UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GOVERNMENT ACCOUNTABILITY PROJECT,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; U.S. FOOD & DRUG ADMINISTRATION,

Defendants.

Civil Action No. 07-1702 (CKK)

MEMORANDUM OPINION
(March 9, 2010)

The above-captioned case arises out of a request filed by Plaintiff, the Government Accountability Project, pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq.*, seeking the disclosure and release of agency records consisting of clinical study data regarding the drug ciprofloxacin ("cipro"). Plaintiff has named as Defendants in this action the United States Department of Health and Human Services ("HHS") and the United States Food and Drug Administration ("FDA") (collectively "Defendants"). Currently pending before the Court are the parties' cross-motions for summary judgment. The Court has conducted a searching review of the parties' motions and responsive briefing, the exhibits attached to those filings, the relevant case law as well as statutory and regulatory provisions, and the entire record herein. The lone dispute remaining in this case is the propriety of Defendants' redactions from the responsive documents. Specifically, Defendants redacted certain information from the documents at issue pursuant to two separate FOIA Exemptions — Exemption 4 (confidential

commercial information) and Exemption 6 (personal privacy information). Upon review of Defendants' opening motion and *Vaughn* index, Plaintiff now concedes that the information withheld pursuant to Exemption 6 is properly exempt under FOIA.[1] Accordingly, Defendants' [19] motion for summary is GRANTED-IN-PART as conceded insofar as Defendants assert that they properly withheld information under Exemption 6. Plaintiff continues to challenge the validity of Defendants' redactions pursuant to Exemption 4, however, arguing that Defendants have not met their burden of demonstrating that the material in dispute may be properly withheld as confidential commercial information. The Court agrees and therefore DENIES-IN-PART the Defendants' [19] motion for summary judgment and GRANTS the Plaintiff's [20] cross-motion for summary judgment with respect to the propriety of Defendants' withholdings pursuant to Exemption 4. Defendants are therefore directed to disclose to Plaintiff all information previously redacted as confidential consumer information under Exemption 4, for the reasons set forth.

I. BACKGROUND

The facts of this case are straightforward. Plaintiff submitted a FOIA request to the FDA on June 27, 2007, seeking documents concerning certain clinical study data regarding the drug ciprofloxacin. Defs.' Stmt. ¶ 1.[2] Specifically, Plaintiff requested the following two categories of

[1] *See* Pl.'s Cross-MSJ/Opp'n at 5, n. 1 ("In light of the descriptions provided in the Defendant's [*sic*] *Vaughn* index, Plaintiff does not seek patient information that the Defendant has withheld pursuant to FOIA exemption 6.").

[2] The Court previously advised the parties that it strictly adheres to the text of Local Civil Rule 7(h)(1) and "assumes facts identified by the moving party in its statement of material facts are admitted, unless such a fact is controverted in the statement of genuine issues filed in opposition to the motion." *See, e.g.* Feb. 19, 2009 Order, Docket No. [18]. Defendants filed a statement of material facts as to which there is no genuine dispute ("Defs.' Stmt") in compliance with the Court's requirement, albeit in truncated form consisting of only three stated facts. Plaintiff, however, failed to either respond to Defendants' statement or file its own statement of

documents relating to cipro:

> (ii) in electronic form, . . .: [a]ll goniometry (joint angle motion measurement) data, including but not limited to, all passive range of motion of joints, by protocol, measured in degrees, recorded from all subjects and sorted by site or investigator number, subject or numeric identification number, the joints measured, the dates of measurement and information on the age of the subject at enrollment or first measurement in months or years, or birth month and year, pertaining to domestic and foreign clinical trial studies 1001169 and 100201; and
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> (ii) in paper form: all FDA Division of Scientific Investigations ("DSI") reports and records, domestic and outside of US, concerning all DSI inspections pertaining to clinical trial studies 1001169 and 100201.

Defs.' MSJ, Att. 1 (Second Declaration of Nancy B. Sager) (hereinafter, "Sager Decl.") ¶ 6;[3] *see also* Compl., Docket No. [1], ¶ 6.

Having received no response from Defendants to its FOIA request, Plaintiff filed the instant lawsuit on September 25, 2007, *see generally* Compl., and subsequently moved for judgment on the pleadings based upon Defendants' failure to produce any records responsive to the pending FOIA request, *see* Pl.'s Mot. for J. on the Pleadings, Docket No. [5]. In response, Defendants filed a Motion for an *Open America* Stay. *See* Defs.' Mot. to Stay, Docket No. [7].

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material facts. Accordingly, the Court shall cite exclusively to Defendants' statement of material facts as well as to evidence in the record (including the declarations submitted by the parties) where appropriate, to provide information not covered by Defendants' statement. The Court finds that there is no genuine dispute over the factual issues that are material to resolution of this case.

[3] Defendants have submitted the Second Declaration of Nancy B. Sager in support of their motion for summary judgment. Ms. Sager is the Director of the Division of Information Disclosure Policy ("DIDP") within the Center for Drug Evaluation and Research ("CDER") at the FDA. Sager Decl. ¶ 1. She has supervisory authority over DIDP, which processes and responds to requests made pursuant to FOIA for documents in the possession of CDER, and offers the attached declaration based upon her personal knowledge and information about which she has become knowledgeable through her review of official agency records within CDER's control. *Id.* ¶¶ 2, 4.

On August 4, 2008, this Court issued a memorandum opinion and order denying Defendants' request for an *Open America* stay and granting-in-part Plaintiff's motion for judgment on the pleadings insofar as Plaintiff sought a judgment that Defendants were required to process its FOIA request and release the documents on a rolling basis. *See Gov't Accountability Project v. HHS*, 568 F. Supp. 2d 55, 56 (D.D.C. 2008). Defendants were directed to report back to the Court with an estimate as to the volume of the requested records, the time by which Defendants expected to begin processing the FOIA request, and how long they expected it to take to fully process the request. *Id.* at 57.

Based upon Defendants' response, the Court set a schedule for Defendants' production of the responsive documents and provided Plaintiff additional time to review the documents to determine if any issues remained for litigation. *See* 9/22/08 Min. Order. In addition, the Court required the parties to submit a joint status report advising as to whether any disputes remained necessitating further litigation. *Id.* The parties completed the production and review process as required, thereafter advising the Court that they had been unable to resolve all disputes relating to Plaintiff's FOIA request. *See* 2/19/09 Order, Docket No. [18]; *see also* Defs.' Stmt. ¶¶ 2-3 (indicating that Defendants provided Plaintiff with the responsive documents in two separate installments on October 22, 2008 and again on December 2, 2008). The parties therefore proceeded to file the pending cross-motions for summary judgment. Briefing on the motions is now complete, and the matter is ripe for the Court's adjudication.

II. LEGAL STANDARD

In reviewing a motion for summary judgment under FOIA, the Court must conduct a *de novo* review of the record. *See* 5 U.S.C. § 552(a)(4)(B). In the FOIA context, "*de novo* review

requires the Court to 'ascertain whether the agency has sustained its burden of demonstrating that the documents requested . . . are exempt from disclosure under [] FOIA.'" *Assassination Archives & Research Ctr. v. Cent. Intelligence Agency*, 334 F.3d 55, 57 (D.C. Cir. 2003) (quoting *Summers v. Dep't of Justice*, 140 F.3d 1077, 1080 (D.C. Cir. 1998)). Summary judgment is proper when "the pleadings, the discovery [if any] and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

Under FOIA, all underlying facts and inferences are analyzed in the light most favorable to the FOIA requester; as such, only after an agency seeking summary judgment proves that it has fully discharged its FOIA obligations is summary judgment appropriate. *Moore v. Aspin*, 916 F. Supp 32, 35 (D.D.C. 1996) (citing *Weisberg v. Dep't of Justice*, 705 F.2d 1344, 1350 (D.C. Cir. 1983)). In opposing a motion for summary judgment, a party must offer more than conclusory statements. *See Broaddrick v. Exec. Off. of President*, 139 F. Supp. 2d 55, 65 (D.D.C. 2001) (citing *Laningham v. U.S. Navy*, 813 F.2d 1236, 1241 (D.C. Cir. 1987)).

Congress enacted FOIA for the purpose of introducing transparency to government activities. *See Stern v. Fed. Bureau of Investigation*, 737 F.2d 84, 88 (D.C. Cir. 1984). Congress remained sensitive, however, to the need to achieve balance between this objective and the vulnerability of "legitimate governmental and private interests [that] 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); *see also Summers*, 140 F.3d at 1079. Accordingly, FOIA provides nine exemptions pursuant to which an agency may withhold requested information. *See* 5 U.S.C. §§ 552(a)(4)(B), (b)(1)-(9). The agency must demonstrate the validity

of any exemption that it asserts. *See id.*; *Beck v. Dep't of Justice*, 997 F.2d 1489, 1491 (D.C. Cir. 1993) ("[c]onsistent with the purpose of the Act, the burden is on the agency to justify withholding requested documents"). In addition, summary judgment may be granted on the basis of the agency's accompanying affidavits or declarations if they describe "the justifications for nondisclosure with reasonably specific detail, demonstrate that the information withheld logically falls within the claimed exemption, and are not controverted by either contrary evidence in the record nor evidence of agency bad faith." *Military Audit Project v. Casey*, 656 F.2d 724, 738 (D.C. Cir. 1981). These affidavits may be submitted by an official who coordinated the search, and need not be from each individual who participated in the search. *See SafeCard Servs. v. Sec. & Exch. Comm'n*, 926 F.2d 1197, 1200 (D.C. Cir. 1991).

An agency also has the burden of detailing what proportion of the information in a document is non-exempt and how that material is dispersed throughout the document. *Mead Data Cent. Inc. v. U.S. Dep't of Air Force*, 566 F.2d 242, 261 (D.C. Cir. 1977). Any non-exempt information that is reasonably segregable from the requested records must be disclosed. *Ogelsby v. U.S. Dep't of Army*, 79 F.3d 1172, 1178 (D.C. Cir. 1996). In addition, district courts are required to consider segregability issues *sua sponte* even when the parties have not specifically raised such claims. *Trans-Pac. Policing Agreement v. U.S. Customs Serv.*, 177 F.3d 1022, 1028 (D.C. Cir. 1999).

III. LEGAL DISCUSSION

As indicated above, the sole issue remaining in this case is the propriety of Defendants' withholdings pursuant to Exemption 4. Specifically, Defendants have redacted the following two categories of information under Exemption 4. First, with respect to Plaintiff's request for all

goniometry (joint angle motion measurement) data, in electronic form, pertaining to domestic and foreign clinical trial studies 1001169 and 100201, Defendants have withheld all such "data . . . concern[ing] the cipro oral suspension administered to some of the patients in the two studies." Sager Decl. ¶ 15; *see also* Defs.' MSJ, Att. 5 (*Vaughn* index Table B) (hereinafter, "Table B"). Second, with respect to Plaintiff's request for all reports and records, in paper form, concerning DSI inspections of the clinical trial studies 1001169 and 100201, Defendants withheld "the names of contractors and subcontractors, the location of Bayer's network, investigators, and consultant entities to which doctors involved in the clinical studies were paid consultants/ contractors." Sager Decl. ¶ 16; *see also* Defs.' MSJ, Att. 4 (*Vaughn* index Table A) (hereinafter, "Table A").

Documents may be withheld under Exemption 4 if they constitute "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4). Defendants concede that "the instant case implicates only confidential commercial information, not trade secrets." Defs.' MSJ at 4. Accordingly, the redacted information may be properly withheld only if Defendants demonstrate that such material is (a) "commercial or financial information" that has been (b) "obtained from a person and that is (c) "confidential" in nature. In this case, Plaintiff does not dispute that the information at issue is commercial or financial information obtained from a person, but rather challenges only Defendants' assertion that the information withheld is "confidential." *See* Pl.'s Cross-MSJ/Opp'n at 8-10.

Determination of whether information is confidential depends "in part on whether it was provided to the government voluntarily or under compulsion." *McDonnell Douglas Corp. v.*

Nat'l Aeronautics & Space Admin., 180 F.3d 303, 304 (D.C. Cir. 1999). In this case, Defendants assert and Plaintiff does not dispute that the government requires submission of the information at issue as part of the drug application process. *See* Defs.' MSJ at 5-6; Pl.'s Cross-MSJ/Opp'n at 8.[4] As such, the information "will be considered confidential only if disclosure would be 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." *McDonnell Douglas*, 180 F.3d at 305 (quoting *Critical Mass Energy Project*, 975 F.2d at 879 (reaffirming test of *Nat'l Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974), but confining it to cases of compelled disclosure)).

Defendants in this case argue that the information at issue qualifies as confidential pursuant to the latter prong, *i.e.*, the "competitive harm" prong. Defs.' MSJ at 6.[5] In order to show competitive harm, the FDA must demonstrate both "actual competition and a likelihood of substantial competitive injury." *CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1152 (D.C. Cir. 1987). A "competitive injury" is one "flowing from the affirmative use of proprietary information by competitors." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291, n. 30 (D.C. Cir. 1983) (hereinafter, "*Public Citizen Health Research Group I*") (internal quotation marks omitted). "No actual adverse effect on competition need be shown," and "[t]he

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[4] The manner in which drug companies submit information to the FDA as part of the drug application process has been fully explained by previous decisions in this Circuit. *See, e.g., Public Citizen Health Research Group v. FDA*, 185 F.3d 898, 901 (D.C. Cir. 1999) (hereinafter, "*Public Citizen Health Research Group II*"); *Webb v. HHS*, 6969 F.2d 101, 102-03 (D.C. Cir. 1982).

[5] Defendants do not make an argument that the information qualifies as confidential under the first prong considering the effect of disclosure on the government's ability to obtain similar information in the future. *See* Defs.' MSJ at 6.

court need only exercise its judgment in view of the nature of the material sought and the competitive circumstances in which the [submitters] do business, relying at least in part on relevant and credible opinion testimony." *Nat'l Parks*, 547 F.2d at 683. As the D.C. Circuit has made clear, "the court need not conduct a sophisticated economic analysis of the likely effects of disclosure," but "[c]onclusory and generalized allegations of substantial competitive harm, of course, are unacceptable and cannot support an agency's decision to withhold requested documents." *Public Citizen Health Research Group I*, 704 F.2d at 1291 (internal citations and quotation marks omitted).

Ultimately, the Court finds that Defendants have failed to meet their burden of showing a "a likelihood of substantial competitive injury." As is discussed in detail below, Defendants have proffered only vague and conclusory allegations in support of their claim that release of the information at issue will likely cause competitive harm. Accordingly, even assuming that Defendants have sufficiently shown the existence of actual competition, Defendants' motion for summary judgment must be denied. Proof of ***both*** "actual competition and a likelihood of substantial competitive injury" is necessary to demonstrate that the material at issue is confidential commercial information exempt from disclosure under FOIA Exemption 4, *see CNA Fin. Corp.*, 830 F.2d at 1152, and Defendants have failed to show that the latter requirement is met in this case.

Before turning to Defendants' arguments specific to the issue of substantial competitive injury, however, the Court first addresses Defendants' repeated references in their briefing to certain statutory and regulatory provisions that govern the FDA's public disclosure obligations. Upon an initial reading of Defendants' motion and supporting memoranda, it is difficult to

discern whether Defendants purport to rely upon these provisions as substantive support for their decision to withhold the material in this case. Careful review, however, makes clear that Defendants do ***not*** affirmatively rely on these provisions to justify the withholdings at issue. While Defendants do refer to these provisions at various points throughout their briefing, they at no time advance an argument that the relevant statutes and/or regulations prohibit the agency from disclosing the information in dispute.[6] Nonetheless, given the somewhat obscure nature of Defendants' arguments on this point and cognizant of the importance of ensuring a clear record, the Court pauses briefly to delineate the exact contours of Defendants' reliance on these provisions.

First, in arguing that actual competition exists, Defendants explain that FDA regulations "explicitly prohibit the agency from acknowledging the existence of a pending drug application unless the existence has already been acknowledged by the manufacturer," and that, even then, the "FDA cannot disclose any information regarding a pending application until that application is approved." Defs.' MSJ at 7 (citing 21 C.F.R. §§ 312.130, 314.430(c) & (d)). Accordingly, Defendants urge that the absence of evidence regarding the number and type of now-pending drug applications for cipro products should not be read as indicating a lack of actual competition in the cipro market, as the FDA cannot comment or publicly disclose such applications; Defendants instead direct the Court to evidence regarding the number of already approved new drug applications ("NDAs") and abbreviated new drug applications ("ANDAs") for cipro

[6] Indeed, Defendants have moved to withhold the information as exempt only under FOIA Exemption 4 — and not under FOIA Exemption 3 as well, which"permits the government to withhold information 'specifically exempted from disclosure by statute'" in certain circumstances. *Public Citizen, Inc. v. Rubber Mfrs. Ass'n*, 533 F.3d 810, 813 (D.C. Cir. 2008) (quoting 5 U.S.C. § 552(b)(3)).

products — the existence of which may be publicly disclosed — as proof that actual competition exists. *See id.* at 6-7; *see also* Defs.' Opp'n/Reply at 2-3. At no point, however, do Defendants argue that the information at issue in this case is subject to these specific regulatory provisions; that is, Defendants make no argument that they are precluded from releasing the withheld material because it is drawn from a pending drug application and therefore cannot be publicly disclosed. *See generally* Defs.' MSJ; Defs.' Opp'n/Reply.

Second, Defendants refer the Court to 21 U.S.C. § 355(l)(1) and its implementing regulations located at 21 C.F.R. § 314.430(f). *See* Defs.' MSJ at 8; Defs.' Opp'n/Reply at 3. These provisions govern the "[p]ublic disclosure of safety and effectiveness data" submitted as part of an NDA or ANDA. *See* 21 U.S.C. § 355(l)(1); 21 C.F.R. § 314.430(f). As Defendants note, 21 U.S.C. § 355(l)(1) provides that

> [s]afety and effectiveness data and information which has been submitted in an [new drug application] for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown–
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> (E) upon the effective date of the approval of the first application under subsection (j) of this section which refers to such drug or upon the date upon which the approval of an application under subsection (j) of this section which refers to such drug could be made effective if such an application had been submitted.

21 U.S.C. § 355(l)(1). The FDA's implementing regulation, 21 C.F.R. § 314.430(f), mirrors the statutory provision, providing that:

> [a]ll safety and effectiveness data and information which have been submitted in an application and which have not previously been disclosed to the public are available to the public, upon request, at the time any one of the following events occurs unless extraordinary circumstances are shown:

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> (5) For applications submitted under section 505(b) of the act [*i.e.,* new drug applications], the effective date of the approval of the first abbreviated application submitted under section 505(j) of the act [*i.e.*, abbreviated new drug applications] which refers to such drug, or the date on which the approval of an abbreviated application under section 505(j) of the act which refers to such drug could be made effective if such an abbreviated application had been submitted.

21 C.F.R. § 314.430(f).

The FDA asserts — and Plaintiff does not dispute — that it was not required to automatically disclose the withheld goniometry data relating to the cipro oral suspension under these provisions as there currently is "no approved ANDA referencing the NDA for the cipro oral suspension, nor would an ANDA be eligible for approval . . . had one been submitted." *Id.* Accordingly, because the FDA was not required to release the data relating to the cipro oral suspension under these provisions and because the FDA has released all other requested information concerning the raw goniometry data, the FDA represents that it has "provided plaintiff with all of the goniometry (joint angle motion measurement) data . . . that was required to be disclosed pursuant to 21 U.S.C. § 355(l)(1)(E) and 21 C.F.R. § 314.430(f)(5)." Defs.' MSJ at 8; *see also* Sager Decl. ¶ 14 ("In accordance with 21 U.S.C. § 355(l)(1)(E) and 21 C.F.R. § 314.430(f)(5), all of the responsive data pertaining to cipro products for which abbreviated new drug applications [] either have been approved or could have been approved were provided to plaintiff.").

Plaintiff, however, has not challenged the FDA's compliance with its disclosure obligations under 21 U.S.C. § 355(l)(1)(E) and 21 C.F.R. § 314.403(f)(5). Consequently, the question of whether the FDA has fully complied with these provisions is not presently before the

Court, and the FDA's representations on that point are immaterial. Moreover, the Court emphasizes that while Defendants affirmatively argue that the relevant statutory and regulatory provisions do not ***require*** them to disclose the raw data relating to the cipro oral suspension, they do not argue the reverse — *i.e.,* that the provisions explicitly ***prohibit*** them from disclosing the withheld material.[7] *See generally* Defs.' MSJ at 8; Defs.' Opp'n/Reply at 3-4. Nor do Defendants argue that these provisions are somehow relevant to the determination of whether information may be withheld as "confidential commercial information" under Exemption 4. *See generally* Defs.' MSJ; Defs.' Opp'n/Reply. Although Defendants appear to have made the assumption in this case that safety and effectiveness data always qualifies as confidential consumer information that must be withheld under FOIA Exemption 4, unless and until the FDA is obligated to disclose the material under 21 U.S.C. § 355(l)(1)(E) and 21 C.F.R. § 314.403(f)(5),[8] they have not explicitly advanced any such argument and proffer no legal or factual support for such an assumption. As such, Defendants' citations to and reliance on the

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[7] While the Court need not, and does not, decide whether such an argument would have merit, even if asserted, it notes that the particular statutory and regulatory provisions quoted by Defendants address only the FDA's ***affirmative*** disclosure obligations. *See* 21 U.S.C. § 355(l)(1)(E) ("Safety and effectiveness data and information . . . shall be made available to the public, upon request, unless extraordinary circumstances are shown . . . ."); *see also* 21 C.F.R. § 314.403(f)(5) ("All safety and effectiveness data and information . . . are available to the public, upon request, at the time any one of the following events occurs unless extraordinary circumstances are shown . . . ."). These provisions stand in direct contrast to other sections of the implementing regulations — not cited by Defendants — that directly prohibit public disclosure of certain information. *See, e.g.,* 21 C.F.R. § 314.430(g) ("The following data and information in an application or abbreviated application are not available for public disclosure unless . . . .").

[8] *See* Defs.' MSJ at 8 (explaining that the withheld material does not fall within the category of information that the FDA is required to disclose under these provision and therefore concluding, without further explanation, that "the data relating to the cipro oral suspension [thus] continues to meet the standard set forth in *National Parks*, and FDA properly withheld it pursuant to Exemption 4").

above-quoted statutory and regulatory provisions are irrelevant to the only question now before the Court — namely, whether the redacted information was properly withheld under FOIA Exemption 4.

With that understanding, the Court turns now to the merits of Defendants' arguments specific to the question of whether the information in dispute is properly characterized as confidential commercial information pursuant to Exemption 4. As indicated previously, Defendants assert that the withheld material qualifies as confidential under the "competitive harm" prong, which requires proof of "actual competition and a likelihood of substantial competitive injury." Defendants' sole evidence that disclosure of the information in dispute would likely result in "substantial competitive injury" is as follows, reprinted in full:

> If [the] FDA were to disclose the information that the agency has withheld as confidential consumer information, a competitor could use that [] information to support its own new drug application [] without having to incur the time and expense involved in developing the information itself. In addition, the owner of the protected-but-improperly-released information could sue [the] FDA on the grounds that [the] FDA's release jeopardized its competitive market by providing competitors with critical information that could speed up the development of a competing project.

Sager Decl. ¶ 17. This assertion, however, is conclusory in nature and wholly insufficient to support a finding that the information at issue is properly exempt under FOIA for three principal reasons.

First, Ms. Sager has not differentiated between the categories of information withheld in this case. As previously discussed, Defendants redacted two basic categories of information: (1) all goniometry (joint angle motion measurement) data concerning the cipro oral suspension; and (2) the names of contractors and subcontractors, the location of Bayer's network, investigators, and consultant entities. Ms. Sager, however, has failed to discriminate between the types

information at issue, instead broadly claiming that release of either category of information, without distinction, would likely result in substantial competitive injury. Such a blanket statement is wholly unpersuasive.

Second, the explanation lacks any supporting detail demonstrating that a competitor could, in fact, use the withheld material "to support its own new drug application [] without having to incur the time and expense involved in developing the information itself." Defendants' briefing similarly fails to elucidate on how a competitor could utilize either category of information at issue to its advantage, instead broadly asserting only that "the withheld information could permit a compet[ing] generic manufacturer to more easily design around the patent(s)." Defs.' Opp'n/Reply at 3; *see also* Defs.' MSJ at 9 (indicating, without explanation, that release may "provid[e] competitors with critical information that permit the competitor to more quickly and easily develop a competing product"). The conclusory nature of Defendants' explanation on this point is fatal to their motion. Although it is true that this "court need not conduct a sophisticated economic analysis of the likely effects of disclosure," it is nonetheless well settled that such "[c]onclusory and generalized allegations of substantial competitive harm" as asserted by Defendants "are unacceptable and cannot support an agency's decision to withhold requested documents." *Public Citizen Health Research Group I*, 704 F.2d at 1291 (D.C. Cir. 1983) (internal citations and quotation marks omitted). For this reason, "courts in this Circuit routinely reject Exemption 4 arguments that are grounded in generalizations." *In Defense of Animals v. Nat'l Inst. of Health*, 543 F. Supp. 2d 70, 79 (D.D.C. 2008) (listing cases).

The D.C. Circuit's opinion in *Public Citizen Health Research Group II* is of particular assistance in evaluating whether an agency has proffered evidence sufficient to demonstrate the propriety of its withholdings under Exemption 4. In that case, the plaintiff challenged the FDA's decision to withhold information included in five investigational new drug applications as confidential commercial information. *See Public Citizen Health Research Group II*, 185 F.3d at 900. The D.C. Circuit held that the intervenor-defendant had met its burden of nondisclosure as to four of the five applications at issue because its proffered evidence of competitive harm was "sufficiently specific" to support a finding that release would cause it substantial competitive harm. *See id.* at 905-06. The Court of Appeals held, however, that the intervenor-defendant had failed to meet its burden with respect to the fifth application because it had presented "only conclusory allegations that disclosure would cause competitive harm." *Id.* at 906. In so doing, the court rejected as insufficient the intervenor-defendant's broad assertions that, for example, disclosure "'would reveal substantial basic research' as well as 'disease models . . . that have been developed [] at great expense,'" and that the information at issue "'ha[d] significant value . . . [and would be applicable] to any drug product . . . of a similar chemical type.'" *Id.* Defendants' assertions in this case are substantially similar to — if not more conclusory in nature than — the explanation that the D.C. Circuit found to be insufficient in *Public Citizen Health Research Group II.* Defendants offer no explanation whatsoever as to how a competitor could use the information at issue to support their own drug applications, simply concluding that such information could be used in some unspecified manner to the submitters' disadvantage.[9]

[9] Although not dispositive, the Court notes that Defendants have failed to even explain the actual source of the information in dispute. While it is apparent from the FOIA request that the material at issue pertains to two particular clinical studies, Defendants have not identified the

Rather than provide any evidence particular to the alleged harm that would result from the disclosure of the information at issue in this case, Defendants instead rely heavily on previous D.C. Circuit decisions in which the court has generally observed that certain information submitted to the FDA as part of a drug application may be exempt under FOIA Exemption 4. *See* Defs.'s MSJ at 6 (quoting *Judicial Watch Inc. v. FDA*, 449 F.3d 141, 148-49 (D.C. Cir. 2006)); *see also* Defs.' Opp'n/Reply at 4 (quoting *Webb v. HHS*, 696 F.2d 101, 103 (D.C. Cir. 1982)). Defendants' reliance is misplaced. Such observations regarding the general nature of submissions to the FDA are not a substitute for a specific showing by Defendants that the material in this case is confidential commercial information. "Exemption 4 does not categorically exempt all information" submitted in a drug application to the FDA; instead, the government retains the burden of demonstrating that the specific information withheld in any particular instance qualifies as confidential commercial information exempt under FOIA Exemption 4. *Judicial Watch*, 449 F.3d at 149. Defendants have not met that burden in this case.

Defendants' failure to do so, by itself, requires that the Court deny Defendants' motion for summary judgment, as the "Government 'ultimately has the onus of proving that the [documents] are exempt from disclosure.'" *Public Citizen Health Research Group II*, 185 F.3d

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actual individual or entity that submitted the information to the FDA nor have they specifically indicated the manner in which such information was originally submitted to the FDA (although Defendants' briefing strongly suggests that the material was submitted as part of a drug application). As the Court's inquiry focuses on the substantial competitive harm that disclosure would cause "to the entity that submitted the information," *see Judicial Watch, Inc. v. FDA*, 449 F.3d 141, 148 (D.C. Cir. 2006), Defendants' failure to actually identify the entity or individual that submitted the information is indicative of the general insufficiency of the Defendants' evidence on this point.

at 904 (quoting *Nat'l Ass'n of Gov't Employees v. Campbell*, 593 F.2d 1023, 1027 (D.C. Cir. 1978)). It is not the plaintiff's burden to show an absence of competitive harm. *Id.* at 905. Nonetheless, the Court briefly notes that Plaintiff has submitted the declaration of Juan N. Walterspiel, M.D., F.A.A.P., a board certified pediatric infectious disease specialist with experience in the use of quinolones such as cipro. *See* Pl.'s Cross-MSJ/Opp'n, Att. 1 (Declaration of Juan N. Walterspiel) (hereinafter, "Walterspiel Decl."), ¶ 1. With respect to the goniometry data withheld by the FDA, Dr. Walterspiel avers that

> it would be impossible for any competitor to glean information on the specific composition of a formulation of ciproflaxin oral suspension from goniometry data. The only meaningful information that a competitor could reasonably glean from goniometry data is that the oral suspension performed in a manner equal to other formulations as far as joint safety is concerned, and that fact the FDA has analyzed and already made available to the public.

Id. ¶ 9. Defendants make no effort to address this particular statement in their combined opposition/reply nor have they provided any additional evidence to support their conclusory but contrary position that a "competitor could use [the withheld] information to support its own new drug application." *See generally* Defs.' Opp'n/Reply. Their failure to do so further illustrates the inadequacy of Defendants' explanation for withholding the material at issue. Dr. Walterspiel's assertion that it would be impossible for a competitor to use the raw data at issue in a manner that would result in substantial competitive harm to the submitter of the information is therefore uncontested.

Third and finally, Defendants' statement averring that the owner of the information could sue the FDA for release of the information — even if true — is not the type of alleged harm that qualifies as a "competitive injury" under FOIA Exemption 4. The D.C. Circuit has made clear that a "competitive injury" is one "flowing from the affirmative use of proprietary information by

competitors." *Public Citizen Health Research Group I*, 704 F.2d at 1291, n. 30 (internal quotation marks omitted). The FDA's own fear that it may be sued by the submitter of the information is irrelevant to the inquiry at hand.[10]

Accordingly, as Defendants have failed to provide sufficient evidence to support their position that disclosure of the redacted information would result in substantial competitive harm, and as there is no dispute about an issue of fact material to the Defendants' burden on that point, the Court finds that summary judgment in favor of Plaintiff is warranted insofar as it asserts that Defendants have improperly withheld information under Exemption 4. Defendants' [19] motion for summary judgment is therefore DENIED and Plaintiff's [20] cross-motion for summary judgment is GRANTED with respect to the propriety of Defendants' withholdings pursuant to Exemption 4. Defendants are directed to release to Plaintiff all information previously withheld as confidential commercial information, as set forth in Table B of the Sager Declaration.

Finally, as explained above, under D.C. Circuit precedent, district courts are required to consider segregability issues *sua sponte* even when the parties have not specifically raised such claims. *Trans-Pac. Policing Agreement*, 177 F.3d at 1028. In this case, neither party has raised the issue. *See generally* Defs.' MSJ; Pl.'s Cross-MSJ/Opp'n. Nevertheless, the Court must ensure that the government has disclosed all reasonably segregable information. *Id.* First, with respect to the material withheld under Exemption 4, the Court has now ordered that all requested

[10] Defendants have also failed to explain on what legal basis the owner of the information at hand could sue the FDA in this case. Absent such an explanation, Ms. Sager's conclusory statement is wholly insufficient to demonstrate that disclosure would in fact risk exposing the FDA to the threat of a lawsuit. Accordingly, even if this statement were relevant to the Court's present inquiry, it would nonetheless be insufficient to support Defendants' decision to withhold the information.

non-exempt information be disclosed to Plaintiff; as such, segregability is no longer at issue with respect to that material. Second, with respect to the information withheld under Exemption 6 — which Plaintiff does not dispute is properly exempt — the Court finds that Defendants have sufficiently demonstrated that they have released all reasonably non-exempt information. Ms. Sager explains in her declaration that the relevant documents were reviewed "page-by-page and line-by-line" and that the redactions were then re-reviewed for accuracy. Sager Decl. ¶ 8. The *Vaughn* index attached to Ms. Sager's declaration further indicates that Defendants only redacted specific references to patient initials, patient hospital admission dates, names of low-level employees and other identifying information. *See* Table A. Accordingly, the Court finds that Defendants have disclosed all reasonably segregable information.

IV. CONCLUSION

For the reasons set forth above, Defendants' [19] motion for summary judgment is GRANTED-IN-PART as conceded to the extent Defendants assert that information was properly withheld pursuant to Exemption 6. Defendants' [19] motion for summary judgment, however, is DENIED-IN-PART and Plaintiff's [20] cross-motion for summary judgment is GRANTED with respect to the propriety of Defendants' withholdings pursuant to Exemption 4. Defendants are therefore directed to disclose to Plaintiff all information previously redacted as confidential consumer information under Exemption 4. An appropriate Order accompanies this Memorandum Opinion.

Date: March 9, 2010

/s/
COLLEEN KOLLAR-KOTELLY
United States District Judge