IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JUDICIAL WATCH, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 07-00561 (RCL)
	)	
U.S. FOOD AND DRUG ADMINISTRATION	)	
	)	
	)	
Defendant.	)	
	)	

PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

Plaintiff, Judicial Watch, Inc. ("Judicial Watch"), by counsel and pursuant to Rule 56(f) of the Federal Rules of Civil Procedure, respectfully submits this opposition to Defendant Food and Drug Administration's ("FDA") motion to dismiss or, in the alternative, for summary judgment. As grounds therefor, Judicial Watch states as follows:

MEMORANDUM OF LAW

I. Introduction.

"Ours is a government of laws, laws duly promulgated and laws duly observed. No one is above the law: not the executive, not the Congress, and not the judiciary. One of our laws is the Freedom of Information Act (FOIA). That law, no less than any other, must be duly observed." *American Civil Liberties Union v. Dep't of Defense*, 339 F. Supp. 2d 501, 502 (S.D.N.Y. 2004) (internal citations omitted). This statement is one regarding which the FDA needs reminding. Inexplicably, after not one, but three instances of non-compliance, the FDA now seeks dismissal or, in the alternative, summary judgment.

The FDA's non-compliance is replete throughout this case; indeed, it is the reason for this

case. When served with a FOIA request on August 22, 2006, the FDA did no more than acknowledge its receipt. Only after the FDA was served with a lawsuit after its near-seven months of silence, did the FDA produce records responsive to Judicial Watch's August 26, 2006 request. Similarly, when served with two related FOIA requests in mid-April 2007, the FDA did no more than acknowledge receipt of the requests. It was only after the Court permitted Judicial Watch to amend its complaint to include these two additional claims of non-compliance that the FDA produced records responsive to Judicial Watch's April 2007 requests.

Even with the productions, the FDA is still not complying with its FOIA obligations. Namely, the searches performed by the FDA were not reasonable. As evidence of this, are numerous demonstrated examples of missing information as well as the FDA's insufficiently detailed declarations. Despite the FDA's oleaginous assertions to the contrary, genuine issues of material fact do remain and summary judgment should not be granted.

II. Argument.

A. Summary Judgment Standard.

In FOIA litigation, as in all litigation, summary judgment is appropriate only when the pleadings and declarations demonstrate that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); Fed.R.Civ.P. 56(c). In FOIA cases, the agency decisions to "withhold or disclose information under FOIA are reviewed *de novo* by this court." *Judicial Watch, Inc. v. U.S. Postal Service*, 297 F. Supp. 2d 252, 256 (D.D.C. 2004). In reviewing a motion for summary judgment under FOIA, the court must view the facts in the light most favorable to the requestor. *Weisberg v. United States Dep't of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984).

For an agency to prevail, it must "prove that each document that falls within the class requested either has been produced, is unidentifiable, or is wholly exempt from the Act's inspection requirements." *Goland v. CIA*, 607 F.2d 339, 352 (D.C. Cir. 1978).

Summary judgment is not appropriate in this case because a genuine issue of material fact exists as to the adequacy of the FDA's searches.

B. <u>The FDA Failed to Conduct a Reasonable Search</u>.

FOIA mandates that government agencies make "reasonable efforts to search" for records responsive to a FOIA request. 5 U.S.C. § 552(a)(2)(E)(ii)(C). The law of this Circuit regarding the reasonableness of agency FOIA searches is clear. In responding to a FOIA request, an agency is required to show that it made "a good faith effort to conduct a search for the requested records, using methods that can be reasonably expected to produce the information requested." *Nation Magazine v. United States Customs Service*, 71 F.3d 885, 890 (D.C. Cir. 1995) (quoting *Oglesby v. United States Dept. of the Army*, 920 F.2d 57, 68 (D.C. Cir. 1990)). An agency is not required to search every record system, but it "cannot limit its search to only one record system if there are others likely to turn up the information requested." *Campbell v. United States Dept. of Justice*, 164 F.3d 20, 28 (D.C. Cir. 1998); *Oglesby*, 920 F.2d at 68.

The burden of persuasion as to the reasonableness of a search falls on the agency. *McGhee v. CIA*, 697 F.2d 1095, 1101 (D.C. Cir. 1983). Any affidavit(s) submitted by the agency describing its search for documents must be "relatively detailed and non-conclusory, and . . . submitted in good faith." *Safecard Services, Inc. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991) (quoting *Ground Saucer Watch, Inc. v. CIA*, 692 F.2d 770, 771 (D.C. Cir. 1981)). At the very least, the affidavit must denote which files the agency searched, and must explain in a systematic

way how the agency's documents were located in order to enable the Plaintiff to challenge the procedures utilized during the search. *Oglesby*, 920 F.2d at 68. Additionally, if the reasonableness of the search is challenged, as it is in this case, the agency must "demonstrate 'beyond a material doubt' that the search was reasonable." *Truitt v. Dep't of State*, 897 F.2d 540, 542 (D.C. Cir. 1990) (quoting *Weisberg v. U.S. Dep't of Justice*, 705 F.2d 1344, 1351 (D.C. Cir. 1983)).

1. Missing Records Demonstrate That the FDA Did Not Conduct a Reasonable Search.

Agencies are required to make "more than perfunctory searches and, indeed, to follow through on obvious leads to discover requested documents." *Valencia-Lucena v. U.S. Coast Gaurd*, 180 F.3d 321, 325 (D.C. Cir. 1999). This requirement is fulfilled only if the agency can "demonstrate beyond a material doubt that its search was 'reasonably calculated to uncover all relevant documents." *Id.* (quoting *Truitt*, 897 F.2d at 542). The FDA has failed to demonstrate that it conducted reasonable searches for records responsive to Judicial Watch's requests. Several examples of missing information highlight this point.

First, in the Murray production, the FDA included a copy of a portion of a U.S. House of Representatives Subcommittee hearing transcript. *See* Exhibit 1 attached hereto. In response to a question posed by Congresswoman Rosa DeLauro concerning meetings with FDA officials regarding Barr Laboratories application for Plan B over-the-counter status, the response included reference to a briefing given by Dr. Crawford and Dr. Galson to Senators Murray, Clinton, and Kennedy on April 6, 2005. *Id.* Missing from both the Clinton and Murray productions is the briefing material used for that meeting. It is simply unreasonable to think that two medical

doctors, one the acting director of the FDA's Center For Drug Evaluation and Research at the time, would brief three sitting U.S. Senators and not rely on any notes or written information.

Second, all three productions include only the Senators' "Questions for the Record" for Dr. Andrew C. Von Eschenbach, rather than any records of Dr. Von Eschenbach's nomination.[1] Dr. Von Eschenbach is the current FDA Commissioner and his role in obtaining over-the-counter status for Plan B was the subject of much consternation from both sides of the debate, including the very public hold Senators Clinton and Murray placed on Dr. Von Eschenbach's nomination. Surely, the FDA res records regarding Dr. Von Eschenbach's nomination. In fact, in an August 7, 2006 statement and press release, Senator Clinton stated that she questioned Dr. Von Eschenbach about recess appointments. *See* Exhibit 2, attached hereto. Senator Clinton's "Questions of Record" contain no such question. *See* Exhibit 3, attached hereto.

Third, Judicial Watch maintains that it is highly unlikely that the FDA has *no* records of any kind regarding the hold Senators Clinton and Murray placed on Dr. Von Eschenbach's nomination. Senators Clinton and Murray were very public about placing the hold on Dr. Von Eschenbach's nomination, and all three Senators arranged a meeting with him. The assertion that no correspondence or records resulted from either the meeting, or the hold, is risible.

2. <u>Inadequately Detailed Declarations Fail to Support the FDA's Search</u>.

To demonstrate the reasonableness of its search, the agency's affidavits must be "relatively detailed, nonconclusory, and submitted in good faith." *Founding Church of Scientology v. NSA*, 610 F.2d 824, 836 (D.C. Cir. 1979). Because of the "peculiarities inherent in

---

[1] All three productions included records on the March 17, 2005 nomination of Dr. Lester Crawford.

FOIA litigation, with the responding agencies often in sole possession of requested records and with information searches conducted only by agency personnel," courts have relied on the agency affidavits "to determine whether the statutory obligations of FOIA have been met." *Perry v. Block*, 684 F.2d 121, 126 (D.C. Cir. 1982). However, reliance on agency affidavits is not blind and does not require courts to "accept glib government assertions of complete disclosure or retrieval." *Id.* Additionally, the D.C. Circuit had held that instances of countervailing evidence, inconsistency of proof, and "positive indications of overlooked materials" can rebut agency affidavits, as well as evidence of bad faith. *Id.* at 127-28 (internal citations omitted).

The declarations submitted by the FDA are not sufficiently detailed, particularly in light of the above-mentioned examples of countervailing evidence. None of the declarations submitted describe the search terms or the type of search performed. Rather, each declaration simply asserts that the declarant "conducted a search" or "supervised a search." *See* May 2, 2007 Declaration of Lisa C. Granger at ¶ 10 (no search terms or detail of system); June 12, 2007 Declaration of Lisa M. Granger at ¶ 11 (no search terms or detail of system); April 26, 2007 Declaration of Indya Mungo at ¶ 5 (no search terms); July 11, 2007 Declaration of Indya Mugno at ¶ 6 (no search terms); May 1, 2007 Declaration of Karen E. Schifter at ¶ 4 (no search terms or system); July 12, 2007 Declaration of Karen E. Schifter at ¶ 5 (no search terms or system); Declaration of Carol H. Crim at ¶ 4 (no search terms or system); and Declaration of Kelly Palmer at ¶ 5 (no search terms or system).

Ms. Granger's Declarations state that she searched the Office of Legislation "tracking system," but neither declaration described what the "OL tracking system" is or how it operates. *See* May 2, 2007 Declaration of Lisa C. Granger at ¶ 10; June 12, 2007 Declaration of Lisa M.

Granger at ¶ 11; April 26, 2007 Declaration of Indya Mungo at ¶ 5; July 11, 2007 Declaration of Indya Mugno at ¶ 6. Similarly, Mr. Mungo's declarations state that she searched the "Office of Secretariat's Agency Information Management System ('AIMS')" but never describes the AIMS system or how it operates. The other declarations fail to identify in any way, what system was used in the searches.

Also missing from the FDA's affidavits is any description of how the search was actually conducted, including what each declarant found as a result of the search. The FDA does make clear that Ms. Granger coordinates the production, but none of the declaration state what records were actually found as a result of their nondescript search.[2] *See* April 26, 2007 Declaration of Indya Mungo at ¶ 5 (made the responsive documents available to the Office of Legislation); July 11, 2007 Declaration of Indya Mugno at ¶ 7 (forwarded responsive documents to the Office of Legislation); May 1, 2007 Declaration of Karen E. Schifter at ¶ 5 (produced non-duplicative documents to the Office of Legislation); July 12, 2007 Declaration of Karen E. Schifter at ¶ 6 (produced non-duplicative documents to the Office of Legislation); Declaration of Carol H. Crim at ¶ 4 (produced responsive records); and Declaration of Kelly Palmer at ¶ 5 (forwarded responsive documents to the Office of Legislation).

The D.C. Circuit held that an affidavit that does not show, with reasonable detail, that the search method "was reasonably calculated to uncover all relevant documents" does not satisfy the FOIA burden. *Oglesby*, 920 F.2d at 68. Similarly, an affidavit that fails to "identify the terms

---

[2] Ms. Crim does state that the records she produced reflected the "dates of meetings between the Commissioner and Senator Clinton." Crim Decl. at ¶ 4. Judicial Watch assumes these records consist of the emails and reminders of appointments. However, a sufficiently detailed declaration should not require assumptions on the part of the Court or the requestor.

searched or explain how the search was conducted" does not satisfy the FOIA burden. *Id.* The FDA's declarations have clearly not met FOIA's burden for sufficiently detailed. As the D.C. Circuit held:

> If the agency can lightly void its responsibilities by laxity in identification or retrieval of desired materials, the majestic goals of the [FOIA] Act will soon pass beyond reach. And if, in the fact of well-defined requests and positive indications of overlooked materials, an agency can so easily avoid adversary scrutiny of its search techniques, the Act will inevitably become nugatory.

Founding Church, 610 F.2d at 837.

III. Conclusion.

For the foregoing reasons, the FDA's motion to dismiss or, in the alternative, for summary judgment should be denied.

July 30, 2007

Respectfully submitted,

JUDICIAL WATCH, INC.

/s/ Meredith L. Di Liberto
D.C. Bar No. 487733
Paul J. Orfanedes
D.C. Bar No. 429716
Suite 500
501 School Street, S.W.
Washington, DC 20024
(202) 646-5172

Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JUDICIAL WATCH, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 07-00561 (RCL)
	)	
U.S. FOOD AND DRUG ADMINISTRATION	)	
	)	
	)	
Defendant.	)	
	)	

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

Plaintiff Judicial Watch, Inc. ("Judicial Watch"), by counsel and pursuant to LcvR 56.1, submits the following response to Defendant U.S. Food and Drug Administration's ("FDA") Statement of Material Facts as to Which There is No Genuine Issue:

1. Undisputed.

2. Undisputed.

3. Undisputed that the FDA sent Judicial Watch records responsive to the Clinton FOIA request. Deny any implication that it was a full production.

4. Undisputed.

5. Undisputed.

6. Dispute that the FDA has produced all records responsive to the Enzi and Murray FOIA requests.

7. Dispute as to the thoroughness of the searches performed by the FDA.

8. Dispute.

9. Dispute.

10. Dispute.

Judicial Watch respectfully submits the following statement of material facts as to which there is no genuine issue:

1. The FDA failed to comply with the statutory deadlines imposed by FOIA on each of the FOIA requests sent by Judicial Watch.

2. The FDA waited almost eight months to produce records responsive to the Clinton FOIA request.

3. Despite ongoing litigation, the FDA waited almost three months to produce records responsive to the Enzi and Murray FOIA requests.

July 30, 2007

Respectfully submitted,

JUDICIAL WATCH, INC.

/s/ Meredith L. Di Liberto
D.C. Bar No. 487733
Paul J. Orfanedes
D.C. Bar No. 429716
Suite 500
501 School Street, S.W.
Washington, DC 20024
(202) 646-5172

Attorneys for Plaintiff