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., Defendants-Intervenors.	Civil Action No. 11-1681 Judge Beryl A. Howell

REPLY IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

As plaintiff Public Citizen explained in its memorandum in support of summary judgment, the documents it seeks from defendant Department of Health and Human Services (HHS) are not exempt from disclosure under Exemptions 4 or 6 of the Freedom of Information Act (FOIA), and HHS did not conduct an adequate search in response to the request. The arguments made by HHS, Pfizer, and Purdue in response are unavailing. **First**, the documents at issue in this case are not "confidential" for the purpose of Exemption 4, as set forth in the two-prong *National Parks* test, and HHS's attempt to add what amounts to a third prong to the *National Parks* test should be rejected. **Second**, some of the withheld documents must be disclosed for the separate reason that they reveal only potential or actual illegal activity. Information about such activity is not "commercial" for the purpose of Exemption 4. **Third**, HHS's withholdings under Exemption 6 are not moot. It is clear from the Pfizer *Vaughn* index that HHS relied on Exemption 6 to withhold information beyond employee names, e-mail addresses, signatures, and telephone numbers. **Fourth**, HHS failed to conduct an adequate search for missing Pfizer responses and corrective action plans; the documents to which HHS points as the missing documents are not the ones absent from the Pfizer *Vaughn* index. **Fifth**, none of Pfizer's separate arguments has any merit. And **sixth**, the Court should reject HHS's request for another chance to meet its burden in this case.

ARGUMENT

I. The Documents Sought by Public Citizen Are Not Covered by Exemption 4.

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). The two-prong test set forth in *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770

(D.C. Cir. 1974), applies to mandatory submissions, such as those Public Citizen seeks here. Under that test, information is confidential 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 Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 878 (D.C. Cir. 1992) (en banc) (quoting *Nat'l Parks*, 498 F.2d at 770). 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).

Exemption 4 does not apply to the records sought here. As an initial matter, HHS's argument that the Court should consider the impact of possible disclosure on the agency's ability to negotiate future CIAs in its analysis of confidentiality would add what amounts to a third prong to the *National Parks* test and should be rejected. Moreover, under the two-prong *National Parks* test, the records are not confidential because they will neither impair the government's ability to obtain necessary information in the future nor cause substantial competitive harm to the companies. In addition, several categories of documents sought by Public Citizen, as identified in Part I.D, reveal likely or actual unlawful activity. Accordingly, these documents cannot be commercial.

A. HHS's attempt to add a third prong to the *National Parks* test to account for its ability to negotiate future CIAs should be rejected.

In its initial filing, HHS asserted that the government's interest in negotiating CIAs is a relevant consideration in determining whether the government's ability to obtain necessary information in the future will be impaired for the purpose of *National Parks*' first prong. HHS's S.J. Mem. at 26; *see also* Pfizer's S.J. Mem. at 20-22. As Public Citizen has explained, Pl.'s S.J. Mem. at 32, however, the D.C. Circuit rejected such a theory in *Washington Post Co. v. HHS*,

865 F.2d 320, 326 (D.C. Cir. 1989) (*Washington Post II*). HHS and Pfizer assert that *Washington Post II* does not control because, in that case, the government had waived any argument that the risk of future nonparticipation in a government program was relevant to Exemption 4. *See* HHS's Reply at 13 n.4; Pfizer's Reply at 12-13. It is true that the D.C. Circuit concluded that the government failed to raise such an argument as a separate cognizable interest, apart from the two recognized in the *National Parks* test. *See Washington Post II*, 865 F.2d at 327 & n.9. But to conclude that the nonparticipation argument was waived, the court necessarily held that it was outside the scope of the government's interest in obtaining necessary information in the future, which the court *did* consider. *See id.* at 323.

In its reply, HHS now urges the Court to recognize an interest in program effectiveness—here, the interest in negotiating CIAs—as separate from the two interests embodied by the *National Parks* two-prong test. *See* HHS's Reply at 13-14. HHS's theory should be rejected. HHS is correct that in *Critical Mass*, the D.C. Circuit indicated "that the two interests identified in the *National Parks* test are not exclusive." 975 F.2d at 879. But *Critical Mass* did so in the context of holding that Exemption 4 also protects a private interest in preserving confidential information *voluntarily* submitted to the government, so long as that information is not customarily shared with the public. *Id.* at 878. Although *Critical Mass* noted that a vacated panel opinion in the case had concluded that Exemption 4 "protects a governmental interest in administrative efficiency and effectiveness," *id.* at 879, it did not so hold, *see id.* at 880. And although some district court decisions—such as those cited by HHS—have directly or indirectly relied on *Critical Mass* to recognize a "program effectiveness" interest under Exemption 4, the D.C. Circuit has ignored its dicta in the twenty years since *Critical Mass*. In fact, it has stated on numerous occasions that involuntarily shared information is confidential "only" if it meets

National Parks' two-prong test. *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 559 (D.C. Cir. 2010); *accord McDonnell Douglas Corp. v. NASA*, 180 F.3d 303, 305 (D.C. Cir. 1999); *Pub. Citizen Health Research Group v. FDA*, 185 F.3d 898, 903 (D.C. Cir. 1999); *Trans-Pac. Policing Agreement v. U.S. Customs Serv.*, 177 F.3d 1022, 1026 (D.C. Cir. 1999); *Bartholdi Cable Co., Inc. v. FCC*, 114 F.3d 274, 281 (D.C. Cir. 1997).

Moreover, HHS's argument is at odds with the Supreme Court's decision in *Federal Open Market Committee of the Federal Reserve System v. Merrill*, 443 U.S. 340 (1979). *Merrill* held that Exemption 5, which protects certain inter-agency or intra-agency documents, *see* 5 U.S.C. § 552(b)(5), did not "confer[] general authority upon an agency to delay disclosure of intra-agency memoranda that would undermine the effectiveness of the agency's policy if released immediately." 442 U.S. at 353. It concluded that such a position would "run counter to Congress' repeated rejection of any interpretation of the FOIA which would allow an agency to withhold information on the basis of some vague 'public interest' standard." *Id.* at 354. Yet HHS now seeks to import such a vague public interest standard into Exemption 4 by focusing on the effectiveness of its CIA negotiations.

The Second Circuit has rejected a similar argument as inconsistent with *Merrill*. In *Bloomberg, L.P. v. Board of Governors of the Federal Reserve System*, that court considered disclosure under FOIA of records about loans that the Federal Reserve Banks made to private banks. 601 F.3d 143, 145-46 (2d Cir. 2010). Just as HHS argues that disclosure would hinder the negotiation of meaningful future CIAs, the Board of Governors in *Bloomberg* argued that if banks' information were disclosed, "banks under stress m[ight] hesitate to seek relief or rescue," *id.* at 150-51, and thus impair the Board's mission "to furnish critical infusions to distressed banks on a confidential basis," *id.* at 150. *Bloomberg* rejected the Board's argument that

Exemption 4 applied, holding that such a position would "give impermissible deference to the agency" and be "the functional equivalent" of the public interest standard that *Merrill* rejected.[1] *Id.* This Court should likewise reject HHS's argument.

HHS's argument about its ability to negotiate CIAs fails as well because HHS has provided only general and conclusory statements to support its theory of harm. *See* Demske Decl. ¶¶ 4-5 (stating that protection of information is a "recurrent issue" in negotiations and release would "severely impair our ability to negotiate meaningful CIAs"); Weinstein Suppl. Decl. ¶ 3 (stating that "disclosure of a company's proprietary information . . . would hinder the negotiations between OIG and health care providers"). Notably, not one declarant states that companies will likely refuse to negotiate CIAs rather than risk public disclosure of their annual reports to OIG, nor does anyone explain how CIAs could thereby become less meaningful. HHS also provides no evidence about the importance of negotiating CIAs to the HHS Office of Inspector General's (OIG) mission. Public Citizen's FOIA request sought to examine the effectiveness of the CIAs for that very purpose.

In contrast, Public Citizen introduced detailed testimony from Dr. Aaron Kesselheim, Assistant Professor of Medicine at Harvard Medical School and a Research Associate with the Department of Health Policy and Management at the Harvard School of Public Health. Dr. Kesselheim explained that "the possibility that some CIA-mandated compliance information might one day be publicly available through a FOIA request" is unlikely to outweigh the factors favoring the government in settlements that lead to CIAs. Kesselheim Decl. ¶ 16. He also stated

[1] The Second Circuit noted that the early panel opinion in *Critical Mass Energy Project v. Nuclear Regulatory Commission*, 830 F.2d 278, 287 (D.C. Cir. 1987), had been overruled on other grounds, but the Second Circuit nonetheless appeared to treat that opinion as precedential on the "program effectiveness" issue. *See* 601 F.3d at 150. As noted above, however, the panel opinion was vacated in its entirety by the D.C. Circuit en banc. *See Critical Mass*, 975 F.2d at 880.

that "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." *Id.* In response, HHS states only that it "does not dispute that there are a variety of factors that companies consider when entering into a CIA" but disputes that the release of information is not among those factors. HHS's Resp. to Pl.'s Statement of Material Facts ¶ 44.[2] Because HHS's statement does not respond to Dr. Kesselheim's testimony about the key determinants in settlement negotiations, Dr. Kesselheim's assessment should be deemed undisputed. *See* Local Rule 7(h).

B. HHS has not demonstrated that disclosure is likely to impair the government's ability to obtain necessary information in the future.

Turning to the first prong of the actual *National Parks* test, HHS argues that the records at issue are confidential because their disclosure would impair the government's ability to obtain necessary information in the future from companies subject to CIAs. HHS's argument should be rejected.

1. The undisputed facts demonstrate that disclosure will not impair the government's ability to obtain necessary information in the future.

Based on the undisputed facts, disclosure is not likely to impair HHS's ability to obtain necessary information in the future. First, HHS has conceded that "CIAs generally make explicit what needs to be reported." Pl.'s Statement of Material Facts ¶ 42; HHS's Resp. to Pl.'s Statement of Material Facts ¶ 42. Second, it agrees that "[d]espite the possibility of public availability of the compliance reports, companies nonetheless remain incentivized to provide the maximum amount of evidence supporting their CIA compliance." Pl.'s Statement of Material Facts ¶ 43; HHS's Resp. to Pl.'s Statement of Material Facts ¶ 43. Third, HHS cites no evidence

[2] Pfizer and Purdue have not responded to Public Citizen's statement of material facts. Under Local Rule 7(h), this Court may therefore assume those facts are admitted by the defendants-intervenors. *See, e.g.*, *SEC v. Banner Fund Int'l*, 211 F.3d 602, 616 (D.C. Cir. 2000); *Hunter v. Rice*, 480 F. Supp. 2d 125, 130 (D.D.C. 2007).

to dispute that "if companies provide only the 'bare minimum'" required under a CIA, "such material will provide adequate documentation about their compliance behaviors." Pl.'s Statement of Material Facts ¶ 42; HHS's Resp. to Pl.'s Statement of Material Facts ¶ 42. The Court should thus deem this fact admitted under Local Rule 7(h). *Fed. Ins. Co. v. Olawuni*, 539 F. Supp. 2d 63, 68 (D.D.C. 2008). On these facts, it is clear that companies will continue to provide necessary information, despite possible public disclosure.

2. HHS's evidence is based on circular reasoning and does not show that disclosure will cause HHS to lose access to any information necessary to monitor CIAs.

Even setting aside HHS's factual admissions, HHS's own evidence is insufficient to meet its burden on *National Parks*' first prong for at least three reasons. First, HHS's declarations begin with the premise that the withheld records *are* confidential and that release would *therefore* impair the government's ability to obtain necessary information in the future. The government then asserts, in circular fashion, that such impairment indicates that the records are confidential under *National Parks*' first prong. For example, Mr. Gregory Demske, OIG's Assistant Inspector General for Legal Affairs, described the following outcome "[i]f the OIG were to release *confidential proprietary information* submitted under a CIA":

> [H]ealth care providers currently under CIAs would be reluctant to provide complete information; for example, in reporting instances of possible noncompliance, providers may hesitate to fully explain the circumstances or submit their full investigative reports if they are concerned that the public may have access to that information, which could harm them competitively. The resulting withholding of information would impair the OIG's ability to monitor the CIAs.

Demske Decl. ¶ 5 (emphasis added); *see also* Nowicki Decl. ¶ 36. But Mr. Demske's statement does not address whether releasing information that is not already deemed confidential—presumably under the competitive harm prong of *National Parks*, discussed *infra*, Part I.C—will

affect the government's ability to obtain necessary information in the future. As such, his declaration fails to justify withholding under *National Parks*' first prong alone.

Second, the government's impairment argument hinges on similarly circular reasoning with respect to the CIA FOIA provisions. At bottom, HHS contends that companies' submissions are FOIA-exempt, so companies reasonably expect—based on the CIA FOIA provisions that permit disclosure of submissions unless otherwise exempt under FOIA—that HHS will not release their records. HHS then contends that companies will be less likely than they currently are to provide necessary information if their information were released, and thus the records are exempt under *National Parks*' first prong. *See* HHS's Reply at 10-11.

HHS characterizes Public Citizen's focus on the CIA FOIA provisions as an argument that companies waive their rights under FOIA by agreeing to CIAs. *Id.* at 11. Because Public Citizen has not made this argument, the cases cited by HHS in its reply—*Lakin Law Firm, P.C. v. FTC*, 352 F.3d 1122 (7th Cir. 2003), and *Hill v. Department of Agriculture*, 77 F. Supp. 2d 6 (D.D.C. 1999), *aff'd*, 2000 WL 520724 (D.C. Cir. Mar. 7, 2000)—are inapposite. What Public Citizen has argued is that release in this case will not change settled expectations, since Pfizer, Purdue, and other companies have always expected that their submissions could be released if not exempt under FOIA. *See* Pl.'s S.J. Mem. at 31 (and evidence cited therein). The CIA FOIA provisions do not render the documents exempt under the government impairment prong just because the companies (mistakenly) believe that the documents are exempt.

Third, even assuming that companies now submit some information beyond that required by CIAs, the government has not introduced any evidence that it expects a loss of information *necessary* to monitor CIAs, nor does it explain why it cannot negotiate future CIAs to require more information, should public disclosure affect the quality of submissions. In response to

plaintiff's evidence that the "bare minimum" under CIAs "will provide adequate documentation about [companies'] compliance behaviors," Pl.'s Statement of Facts ¶ 42, the government obliquely responds by stating that it does not agree "that there is no value in information submitted in excess of the 'bare minimum.'" HHS's Resp. to Pl.'s Statement of Facts ¶ 42; *see also* Pfizer's Reply at 14 (asserting that disclosure "would cause companies to be reluctant to provide expansive information," which "would certainly diminish the quality of the information received by the OIG"). HHS's assertion—even if it were supported by evidence, which it is not—is insufficient to satisfy the applicable legal standard: Because "[a] minor impairment cannot overcome the disclosure mandate of FOIA," the appropriate inquiry is "whether the impairment is significant enough to justify withholding the information." *Wash. Post Co. v. HHS*, 690 F.2d 252, 269 (D.C. Cir. 1982) (*Washington Post I*). The government's unsupported assertion that there is some value in information submitted in excess of that required by a CIA falls far short of meeting that standard.

3. Under the public interest balancing test applicable to* National Parks*' first prong, Public Citizen should prevail.

Even if HHS could demonstrate that release of the information would hinder its ability to obtain necessary information in the future, the Court is "required to conduct [a] rough balancing of the extent of impairment and the importance of the information against the public interest in disclosure." *Washington Post II*, 865 F.2d at 326-27 (internal quotation marks omitted); *see also* Pl.'s S.J. Mem. at 33-34. The companies do not dispute that a balancing test applies, and although HHS disagrees in its response to Public Citizen's statement of facts, *see* HHS's Resp. to Pl.'s Statement of Facts ¶¶ 47-49, it provides no discussion or case cites. Like the defendant-intervenors, then, HHS has waived any objection to such a test. *See, e.g.*, *Jones v. Bernanke*, 557 F.3d 670, 676-77 (D.C. Cir. 2009). In any event, HHS and the companies do not provide any

rationale for concluding that the government interest in maintaining the quality of current information outweighs the strong public interest in disclosure. *See generally* HHS's Reply at 9-14; Pfizer's Reply at 12-14. And although HHS claims to dispute Public Citizen's evidence regarding the public interest, *see* HHS's Resp. to Pl.'s Statement of Facts ¶¶ 48-49, it cites no evidence in rebuttal. Public Citizen's evidence should thus be deemed admitted. *Fed. Ins. Co.*, 539 F. Supp. 2d at 68. Because the public interest in disclosure outweighs any possible impairment, the records are not confidential under *National Parks*' first prong.

4. The defendants' heavy reliance on* Hersh *is misplaced.

In support of their government impairment argument, HHS and Pfizer rely heavily on *Hersh & Hersh v. HHS*, 2008 WL 901539 (N.D. Cal. Mar. 31, 2008). *Hersh* held that disclosure of a company's annual reports and certain other documents submitted "pursuant to a felony plea agreement and [CIA]" with OIG was "likely to impair the Government's ability to obtain necessary information in the future." *Id.* at *1, *6. It concluded that the documents were covered by Exemption 4 because disclosure would both impair the government's ability to monitor CIAs and to negotiate them. *Id.* at *6-*7.

Hersh is distinguishable on at least three grounds. First, *Hersh* concluded that as part of the CIA negotiation between OIG and the company, "and as understood by [the company], the government obligated itself in good faith not to disclose the documents or information received pursuant to the CIA." *Id.* at *7. That conclusion was central to *Hersh*'s holding. *See id.* But whether or not that conclusion was accurate in *Hersh*, it certainly is not accurate here. *See* Pl.'s S.J. Mem. at 14, 31-32; Murray Decl. ¶ 8, Attach. G. Second, *Hersh* assumed that the government's ability to negotiate future CIAs was a proper consideration under *National Parks*' first prong. *See* 2008 WL 901539, at *6-*7. It does not appear that the plaintiff contested that

legal assumption, nor is it clear how the court would have evaluated the government impairment prong had it considered the impact of disclosure only on OIG's ability to monitor CIA compliance, not its ability to negotiate CIAs. Third, the plaintiff in *Hersh* introduced no expert testimony to dispute the assertions of impairment. *See generally* Docket Report, *Hersh & Hersh*, No. 06-4234 (N.D. Cal.). In contrast, Public Citizen introduced expert declarations that—at a minimum—rebut any of HHS's evidence on this issue.

C. HHS has failed to demonstrate that disclosure is likely to cause substantial competitive harm to Pfizer or Purdue.

HHS argues that the records sought by Public Citizen are also "confidential" under the second prong of the *National Parks* test because disclosure is likely to cause Pfizer and Purdue substantial competitive harm. In making this argument, HHS relies largely on the same general and conclusory statements predicting competitive harm on which it relied in support of its initial motion. As Public Citizen has explained, these assertions are insufficient to meet the government's burden under Exemption 4, *see* Pl.'s S.J. Mem. at 21, and Public Citizen's detailed evidence points to the opposite conclusion, *see id.* at 22-30.[3] Moreover, Exemption 4 does not cover records that disclose a company's engagement in unlawful activity, such as those whose disclosure leads to "embarrassing publicity." *See Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291 n.30 (D.C. Cir. 1983); *see also* Pl.'s S.J. Mem. at 21. Nonetheless, a few points that affect the competitive harm analysis warrant reply.

1. HHS misapplies the governing legal standard for substantial competitive harm.

HHS argues that "when a company invests time and other resources into developing policies and procedures, among other things, [it] will face competitive harm if those products are

[3] After further review, Public Citizen has determined that HHS released the names of the Independent Review Organizations for both Pfizer and Purdue. It thus no longer asserts that HHS improperly withheld this particular information.

released to the public." HHS's Reply at 15-16 (alterations and internal quotation marks omitted). HHS wrongly contends that Public Citizen "conceded" this argument, HHS's Reply at 16, and it misunderstands the governing legal standard.

HHS is mistaken to the extent that it argues that companies suffer competitive harm just by spending time and money on something disclosed to the public, regardless of whether competitors would use to their advantage the product of that time and money. Rather, as Public Citizen has consistently argued, *see* Pl.'s S.J. Mem. at 20-21, the government must show that disclosure is likely to cause substantial competitive harm to the submitter, where such harm "flow[s] 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). And, as the declaration of Dr. Kevin Rodondi, Associate Professor of Clinical Pharmacy at the University of California, San Francisco, makes clear, Pfizer and Purdue's competitors are not likely to use the withheld information to their advantage. *See* Rodondi Decl. ¶¶ 9, 11, 14, 17, 19, 22, 25, 28, 35-36, 39, 44-45.

Worthington Compressors, Inc. v. Costle, on which HHS and Pfizer rely, is not to the contrary. 662 F.2d 45 (D.C. Cir. 1981). In fact, the paragraph of *Worthington* quoted by HHS makes clear that the cost of creating information does not itself give rise to Exemption 4 coverage. *See* HHS's Reply at 15. Exemption 4 attaches only if competitors would and could use that information—that is, enjoy a "potential windfall . . . [from] valuable information," *Worthington*, 662 F.2d at 51—to the disadvantage of the submitter. Such is not the case here.

2. HHS's reliance on* United Technologies *is misplaced.

In addition to more general legal arguments about the withheld documents, HHS argues that three categories of information—Reportable Events, Disclosure Log summaries, and lists of

Ineligible Persons—are analogous to the quality control processes of defense contractors at issue in *United Technologies*, 601 F.3d at 557, and are thus exempt under *National Parks*' second prong. *See* HHS's Reply at 6. HHS's argument should be rejected.

As an initial matter, HHS misreads *United Technologies*, which did not hold, as HHS asserts, "that release of information about a company's proprietary quality control processes would cause [a] company substantial competitive harm." HHS's Reply at 16. Rather, in that reverse-FOIA case under the Administrative Procedure Act, the court rejected an agency's conclusory assertion that release of such information would *not* cause the submitters competitive harm and, therefore, remanded for further agency consideration. *United Techs.*, 601 F.3d at 562, 564-65. Moreover, *United Technologies* concerned records that "describe[d] the timing and criteria of internal inspections." *Id.* at 564. In this case, the timing and criteria of investigations for Reportable Events, Disclosure Log summaries, and lists of Ineligible Persons are no secret; in fact, the CIAs describe the applicable timing and criteria in great detail. *See* Pfizer CIA, Doc. 22-1 at 66-70, 73-74; Purdue CIA, Doc. 22-2 at 34-38, 46.

3. Exemption 4 does not cover records of unlawful activity.

As Public Citizen explained in its earlier memorandum, Exemption 4 does not cover harm, such as reputational injury, caused by release of records that reveal unlawful conduct. *See* Pl.'s S.J. Mem. at 21 (citing *Pub. Citizen Health Research Group*, 704 F.2d at 1291 n.30). As a result, the government's generalized assertions of competitive harm do not apply—as a matter of law—to 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. Each of these categories of records reveals a company's likely

or actual unlawful activity. Exemption 4's coverage does not protect companies either from public rebuke for such activity, *see Pub. Citizen Health Research Group*, 704 F.2d at 1291 n.30, or from competitors' use of information about how to break the law.

4. HHS's evidence is vague, conclusory, and, in Mr. Weinstein's case, permeated by a legally erroneous understanding of competitive injury.

In its opposition and reply, HHS generally recites the kinds of information contained in the withheld records and then states without further evidentiary explanation that the information is exempt from disclosure because its release would cause substantial competitive harm to the drug companies. *See* HHS's Reply at 16-18. What HHS does not do is respond directly to Public Citizen's detailed, category-specific evidence that disclosure is not likely to cause substantial competitive harm to the drug companies. *See* Rodondi Decl. ¶¶ 9, 11, 14, 17, 19, 22, 25, 28, 35-36, 39, 44-45. For example, on ten separate occasions in its response to Public Citizen's statement of facts, HHS relies solely on a single paragraph of Ms. Robin Brooks' declaration to rebut Dr. Rodondi's detailed testimony. *See* HHS's Resp. to Pl.'s Statement of Facts ¶¶ 23-25, 28, 34-38, 40. That paragraph provides in full:

> The records contain Pfizer and Purdue's commercial or financial information. Separate declarations filed by Pfizer and Purdue explain the confidential nature of the information, as well as the competitive nature of the submitter's industry and the likelihood of substantial competitive harm. Thus, the records qualify as confidential commercial or financial information.

Brooks Decl. ¶ 25. This general and conclusory statement falls far short of meeting HHS's burden of showing substantial competitive injury.

Even HHS's flashes of specificity are misplaced. It spends an entire paragraph explaining why Pfizer's organizational structure is "precisely the type of information that the D.C. Circuit has held is confidential." HHS's Reply at 18. But as Public Citizen has made clear, it seeks only specific categories of records among those withheld by HHS. *See* Pl.'s Mot. for S.J.

at 1; Pl.'s S.J. Mem. at 9-13 & n.3. Public Citizen does not seek records documenting Pfizer's organizational structure. *See* Pl.'s Resp. to HHS's Statement of Facts ¶ 42.

HHS's supplemental declaration of Mr. Weinstein addresses with specificity only one category of documents, and even then, only with respect to whether those documents are publicly available. *See* Weinstein Suppl. Decl. ¶ 10. Mr. Weinstein's declaration thus suffers from the same lack of detail that beset HHS's earlier declarations. *See* Pl.'s S.J. Mem. at 21-30. In addition, a legally erroneous understanding of competitive harm permeates Mr. Weinstein's testimony. Mr. Weinstein states that "competitive injury can certainly be based on reputational damage to a company" and that such damage "impacts the recruiting and retention of employees and members to the Board of Directors, results in a loss of confidence in the company and affects patients and health care providers alike." Weinstein Suppl. Decl. ¶ 7. But Exemption 4 does not "guard against . . . reputational injury." *United Techs.*, 601 F.3d at 564; *see also Judicial Watch v. U.S. Dep't of Treasury*, 802 F. Supp. 2d 185, 208 (D.D.C. 2011) (Howell, J.) (rejecting as "irrelevant" to Exemption 4 an assertion that releasing certain information would "cause decreased [employee] morale"); Pl.'s S.J. Mem. at 21. Mr. Weinstein's testimony thus piles legal error upon evidentiary insufficiency, revealing that his vague predictions of harm are based on a fundamental misunderstanding of the scope of Exemption 4. *See, e.g.*, Weinstein Decl. ¶ 25 (predicting "commercial injury"), *id.* ¶ 26 ("negative commercial consequences"); *id.* ¶ 27 ("commercial harm"); *id.* ¶ 31 (stating "disclosure would be detrimental to Purdue").

5. HHS fails to rebut evidence that the age of the documents makes disclosure less likely to cause substantial competitive harm to the companies.

In his declaration in support of Public Citizen, Dr. Rodondi explained that the age of the withheld records makes disclosure even less likely to cause substantial competitive harm to Pfizer and Purdue. *See* Rodondi Decl. ¶¶ 8-9, 14, 17, 19, 25, 44-45. HHS faults Public Citizen

for "vague[ness]," and contends that old information is not necessarily stale. HHS's Reply at 18. But Dr. Rodondi explained why the age of the withheld information *in this case* makes the information less relevant in the marketplace: As HHS concedes, "[t]he pharmaceutical marketplace is in constant flux," and drug companies must "evolve and shift their strategies and tactics to adapt to [a] changing environment," which includes the entry of new competing drugs, loss of patent exclusivity, and changes in reimbursement policy by federal health care programs. Rodondi Decl. ¶ 8 (conceded by HHS Resp. to Pl.'s Statement of Facts ¶ 19); *see id.* ¶ 19 (stating that investigations or legal proceedings "ongoing by 2009 are now probably resolved or public"); *id.* ¶ 44 (discussing impact of end of patent exclusivity for Lipitor and Geodon on usefulness of Pfizer's off-label findings and related documents); *see also id.* ¶¶ 9, 14, 25, 45 (discussing relevance of age generally and with respect to Reportable Events and Disclosure Log summaries).

Mr. Weinstein's supplemental declaration makes no attempt to rebut Dr. Rodondi's category-specific assessments of the impact of age in this case. Instead, Mr. Weinstein responds that "the time period in question is not that long ago" and that "although Purdue has continued to enhance its Compliance Program since that time, it is built on a solid foundation that is captured in the components Purdue put in place in 2007 and 2009, and reflects a substantial ongoing investment of Purdue's resources." Weinstein Suppl. Decl. ¶ 9. Thus, on the issue of age, Public Citizen has introduced specific, detailed evidence that HHS has not rebutted beyond offering a conclusory statement applicable to the withheld documents generally.

6. Dr. Rodondi's testimony about the customization of compliance programs does not support withholding.

HHS seizes on Dr. Rodondi's statement that each drug company customizes its compliance program, arguing that his statement indicates that "Purdue and Pfizer's competitors

could use this information in developing strategies to compete." HHS's Reply at 17-18 (citing Rodondi Decl. ¶ 11). But HHS ignores Dr. Rodondi's adjacent conclusion that public disclosure of the records is "unlikely to cause substantial competitive harm to Pfizer or Purdue." Rodondi Decl. ¶ 11. Moreover, as Dr. Rodondi explained, each company's compliance program is tailored to its unique attributes, such as risk tolerance, products, or markets. *Id.* As a result, the end product of a company's customization is unlikely to be useful to competitors.

D. Some of the withheld documents are not exempt from disclosure under Exemption 4 for the separate reason that they are not "commercial."

In support of its motion for summary judgment, Public Citizen argued that information about a company's violation of laws and regulations is not "commercial," and so is not protected from disclosure by Exemption 4. Pl.'s S.J. Mem. at 17-18. Many of the records that Public Citizen seeks—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.

HHS disputes that "information otherwise plainly commercial in nature . . . [could] lose[] its status simply due to potential fraud or illegal activity." HHS's Reply at 7. Pfizer similarly contends that the records here are commercial because it has a commercial interest in legal compliance. Pfizer's Reply at 6-7. As an initial matter, the documents sought by Public Citizen do not just concern "potential" illegal conduct. Rather, some of the documents may reveal clearly unlawful activity. *See, e.g.*, Pl.'s S.J. Mem. at 10 n.5 (discussing legal bar to employment of ineligible persons); *id.* at 3-4 (discussing illegal, off-label promotion). Moreover, even if a

company has a legitimate interest in legal compliance, *see* Pfizer's Reply at 6-7, it does not give rise to such an interest in information revealing *non-compliance.*

HHS and Pfizer rely on five cases to assert that "courts have upheld the withholding of commercial information of companies accused of potential wrongdoing, even when that information was directly related to the potential wrongdoing." HHS's Reply at 7-8; *see also* Pfizer's Reply at 5-6. In all but one of these five cases, however, the courts did not even address an argument that documents revealing actual or potential illegal activity are not, as a matter of law, "commercial" under Exemption 4. *See Am. Mgmt. Servs., LLC v. Dep't of the Army*, 842 F. Supp. 2d 859, 879-84 (E.D. Va. 2012); *M/A-Com Info. Sys., Inc. v. HHS*, 656 F. Supp. 691, 692-93 (D.D.C. 1986); *Hersh & Hersh*, 2008 WL 901539, at *6; *ISC Group, Inc. v. U.S. Dep't of Def.*, 1989 WL 168858, at *2-*4 (D.D.C. May 22, 1989). Because issues "assumed but never expressly decided . . . do not thereby become precedents," *Am. Portland Cement Alliance v. EPA*, 101 F.3d 772, 776 (D.C. Cir. 1996), these cases are irrelevant. In the remaining case, *Watkins v. U.S. Bureau of Customs & Border Protection*, the plaintiff sought notices of seizure for imported goods that were confiscated on suspicion of being counterfeit. 643 F.3d 1189, 1192 (9th Cir. 2011). The plaintiff argued that the notices could not be commercial because they pertained to "the unlawful importation of counterfeit goods, and not any sort of legitimate commercial activity." *Id.* at 1195. The Ninth Circuit concluded that because the goods were only *suspected* to be counterfeit, it was not certain that they were illegal and, therefore, not commercial. *Id*. It noted that "importers sometimes acquiesce in the [a]gency's seizure and forfeiture of *legitimate* goods." *Id.* In contrast, here, some of the documents would reveal clearly unlawful activity.

This Court should thus hold that Public Citizen is entitled to summary judgment on the alternative ground that the following subset of records sought by Public Citizen is not "commercial" for the purpose of Exemption 4: 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.

II. The Court Should Order HHS to Revisit Its Exemption 6 Withholdings.

HHS argues that its Exemption 6 withholdings are now moot because Public Citizen does not seek the names, phone numbers, signatures, or e-mail addresses of any individuals not already disclosed by HHS and because HHS did not apply Exemption 6 to other information, such as job titles, job descriptions, and personnel actions taken by Pfizer and Purdue. HHS's Reply at 21. Although the lawfulness of HHS's Exemption 6 withholdings are moot as to Purdue, for which the *Vaughn* index reveals only limited Exemption 6 withholdings, the withholdings are not moot as to Pfizer. First, the declaration of Ms. Brooks, on which HHS relies, states that HHS redacted "employee names and personal identifying information, *such as* telephone numbers and email addresses." Brooks Decl. ¶ 27 (emphasis added); *see also* HHS's S.J. Mem. at 28. And the Pfizer *Vaughn* index indicates that HHS withheld information beyond names, signatures, e-mail addresses, and phone numbers. Three entries applicable to Reportable Events state that HHS withheld information because disclosure "would violate the privacy of Pfizer and its employees as the records could expose the number and scope of 'Reportable Events,' the individuals involved in the events, the internal workings of Pfizer's compliance system, and the handling of sensitive employment matters." Pfizer *Vaughn* Index, Entries 41, 115, 151.

For the reasons stated in Public Citizen's motion for summary judgment, the Court should, therefore, order the release of all information withheld under Exemption 6 except for employee names, signatures, e-mail addresses, and telephone numbers. *See* Pl.'s S.J. Mem. at 36-37. Moreover, the Court should direct HHS to review all Exemption 6 withholdings applied to the records themselves, not just those reflected in the *Vaughn* index, which fails to accurately reflect all such withholdings.[4]

III. HHS Failed to Conduct an Adequate Search.

In its opposition and reply, HHS argues that its *Vaughn* index for Pfizer documents accounts for Pfizer's responses and corrective action plans in response to Pfizer's Independent Review Organization (IRO) reports. HHS's Reply at 5. HHS points to Pfizer *Vaughn* Index Entries 174 to 176. *Id.* HHS's contention has two flaws. First, the entries to which HHS points are for documents that cover only the years 2006, 2008, and 2009; Pfizer, however, agreed to submit responses and corrective action plans as necessary under separate cover in the first three years of its CIA (i.e., 2005-2007), and under separate cover or in the IRO reports themselves in the last two years of the CIA (i.e., 2008-2009). *See* Murray Decl. ¶ 9 & Attach. H. Moreover, the letters to which OIG points provide only "supplemental information that [OIG] requested" in response to Pfizer's annual reports. Murray Suppl. Decl. ¶ 5, Attach. D; *see also id.* ¶¶ 6-7 & Attach. E-F (using similar language). As a result, these documents—even if they discuss

[4] *Compare* Pfizer *Vaughn* Index, Entry 40 (not relying on Exemption 6), *with* Murray Suppl. Decl. ¶ 2, Attach. A (relying on Exemption 6); *compare* Pfizer *Vaughn* Index, Entry 114 (relying on Exemption 6), *with* Murray Suppl. Decl. ¶ 3, Attach. B (not relying on Exemption 6); *compare* Pfizer *Vaughn* Index, Entry 150 (relying on Exemption 6), *with* Murray Suppl. Decl. ¶ 4, Attach. C (not relying on Exemption 6). HHS has also withheld entire pages of documents, listing only Exemption 4 in the Pfizer *Vaughn* index to justify such withholdings. Because Public Citizen does not have access to those pages, it cannot identify whether other inconsistencies exist in the application of the exemption between the *Vaughn* index and the documents.

Pfizer's responses to IRO reports—are not the initial responses or corrective action plans required by Pfizer's CIA, *see* Pfizer CIA, Doc. 22-1 at 73; *see also* Pfizer's S.J. Mem. at 10, but follow-up responses to comply with specific requests from OIG.

HHS also contends that its search was nevertheless adequate, even if the responses and corrective action plans were not discovered. HHS's Reply at 3-4. A search is inadequate, however, when an agency fails to "revise its assessment" of what constitutes a reasonable search "to account for leads that emerge[] during its inquiry." *Campbell v. U.S. Dep't of Justice*, 164 F.3d 20, 28 (D.C. Cir. 1998). HHS was on notice during its review of the records disclosed to Public Citizen that Pfizer had intended to submit additional documents required by its CIA under separate cover, and HHS has thus far not identified efforts to look for those specific documents.

HHS also argues that Public Citizen cannot challenge the adequacy of its search because Public Citizen failed to raise the issue in its administrative appeal and in its complaint. HHS's Reply at 5 n.1. The inadequacy of the search, however, became apparent only after HHS filed the *Vaughn* indexes in litigation. Thus, Public Citizen raised the issue at the earliest opportunity. Particularly given that "exhaustion is a prudential consideration rather than a jurisdictional prerequisite," *Wilbur v. CIA*, 355 F.3d 675, 677 (D.C. Cir. 2004), there is no justification for penalizing Public Citizen for not expressly contesting the adequacy of the search before Public Citizen had reason to suspect that the search was inadequate. Moreover, Public Citizen's complaint broadly sought "to compel [HHS] to produce records responsive to [its] FOIA request," a claim that covers the adequacy of HHS's search. Compl. ¶ 1.

IV. Pfizer's Separate Arguments Are Without Merit.

Pfizer makes several separate arguments in which neither HHS nor Purdue joins.

A. The records sought by Public Citizen were submitted involuntarily; Pfizer's argument to the contrary is at odds with well-established law.

Public Citizen, HHS, and Purdue agree that the documents at issue were involuntarily submitted. In its opposition and reply, however, Pfizer again argues that its records were "voluntarily submitted" because "Pfizer voluntarily agreed" to enter a CIA with OIG. Pfizer's Reply at 3. It thus contends that its documents receive greater protection from disclosure under Exemption 4 than do involuntary submissions. *Id.* at 7.

Pfizer's argument is contrary to well-established law. "For purposes of Exemption 4, information provided to the government because it is required for participation in a voluntary government program is treated as a mandatory, as opposed to a voluntary, submission of information." *Judicial Watch, Inc. v. U.S. Dep't of Treasury*, 796 F. Supp. 2d 13, 35 n.8 (D.D.C. 2011) (Howell, J.); *see also Nat'l Parks*, 498 F.2d at 770; *Pub. Citizen Health Research Group v. FDA*, 964 F. Supp. 413, 414 n.1 (D.D.C. 1997). Put another way, if the government has legal authority to enforce a submission, the submission is mandatory. *See Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 244 F.3d 144, 149 (D.C. Cir. 2001).

Under this governing legal standard, the undisputed facts make clear that Pfizer submitted its annual reports involuntarily. Submission of annual reports was a mandatory condition of Pfizer's ability to enter into a CIA. Pl.'s Statement of Material Facts ¶ 11 (citing Murray Decl. ¶ 3, Attach. B; Pfizer CIA, Doc. 22-1 at 72); HHS's Resp. to Pl.'s Statement of Material Facts ¶ 11. And under the terms of the CIA, OIG could penalize Pfizer for non-compliance. *See* Pl.'s Statement of Material Facts ¶¶ 12-13 (citing Pfizer CIA, Doc. 22-1 at 79-82); HHS's Resp. to Pl.'s Statement of Material Facts ¶¶ 12-13.

Pfizer argues in the alternative that at least the "extra information" it provided to OIG, "not specifically required by the CIA, was voluntarily submitted." Pfizer's Reply at 9. Pfizer

has identified only two documents that its CIA did not require, *see* Pfizer's S.J. Mem. at 17 (citing Pfizer *Vaughn* Index, Entries 74, 111), neither of which Public Citizen seeks, Pl.'s S.J. Mem. at 19 & n.10. Pfizer's alternative argument is thus irrelevant here.

B. Pfizer's argument for applying administrative deference to HHS's prediction of substantial competitive harm is unavailing.

Pfizer argues that the Court should defer to HHS's determination regarding substantial competitive harm and government impairment. Pfizer's Reply at 11, 14. But as FOIA states and as case after case in the D.C. Circuit recognizes, judicial review of agency action under FOIA is de novo, and the agency bears the burden of proof to defend its decision to withhold. 5 U.S.C. § 552(a)(4)(B); *see also, e.g.*, *Mobley v. Dep't of Justice*, _ F. Supp. 2d__, 2012 WL 2354352, at *4 (D.D.C. June 8, 2012) (Howell, J.). The two cases cited by Pfizer are not to the contrary. Neither case was brought under FOIA's de novo standard. Rather, in each, a reverse-FOIA litigant asserted an Administrative Procedure Act claim, to which an "arbitrary, capricious, or an abuse of discretion" standard applied. *CNA Fin. Corp.*, 830 F.2d at 1155; *see United Techs.*, 601 F.3d at 562-63.

Pfizer makes a related argument that the Demske declaration is entitled to "dispositive weight" in the competitive harm analysis. Pfizer's Reply at 11-12. But that declaration refers only in passing to competitive harm, relying on such harm as a premise for the main point that disclosure will impair the government's ability to monitor and negotiate CIAs. Demske Decl. ¶ 5. It says nothing about why disclosure is likely to cause substantial competitive harm.

C. Pfizer's documents are not covered by a "self-critical analysis" privilege.

Pfizer continues to assert in its reply that its records are covered by the "self-critical analysis" privilege, but it provides no new arguments or cases in support. *See* Pfizer's Reply at 15. Moreover, Pfizer is silent in the face of Public Citizen's assertion that the privilege, even in

the discovery context, has lost favor in the two decades since the principal case on which Pfizer relies. *See* Pl.'s S.J. Mem. at 35. For the reasons set forth in Public Citizen's earlier memorandum, the Court should hold that Pfizer's records are not privileged.

D. Pfizer's argument that its records "fall outside FOIA" because of Public Citizen's purpose in seeking them is frivolous.

Pfizer argues that the withheld records "fall[] outside FOIA" because they do not "demonstrate what the government is up to but will instead[] illuminate only the actions of private companies." Pfizer's Reply at 17 (internal quotation marks omitted). As an initial matter, the withheld records will provide insight into the success of the government's activities in enforcing CIAs. *See* Kesselheim Decl. ¶ 21. Although HHS states that it disputes Public Citizen's evidence in this regard, it cites no contrary record evidence. *See* HHS's Resp. to Pl.'s Statement of Facts ¶¶ 48-49. As a result, Public Citizen's evidence should be deemed admitted.

More importantly, Pfizer's argument contravenes bedrock FOIA law. FOIA "mandates that an agency disclose records on request, unless they fall within one of nine exemptions," which "are 'explicitly made exclusive.'" *Milner v. Dep't of Navy*, 131 S. Ct. 1259, 1262 (2011) (quoting *EPA v. Mink*, 410 U.S. 73, 79 (1973)); *see also U.S. Dep't of Justice v. Tax Analysts*, 492 U.S. 136, 151 (1989). Pfizer's attempt to create an "Exemption 10" out of whole cloth should be rejected.

V. This Court Should Reject HHS's Request for a Third Chance to Meet Its Burden.

HHS asks this Court to "give[] [it] an opportunity to submit supplemental declarations" if the Court determines that HHS's "declarations are insufficient to justify withholding." HHS's Reply at 21 n.6. The Court should decline the invitation. In its earlier memorandum, Public Citizen challenged the sufficiency of HHS's declarations and produced detailed, category-specific evidence of its own. In response, HHS submitted only a three-page supplemental

declaration that—like the others—failed to provide the specificity necessary to meet the agency's burden. Moreover, HHS responded to Public Citizen's statement of facts in many instances without citing any contrary evidence at all or by citing only general and conclusory statements to rebut detailed evidence from the four declarations introduced by Public Citizen. HHS had the burden of proof and ample opportunity to meet it, if it could. If the Court agrees with Public Citizen that HHS has not met its burden, Public Citizen is entitled to summary judgment. A third chance for the government to present evidence is unwarranted. *See Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 861, 871 (D.C. Cir. 1980); *see also S. Alliance for Clean Energy v. U.S. Dep't of Energy*, 2012 WL 1021487, at *15 (D.D.C. Mar. 28, 2012) (noting, in light of the impact of delay on public access to information, that "there may be a very legitimate reason . . . to consider the strong medicine of immediate disclosure instead of ordering second chances for sophisticated repeat-players in FOIA litigation").

CONCLUSION

For the foregoing reasons and those stated in Public Citizen's memorandum in support of its motion for summary judgment, 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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