin R. Brooks, HHS does not appear to have acknowledged these missing documents or attempted a follow-up search to find them. *See* Brooks Decl. ¶ 13, Doc. 22-1 at 4. HHS's search was thus inadequate. *See Campbell v. U.S. Dep't of Justice*, 164 F.3d 20, 28 (D.C. Cir. 1998) (holding that FBI's search was inadequate where it failed to "revise its assessment" of what constituted a reasonable search "to account for leads that emerged during its inquiry"). This Court should order HHS to conduct an additional search for these documents.

CONCLUSION

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

Respectfully submitted,

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May 31, 2012

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

PLAINTIFF'S STATEMENT OF GENUINE ISSUES
AND RESPONSE TO DEFENDANT'S STATEMENT OF MATERIAL FACTS
AS TO WHICH THERE IS NO GENUINE ISSUE

Plaintiff does not believe that there exist genuine issues of material fact that are necessary to be litigated in this case. Plaintiff believes that the case can be decided based on the facts set forth in its own statement of material facts, filed May 31, 2012, and the cases and argument set forth in the Memorandum in Support of Plaintiff's Motion for Summary Judgment and Opposition to Defendant's and Defendant-Intervenors' Motions for Summary Judgment (Pl.'s SJ Mem.). Plaintiff responds to the statement of material facts filed by defendant Department of Health and Human Services (HHS) as follows:

1. Undisputed.

2. Undisputed.

3. Plaintiff disputes that HHS searched all reasonably likely locations to find responsive documents. *See* Pl.'s SJ Mem. at 37-38, and cases and other material cited therein; Murray Decl. ¶ 9, Attach. H. Plaintiff does not dispute the remainder of this paragraph.

4. Undisputed.

5. Undisputed.

6. Undisputed.

7. Undisputed.

8. Undisputed.

9. Plaintiff does not dispute that annual reports *may* contain information about business plans and processes, costs, marketing initiatives, product development, product pricing, and security. Whether this information is confidential and proprietary to the health care provider or to the third party that performs an audit reflects a disputed legal conclusion, not a factual matter.

10. Undisputed.

11. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case. Whether protections for information are "a recurrent issue" for health care providers that enter Corporate Integrity Agreements (CIAs) is not relevant to the legal inquiry in this case. To the extent that this paragraph suggests that negotiations hinge on protections for information, Plaintiff disputes this assertion. Provisions indicating that some information submitted may be disclosed in response to a FOIA request are common in CIAs with drug manufacturers. *See* Murray Decl. ¶ 4, Attach. C.

12. Whether information submitted under a CIA is confidential or proprietary is a disputed legal conclusion, not a factual matter. Plaintiff disputes the remainder of this paragraph. *See* Pl.'s SJ Mem. at 30-34, Kesselheim Decl. ¶¶ 13-14, 16, 20.

13. Undisputed.

14. Undisputed.

15. Undisputed.

16. Disputed. All pharmaceutical companies are required to be in full compliance with appropriate laws and regulations, whether or not they are subject to a CIA. Rodondi Decl. ¶ 10. Most, if not all, pharmaceutical companies have implemented robust compliance programs to ensure these laws are met, and regular exchanges of information, policies, procedures and recommended programs on compliance are discussed in public forums at professional meetings throughout the year. *Id.*

17. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case. Public Citizen does not seek disclosure of compliance training modules.

18. Plaintiff does not dispute that Pfizer *treats* its policies and procedures as confidential and proprietary. Whether these documents actually are confidential is a disputed legal question, not a factual matter. The remainder of this paragraph is undisputed.

19. Undisputed.

20. Plaintiff agrees that it seeks portions of Pfizer's Annual Reports, including portions of Independent Review Organization (IRO) Reports. Plaintiff does not, however, seek those reports in their entirety. *See* Pl.'s SJ Mem. at 9-13 (describing records sought in litigation).

21. Undisputed.

22. Plaintiff does not dispute that Pfizer's documents were marked "Confidential and FOIA Exempt." Whether the documents contain "confidential commercial information" is a disputed legal question, not a factual matter. HHS has not defined what it means by the term "sensitive" as used in this paragraph. To the extent that HHS is using the term as a synonym for confidential, commercial information, that term is a disputed legal conclusion, not a statement of fact.

23. Undisputed.

24. Undisputed.

25. Plaintiff states that this paragraph contains only disputed legal conclusions, not facts.

26. Whether the materials described in this paragraph "constitute commercial or financial information that is likely to cause competitive harm to Pfizer" is a disputed legal conclusion, not a factual matter. Public Citizen does not dispute the remainder of this paragraph.

27. To the extent that any records sought by Plaintiff demonstrate that Pfizer's training materials violate applicable laws or regulations, Public Citizen disputes that Pfizer's training materials reflect Pfizer's "business" judgment. *See* Pl.'s SJ Mem. at 17-18, and the cases and materials cited therein. Plaintiff otherwise disputes that this paragraph sets forth a statement material to the disposition of this case because Plaintiff does not seek disclosure of training materials themselves.

28. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case because Plaintiff does not seek disclosure of training materials themselves.

29. Plaintiff does not dispute the first sentence of this paragraph. Plaintiff agrees with the second sentence that *part* of the IRO's role is to make an independent evaluation of Pfizer's Promotional and Product Related Functions. The IRO is also charged with other responsibilities, as set forth in the Pfizer CIA, Doc. 22-1 at 62-66, Attach. A, C.

30. Plaintiff does not dispute the first sentence of this paragraph. Plaintiff disputes that the remainder of this paragraph sets forth a statement material to the disposition of this case because Plaintiff does not seek disclosure of IRO engagement letters or workplans.

31. Plaintiff agrees that the IRO reports contain, among other things, the materials cited in this paragraph. Whether the materials described in this paragraph are "highly confidential" is a disputed legal conclusion, not a factual matter.

32. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case because Plaintiff does not seek materials "related to the IRO's engagement." Plaintiff understands HHS's reference to related materials not to include the IRO reports (including the name of the IRO), Pfizer's response to the IRO reports, and any applicable corrective action plans. Plaintiff also contends that whether information is confidential and commercial is a disputed legal conclusion, not a factual statement. HHS has not defined what it means by the term "sensitive" as used in this paragraph. To the extent that HHS is using the term as a synonym for confidential, commercial information, that term is a disputed legal conclusion, not a statement of fact.

33. Plaintiff disputes that this paragraph provides a complete definition of Reportable Events. The governing definition of Reportable Events and Pfizer's responsibilities with respect to them is supplied by Pfizer's CIA, Doc. 22-1 at 69-70, 74.

34. Plaintiff agrees with sentence one that Reportable Event summaries include information about the Reportable Event, Pfizer's internal investigation, and corrective actions. The portion of sentence one stating that information about Reportable Events is commercial sets forth a disputed legal conclusion, not a statement of fact. HHS has not defined what it means by the term "sensitive" as used in sentence one. To the extent that HHS is using the term as a synonym for confidential, commercial information, that term is a disputed legal conclusion, not a statement of fact. To the extent that the reference to "sensitive commercial information" in sentence one addresses an issue of fact, Plaintiff disputes it. *See* Pl.'s SJ Mem. at 17-18, and cases and materials cited therein; Rodondi Decl. ¶ 14. Sentence two consists of a disputed legal conclusion, not a factual statement. Plaintiff disputes the portions of the third and fourth sentences stating that release of Reportable Event summaries would be detrimental to OIG's interests and chill future disclosures. *See* Pl's SJ Memo. at 30-34, and cases and other materials cited therein; Kesselheim Decl. ¶¶ 13-14, 16. Plaintiff further states that the reference in sentence three to other companies' practices sets forth speculation that is not based on the expertise of the cited declarant.

35. Plaintiff does not dispute that Reportable Event summaries contain descriptions of corrective action. Plaintiff does not dispute that the Reportable Event summaries *may* contain information about whether Pfizer complied with its CIA; Plaintiff states that such information reflects instances of non-compliance with applicable federal laws or FDA requirements as well. Pfizer CIA, Doc. 22-1 at 69. Plaintiff does not dispute that Reportable Event summaries contain descriptions of sale and marketing tactics to the extent such tactics constitute a Reportable Event, i.e., an incident that a reasonable person would conclude violates laws applicable to federal

health care programs and/or FDA requirements relating to off-label promotion. *See* Pfizer CIA, Doc. 22-1 at 69.

36. Plaintiff disputes that summaries of ongoing government investigations or legal proceedings are not released by Pfizer or its competitors. Any ongoing investigations or legal proceedings that are significant or material should be reflected in the company's annual or other reports to its shareholders and therefore available to the public. *See* Pl.'s SJ Mem. at 24-25, and cases and materials cited therein; Rodondi Decl. ¶ 17. Plaintiff states that the characterization of this information as confidential and the assertion that it would cause competitive harm to Pfizer if released are disputed legal conclusions, not statements of fact. Plaintiff disputes that whether this information would be helpful to adversaries in current litigation is not a statement material to the disposition of this case. *See* Pl.'s SJ Mem. at 25, and cases and materials cited therein. HHS has not defined what it means by the term "sensitive" as used in this paragraph. To the extent that HHS is using the term as a synonym for confidential, commercial information, that term is a disputed legal conclusion, not a statement of fact.

37. Plaintiff does not dispute that the CIA requires Pfizer to submit the information identified in the paragraph. The assertion that this information is confidential is a disputed legal conclusion, not a statement of fact. Plaintiff disputes the rest of the paragraph. *See* Pl's SJ Mem at 23-24; Rodondi Decl. ¶ 22.

38. Plaintiff does not dispute sentence one. Plaintiff agrees that some correspondence between companies and FDA may be publicly available. The statement in sentence two that communications with FDA are typically "confidential commercial information" is a disputed legal conclusion, not a statement of fact.

39. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case. Plaintiff does not seek disclosure of the notifications described in this paragraph.

40. Plaintiff does not dispute the first and second sentences of this paragraph. The statement that the information is "confidential" and "would cause significant competitive harm to Pfizer" is a disputed legal conclusion, not a statement of fact. Plaintiff disputes that release of the disclosure log summaries without names and identifying information would discourage individuals from making reports. *See* Pl.'s SJ Mem. at 22-23, and cases and materials cited therein; Kesselheim Decl. ¶¶ 18-19. Plaintiff also disputes that release of this information would encourage entities to provide bare bones reports. *See* Pl.'s SJ Mem. at 30-34 and cases and materials cites therein; Kesselheim Decl. ¶¶ 13-14.

41. Plaintiff does not dispute sentences one and two. Plaintiff disputes sentence three's assertion that all information discussed in the paragraph is highly confidential because it is a disputed legal conclusion, not a statement of fact. Moreover, detailing session information is not Pfizer-generated and is commercially available. It is, thus, not confidential Pfizer information. *See* Pfizer CIA, Doc. 22-1 at 70.

42. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case. Plaintiff does not seek disclosure of Pfizer's organizational structure charts.

43. Plaintiff states that this paragraph consists of disputed legal conclusions, not statements of fact.

44. Undisputed.

45. Undisputed.

46. Plaintiff does not dispute the first sentence. Plaintiff has insufficient information to know what Purdue intended when placing the restrictive legend on the reports.

47. Plaintiff agrees that Purdue submitted the documents identified in sentence one. Plaintiff states that the whether this information is commercial and financial and FOIA exempt is a disputed legal question, not an issue of fact. To the extent that sentence one addresses a statement of fact beyond Purdue's actual submission of the documents identified in the sentence, Plaintiff disputes it. *See* Pl.'s SJ Mem. at 17-18, 20-30, and cases and materials cited therein; Rodondi Decl. ¶¶ 8-11, 14, 17, 19, 22, 25, 34-36, 39. Plaintiff states that sentence two consists of a disputed legal conclusion, not a statement of fact. To the extent sentence two provides a statement of fact, Plaintiff disputes it. *See generally* Pl.'s SJ Mem. 20-30, and cases and materials cited therein; Rodondi Decl. ¶¶ 8-11, 14, 17, 19, 22, 25, 34-36, 39.

48. Undisputed.

49. Plaintiff states that the reference in sentence one to the confidentiality of documents is a disputed legal conclusion, not a statement of fact. Plaintiff does not dispute the remainder of sentence one or sentences two and three.

50. Disputed. *See* Pl.'s SJ Mem. 20-30, and cases and materials cited therein; Rodondi Decl., *e.g.*, ¶¶ 10-11, 22, 33-35, 45.

51. Plaintiff does not dispute that Purdue's promotion policy and procedure are unique. Plaintiff does not have sufficient information to determine whether that policy and procedure "engenders trust and confidence in the company and its sales force professionals," or whether it "compl[ies] with all legal and regulatory requirements."

52. Plaintiff does not dispute that the materials cited in this paragraph relate to Purdue's compliance with legal and regulatory requirements. Plaintiff disputes that these documents are all proprietary in nature. *See* Rodondi Decl. ¶¶ 10-11, 22, 33-35, 45.

53. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case. Plaintiff does not seek the information cited in this paragraph.

54. Plaintiff disputes that this paragraph's reference to employee and Corporate Compliance Council names sets forth a statement material to the disposition of this case. Plaintiff does not seek any individuals' names in the withheld records. Plaintiff does, however, seek the job titles, job descriptions, and company actions taken with respect to Ineligible Persons. To the extent suggested by this paragraph, Plaintiff disputes that the Ineligible Persons information (with names redacted) constitutes identifying information. *See* Pl.'s SJ Mem. at 36-37, and cases and materials cited therein.

55. Undisputed.

56. Undisputed.

57. Plaintiff does not dispute sentence one. Plaintiff does not dispute sentence two's statement regarding the possible contents of the transactions. Plaintiff does not, however, seek all information identified in sentence two, in particular private patient information or customer identities. The reference in sentence two to "confidential" information is a disputed legal conclusion, not a statement of fact. HHS has not defined what it means by the term "sensitive" as used in sentence two. To the extent that HHS is using the term as a synonym for confidential, commercial information, that term is a disputed legal conclusion, not a statement of fact. Sentence three is a disputed legal conclusion, not a statement of fact. Plaintiff does not dispute sentence four.

58. Plaintiff disputes that sentence one sets forth a statement material to the disposition of this case. Plaintiff does not seek information regarding Purdue's selection of an IRO or its engagement agreements. Sentence two is a disputed legal conclusion, not a statement of fact. To the extent that sentence two's reference to the IRO Report and Purdue's response sets forth a statement of fact, Plaintiff disputes it. *See* Rodondi Decl. ¶ 34-35.

59. Plaintiff does not dispute sentences one, two, and four. Plaintiff does not dispute that the database is proprietary and confidential in the sense that Purdue does not disclose the database publicly. Whether the database is confidential as that term is used in FOIA is a disputed legal conclusion, not a question of fact.

60. Plaintiff does not dispute sentence one. Plaintiff disputes sentence two. Plaintiff does not seek the names or any identifying information about individuals in relation to the Disclosure Log summaries. Plaintiff disputes the assertion that revealing the Disclosure Log summaries would have a chilling effect on individual reports. Kesselheim Decl. ¶¶ 18-19.

61. Plaintiff does not dispute sentence one. Plaintiff disputes sentence two. Purdue's CIA contemplates that the Compliance Program need provide only "appropriate confidentiality" for "anonymous communications." Purdue CIA, Doc. 22-2 at 35. Plaintiff does not seek the names and identifying information of any individuals identified in disclosure log summaries.

62. Plaintiff does not dispute sentences one or two. Plaintiff states that sentence three sets forth a disputed legal conclusion, not a statement of fact. To the extent that sentence three addresses an issue of fact, Plaintiff disputes it. Pl.'s SJ Mem. at 24-25, and cases and materials cited therein; Rodondi Decl. ¶¶ 14, 45.

63. Plaintiff does not dispute sentence one. Plaintiff states that sentence two sets forth only a disputed legal conclusion, not a statement of fact. To the extent that sentence two

addresses an issue of fact, Plaintiff disputes it. Pl.'s SJ Mem. at 27-28, and cases and materials cited therein; Rodondi Decl. ¶¶ 17, 19, 45.

64. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case. Plaintiff does not seek internal compliance audits, as listed in the Purdue *Vaughn* Index, Doc. 19, Entries 5, 28.

65. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case. Plaintiff does not seek this category of documents reviewed by Purdue's legal counsel.

66. Plaintiff does not dispute sentence one. Plaintiff states that sentences two and three set forth a disputed legal conclusion, not a statement of fact. Plaintiff disputes that sentence four sets forth a statement material to the disposition of this case. Plaintiff does not seek employee calendar and contact information.

67. Plaintiff does not dispute sentence one. Plaintiff states that sentence two sets forth a disputed legal conclusion, not a statement of fact. To the extent that sentence two addresses an issue of fact, Plaintiff disputes it. *See* Pl.'s SJ Mem. at 31-32, and cases and materials cited therein; Rodondi Decl. ¶¶ 34-36. Plaintiff disputes that sentence three sets forth a statement material to the disposition of this case. Plaintiff does not seek employee names or signatures.

68. Undisputed.

69. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case. Plaintiff does not seek any individuals' names in the withheld records. Plaintiff does, however, seek the job titles, job descriptions, and company actions taken with respect to Ineligible Persons. To the extent suggested by this paragraph, Plaintiff disputes that

the Ineligible Persons information (with names redacted) constitutes identifying information. *See* Pl.'s SJ Mem. at 38-40, and cases and materials cited therein.

70. Plaintiff does not dispute sentence one. Plaintiff states that sentence two sets forth a disputed legal conclusion, not a statement of fact. To the extent sentence two addresses a statement of fact, Plaintiff disputes it. *See* Pl.'s SJ Mem. 31-32, and cases and materials cited therein; Rodondi Decl. ¶¶ 34-36. Plaintiff disputes that sentence three sets forth a statement material to the disposition of this case. Plaintiff does not seek any individuals' names or signatures in the withheld records.

71. To the extent that this paragraph covers names, signatures, e-mail addresses, and phone numbers, Plaintiff disputes that it sets forth a statement material to the disposition of this case. Plaintiff does not seek names, signatures, e-mail addresses, or phone numbers. *Id.* To the extent that this paragraph covers any other information pertaining to an individual, Plaintiff states that this paragraph sets forth a disputed legal conclusion, not a statement of fact. To the extent that this paragraph addresses an issue of fact, Plaintiff disputes it. *See* Pl.'s SJ Mem. at 38-40, and cases and materials cited therein; Pfizer CIA, Doc. 22-1 at 68 (making clear that information about certain Ineligible Persons is publicly available); Purdue CIA, Doc. 22-2 at 37 (same).

72. Plaintiff disputes that this paragraph sets forth a statement material to the disposition of this case. Plaintiff does not seek names, signatures, e-mail addresses, and phone numbers. Without this information, individuals do not have a privacy interest in the remainder of information pertaining to them in the withheld records. *See* Pl.'s SJ Mem. at 38, and cases and materials cited therein.

73. Plaintiff states that this paragraph sets forth legal conclusions, not statements of fact. To the extent that this paragraph sets forth any statements of fact, Plaintiff disputes them. *See* Pl.'s SJ Mem. at 38-40, and cases and materials cited therein; *see also* Wolfe Decl. ¶¶ 11-14; Kesselheim Decl. ¶ 21.

74. Plaintiff does not dispute that HHS took the actions described in this paragraph. It does dispute, however, the accuracy of HHS's segregability determination. Whether HHS released all reasonably segregable, non-exempt portions of the requested records is the legal issue in dispute in this case.

May 31, 2012

Respectfully submitted,

/s/ Julie A. Murray
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

PLAINTIFF'S STATEMENT OF MATERIAL FACTS
AS TO WHICH THERE IS NO GENUINE ISSUE

1. Public Citizen is a nonprofit public interest organization founded in 1971. It has fought for safe, effective, and affordable drugs and medical devices. Wolfe Decl. ¶ 2.

2. In 2009, Public Citizen submitted a FOIA request to the Office of Inspector General (OIG) in the Department of Health and Human Services (HHS), seeking (1) a copy of all annual reports submitted to OIG by Purdue pursuant to the May 2007 Corporate Integrity Agreement between OIG and Purdue, and (2) a copy of all annual reports submitted to OIG by Pfizer pursuant to the May 2004 Corporate Integrity Agreement between OIG and Pfizer. *Id.* ¶ 3.

3. OIG responded to the portion of Public Citizen's request seeking Purdue documents by partially releasing 84 pages of documents with portions withheld, and by

withholding 1,093 pages in full. Its letter in response to the portion of Public Citizen's request seeking Pfizer documents indicated that it was releasing 4,216 pages with portions withheld and withholding in full an additional 5,216 pages of records. *Id.*

4. Public Citizen appealed each of OIG's denials. On administrative appeal, OIG affirmed its denial of Public Citizen's request with respect to the records submitted to OIG by Purdue. At the time Public Citizen filed this lawsuit, OIG had not responded to Public Citizen's appeal with respect to the records submitted to OIG by Pfizer. *Id.* ¶ 4.

5. DOJ investigations of drug manufacturers under the False Claims Act and the Food Drug and Cosmetic Act are particularly powerful because under the Social Security Act companies found to have committed fraud may have their products excluded from reimbursement through federal health insurance programs such as Medicare and Medicaid. *Id.* ¶ 9.

6. Federal health care programs together account for a substantial fraction of drug reimbursement. *Id.*

7. Nearly every DOJ investigation into illegal marketing has resulted in a settlement with the defendant pharmaceutical manufacturer. *Id.*

8. A CIA usually lasts five years and imposes a series of compliance obligations on drug companies, including the submission of annual reports to OIG on the status of the company's compliance activities. Murray Decl. ¶ 3, Attach. B.

9. Drug companies agree to Corporate Integrity Agreement (CIA) obligations in exchange for OIG's agreement not to seek the companies' exclusion from participation in Medicare, Medicaid, and other federal health care programs. *Id.*

10. Pfizer has entered into three CIAs with OIG for conduct engaged in by Pfizer's own employees or the employees of companies that Pfizer acquired. Wolfe Decl. ¶ 11.

11. Submission of annual reports to OIG was a mandatory condition of Pfizer and Purdue's ability to enter into a CIA, for which an annual reporting requirement is a standard term. Murray Decl. ¶ 3, Attach. B; Pfizer CIA, Doc. 22-1 at 72; Purdue CIA, Doc. 22-2 at 45.

12. The Pfizer and Purdue CIAs at issue in Public Citizen's FOIA request provided for stipulated penalties, in nearly all instances accrued on a daily basis, for non-compliance with CIA obligations. *See* Pfizer CIA, Doc. 22-1 at 79-80; Purdue CIA, Doc. 22-2 at 50-51.

13. The Pfizer and Purdue CIAs made clear that if the companies materially breached the agreements, OIG could exclude the companies from all federal health care programs and other federal procurement and non-procurement programs. Pfizer CIA, Doc. 22-1 at 81-82; Purdue CIA, Doc. 22-2 at 53-54. The CIAs defined a "material breach" to include a failure to report a Reportable Event and take corrective action; a failure to hire or use an Independent Review Organization (IRO); or a "repeated or flagrant violation" of any CIA obligations. Pfizer CIA, Doc. 22-1 at 81-82; Purdue CIA, Doc. 22-2 at 53.

14. The Pfizer and Purdue CIAs contained a section, entitled "Designation of Information," which required the company to identify any portions of its submissions that it believed were "potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552." Pfizer CIA, Doc. 22-1 at 76; Purdue CIA, Doc. 22-2 at 48 (same).

15. The "Designation of Information" provision also instructed the company to "refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA." Pfizer CIA, Doc. 22-1 at 76 (emphasis added); Purdue CIA, Doc. 22-2 at 48 (same).

16. Another section in the Pfizer and Purdue CIAs entitled "Disclosures" provided that OIG would "make a reasonable effort to notify [each company]" before releasing information in response to a FOIA request if the company had designated the information "as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules." Pfizer CIA, Doc. 22-1 at 78; Purdue CIA, Doc. 22-2 at 50.

17. The "Disclosures" and "Designation of Information" provisions in the Pfizer and Purdue CIAs are common in CIAs between OIG and other drug manufacturers. *See* Murray Decl. ¶ 4, Attach. C.

18. OIG sent Pfizer a letter in 2003 referring to Pfizer's submissions under its 2002 CIA. Murray Decl. ¶ 8, Attach. G. That letter warned Pfizer that if its "CIA materials [we]re requested under FOIA, such materials m[ight] not be fully exempt." *Id.* OIG also told Pfizer that it "should not assume that all of Pfizer's reports and other documents," even those bearing a "FOIA exempt" marking, "[would] be exempt from a FOIA request." *Id.*

19. Pharmaceutical companies constantly evolve and shift their strategies and tactics to adapt to a changing environment. Companies must keep pace with, for example, the entry of new competing drugs into the market; loss of patent exclusivity of a drug within a drug class and the subsequent introduction of a cheaper generic version; and changes in reimbursement policies from private payers, Medicare, and Medicaid, which may introduce new challenges to successfully positioning a particular drug in the marketplace among those of competitors. Rodondi Decl. ¶ 8.

20. Due to the age of the materials sought by Public Citizen, public disclosure is less likely to cause substantial competitive harm to Pfizer or Purdue, as the competitive pressures in the marketplace have changed relative to the information contained in the requested documents.

Id. ¶ 9.

21. All pharmaceutical companies are required to be in full compliance with appropriate laws and regulations, whether or not they are subject to a CIA. *Id.* ¶ 10.

22. Most pharmaceutical companies have implemented robust compliance programs to ensure that applicable laws are not violated, and regular exchanges of information, policies, procedures and recommended programs on compliance are discussed in public forums at professional meetings throughout the year. *Id.*

23. The compliance programs developed by Pfizer and Purdue are designed to address the same laws and regulations that affect the entire industry. Each pharmaceutical company will highly customize its compliance program consistent with its organization, its products, the markets it serves, the level of risk it is comfortable with, and the advice of legal counsel and specialty consultants. For these reasons, any information released under the FOIA request regarding Pfizer's or Purdue's compliance program, policies, procedures, systems and business judgment required to maintain compliance is unlikely to cause substantial competitive harm to Pfizer or Purdue, as this information will have many similarities to the compliance programs of other companies. *Id.* ¶ 11.

24. The release of Reportable Events would not create a competitive advantage for competitors in the marketplace. Knowledge of events that are a probable violation of criminal, civil, or administrative law, or investigative results or actions taken as a result of these events, does not provide any meaningful or actionable information that a competitor would use to alter its sales tactics. Knowledge of these events does not provide any meaningful or actionable information that a competitor would use to alter its approach to the market to more effectively sell its products. Knowledge of these events does not provide any meaningful or actionable

information that a competitor would use to position its products as more safe and effective than Pfizer or Purdue products. *Id.* ¶ 14.

25. It is unlikely that release of Reportable Events would prompt a shift in a competitor's overarching sales and marketing strategy because the focus in the marketplace is typically on differences in effectiveness and safety of competing products. While some sales tactics might be included in the requested reports, the reports are unlikely to provide any meaningful insights that are not routinely obtained through customers sharing information about competitors; from intelligence gleaned at local, regional and national trade shows and clinical meetings; or from employees changing jobs to work for a competitor. *See id.*

26. Any ongoing investigations or legal proceedings that are significant or material should be reflected in a company's annual or other reports to its shareholders and therefore available to the public. *Id.* ¶ 17.

27. As the requests related to this FOIA are for documents from 2009 or earlier, the age of information about investigations or legal proceedings is less relevant as the investigations or proceedings would likely have been resolved or eventually become public. *Id.*

28. It is not likely that a competitor would use information about a legal proceeding or ongoing government investigation regarding an alleged crime or fraudulent activity by Pfizer or Purdue to more effectively compete, to better position its products in the marketplace, or to create a competitive advantage. It is also unlikely that access to this information would prompt a shift in an overarching sales and marketing strategy because the focus in the marketplace is typically on differences in effectiveness and safety of competing products. Information about ongoing government investigations or legal proceedings is not typically materially useful to a competitor to create a competitive advantage in the marketplace. *Id.* ¶ 19.

29. The process used by the company to screen for ineligible persons or the company's actions taken to comply with its obligations to screen and remove ineligible persons are not unique to a company. They are likely similar to the same actions and processes taken by competing companies to comply with the various rules and regulations governing the pharmaceutical industry. *Id.* ¶ 22.

30. It is unlikely that a competitor would attempt to duplicate Pfizer or Purdue processes on screening for ineligible persons because these processes are widely known and each company tailors its program to its unique circumstances and based on its own assessment of compliance and risk management. It is very unlikely that the release of this information would create any competitive advantage for a competitor in selling its products in the marketplace, as this information is available to the public. *Id.*

31. The information in the disclosure logs would not be materially useful to a competitor to better position its products or to create a competitive advantage in the marketplace, particularly if names and personally identifiable information in the logs are redacted. Incidents reflected in the disclosure logs may include sales and marketing tactics that might violate applicable laws and regulations; however, competitors are equally required to be in compliance with these laws and regulations. Having knowledge of Pfizer's or Purdue's compliance or non-compliance does not provide any meaningful information useful to competitors to position their products in the marketplace. *Id.* ¶ 25.

32. Information on which organizations provide services as an IRO to the pharmaceutical industry is generally available through public means. *Id.* ¶ 28.

33. Having knowledge of the name of Pfizer's IRO provides no meaningful information that could be used by a competitor to better position its products in the marketplace

nor would it provide a competitive advantage to Pfizer competitors. *Id.*

34. The limited categories of information in the IRO Reports, company responses, and company corrective action records that Public Citizen seeks address the following areas: the IRO's assessment of the strength of Pfizer and Purdue's compliance program, whether the companies follow their programs, corrective actions the companies take related to non-compliance or material errors, Purdue's compliance with its CIA, and the IRO's description of Purdue's compliance program. The information sought under the FOIA request regarding Pfizer's and Purdue's compliance program, policies, procedures, systems and business judgment required to maintain compliance, which is reflected in the IRO reports, is unlikely to cause substantial competitive harm to Pfizer or Purdue, as this information will have many similarities to the compliance programs of other companies. This information will not provide actionable information that will allow a competitor to more effectively sell its products in the marketplace or better position its products versus Pfizer or Purdue products. *Id.* ¶ 35 & nn.2-7.

35. The IRO Report information sought by Public Citizen would not cause substantial competitive harm to PriceWaterhouseCoopers if released because many of the methods used to develop the findings and reports are described in both the Pfizer and Purdue CIAs, and information about the design, development and monitoring of compliance programs is discussed in public forums and professional meetings throughout the year. *Id.* ¶ 36.

36. Disclosure of correspondence to the FDA that substantively discusses misbranding or unlawful promotion by Purdue, or information on the promotion, discussion or dissemination of information about off-label uses of Pfizer products, is unlikely to provide information to a competitor that would cause substantial competitive harm. This information is more relevant to Purdue or Pfizer's compliance with applicable laws and regulations, not

commercially sensitive information regarding the products' appropriate use or lawful promotion. *Id.* ¶ 40.

37. The disclosure of (1) off-label findings and Pfizer's response to these findings; (2) the review of detailing sessions for specific drugs where the review reveals off-label promotion; and (3) underlying detailing session records that reveal off-label promotion are unlikely to cause substantial competitive harm to Pfizer. The off-label uses of pharmaceuticals are generally known through experiences and case studies presented in the scientific literature and at professional meetings. Information about how any pharmaceutical company engages in discussions of off-label use, and about how a company manages compliance with applicable standards, is well described through laws, regulations and government guidelines provided to the industry, and is not unique to Pfizer. *Id.* ¶ 44.

38. While the withheld information related to Pfizer's off-label findings may reveal whether Pfizer was engaged in marketing its products for off-label uses, or how the company responded if these practices were uncovered, these records would not provide any meaningful information for a competitor to better position its products versus a Pfizer product. *Id.*

39. The age of the information about Pfizer's off-label findings makes it less relevant. In addition, two of the drugs, Lipitor and Geodon, have now gone off patent and are generically available. The release of the requested information for these two drugs is less relevant to competitors. This is particularly true of any sales or marketing information in the withheld records as the approach to the marketplace by competitors is constantly evolving to adapt to changing market conditions. *Id.*

40. Information relating to Pfizer's or Purdue's compliance or non-compliance with applicable laws, regulations or government guidance to the pharmaceutical industry is unlikely to

be useful to competitors to more effectively position their products versus Pfizer or Purdue products. The methods to develop effective compliance programs are well described and commonly shared through regular educational meetings and through consultants serving the pharmaceutical industry. *Id.* at ¶ 45.

41. There is little risk that HHS's compliance with Public Citizen's request for information related to the oversight of the CIAs will lead companies to under-report compliance information. If a company withheld "full" information required to be submitted by a CIA, and the government learned of this behavior, the government could find that the company violated its CIA. As a result, the company could be subject to federal health program exclusion and fines. Kesselheim Decl. ¶ 13.

42. CIAs generally make explicit what needs to be reported and the timing for this reporting. Even if companies provide only the "bare minimum," such material will provide adequate documentation about their compliance behaviors. *Id.* at ¶ 14.

43. Despite the possibility of public availability of the compliance reports, companies nonetheless remain incentivized to provide the maximum amount of evidence supporting their CIA compliance. If the government overseer becomes concerned that data are being obfuscated or hidden, the company risks being held in noncompliance with the CIA. *Id.* ¶ 14.

44. When a pharmaceutical manufacturer is investigated by the DOJ, the strength and reliability of the evidence supporting the case and the impropriety of the behavior at issue are the key determinants in settlement negotiations. In whistleblower cases, the substantial risk of government program exclusion hangs over the defendant pharmaceutical manufacturer. As a result, in the pharmaceutical cases in which the government intervenes, settlements are overwhelmingly likely. Given all of these factors promoting advantageous settlements for the

government, there is little risk these factors would be outweighed by the possibility that some CIA-mandated compliance information might one day be publicly available through a FOIA request, leading to hypothetical competitive harm. *Id.* ¶ 16.

45. Releasing disclosure logs will not hinder internal company workers with evidence of possible compliance violations from coming forward. People who choose to report their bosses and not participate in illegal pharmaceutical marketing behavior generally possess strong faith in their convictions and are unlikely to be dissuaded by the remote possibility that their names might eventually be revealed many years later through a FOIA request. *Id.* ¶ 18.

46. Revealing disclosure logs without the names of any individuals who made reports of alleged violations, nor any other personally identifiable information about such individuals, makes the possibility that this information will dissuade whistleblowers from coming forward even less likely. *Id.* ¶ 19.

47. To the extent that the annual reports sought by Public Citizen reveal instances of illegal activity by the companies, the public has a strong interest in knowing that OIG had access to this information, and in knowing whether OIG acted forcefully in responding to it. Wolfe Decl. ¶ 14.

48. The withheld information would provide insight into the success of the government's operations and activities in enforcing CIAs imposed for improper marketing activities. The information sought will reveal whether the government's oversight has been successful in ending illegal marketing, or whether the government has uncovered evidence that the internal practices investigated by the DOJ have simply changed. Kesselheim Decl. ¶ 21.

49. Release of the withheld information might inform additional steps to promote the successful execution of the government's CIA oversight, such as enhancing the government's

investigatory resources or seeking protective legislation from the government that might provide overseers with additional needed authorities. *Id.*

May 31, 2012

Respectfully submitted,

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