Case 1:13-cv-06250-SLT-RLM Document 21 Filed 12/24/14 Page 1 of 12 PageID #: 170

IN CLERK'S OFFICE U.S. DISTRICT COURT E.D.N.Y.

★ DEC 2 4 2014 ★

BROOKLYN OFFICE

MEMORANDUM & ORDER

Plaintiff,

-----x

-against-

HENRY PLATSKY,

13-CV-06250 (SLT)(RLM)

FOOD & DRUG ADMINISTRATION, Division of Freedom of Information,

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK

Defendant.

TOWNES, United States District Judge:

Pro se Plaintiff Henry Platsky ("Platsky") brings this action pursuant to the Freedom of

Information Act ("FOIA") seeking an order directing the Defendant Food & Drug

Administration ("FDA") to release to him certain documents he believes the FDA has

wrongfully withheld. (See ECF No. 1.) The FDA filed the instant motion for summary

judgment on May 30, 2014, arguing that it performed an adequate search for responsive

documents.¹ (See ECF No. 20.) For the reasons set forth below, the FDA's motion for summary

judgment is granted.

BACKGROUND²

1. Platsky's complaint and FOIA requests

Sometime around April 2012, Platsky contacted the FDA by telephone to report his

concerns with a medical procedure he underwent during a clinical study conducted in New York

¹ Although the FDA moved for an extension of time to file its motion for summary judgment on April 11, 2014, (ECF No. 17), the FDA nonetheless timely filed its motion for summary judgment pursuant to the original schedule, (*see* ECF No. 20). The FDA's motion for an extension of time (ECF No. 17) is therefore terminated as moot.

² Unless indicated otherwise, the Court recites the facts below from the parties' Local Civil Rule 56.1 Statements of Material Facts and these facts are admitted by the opposing party, properly supported by the record, or deemed admitted for failing to provide proper factual opposition. *See* Local Civil Rule 56.1.

City in 2011. (Def.'s Local Civil Rule 56.1 Statements of Material Facts ("Def.'s 56.1 Stmt.") ¶

8, ECF No. 20-4.) The procedure involved a transrectal ultrasound ("TRUS") device. (Id.)

During the call, Platsky spoke with Dana Walters, an FDA employee. (Walters Decl. ¶ 11, ECF

No. 20-5.) Platsky also sent a letter to the FDA detailing his complaint. (Id. at ¶ 12.) The FDA

division that received Platsky's complaint, the Center for Drug Evaluation and Research

("CDER"), processes and investigates complaints related to drug studies. (*Id.* at \P 4–5.)

Because CDER determined that Platsky's complaint related to a device study, CDER forwarded

Platsky's complaint to the FDA division that monitors device studies, the Center for Devices and

Radiological Health ("CDRH"), on May 1, 2012. (*Id.* at ¶ 14.)

On July 2, 2012, Platsky submitted the following FOIA request to the FDA:

This is a Freedom of Information Act request for the results of your investigation of a concern I brought to the attention of Dana Walters of your office in a letter dated 4/9/2012. My concern involved a procedure used by University Urologists Associates of New York and the refusal of the Institutional Review Board assigned to their research study (the Quorum Review Board) to conduct an investigation into my concern.

Please send all releaseable [sic] material to the address below.

(Compl. Ex. 2, ECF No. 1 at p. 6.) Because Platsky's FOIA request specifically identified

Walters, a CDER employee, the FDA originally routed Platsky's FOIA request to CDER.

(Kotler Decl. ¶ 9.) But as with Platsky's original complaint, the FDA soon determined his FOIA

request should have been directed to CDRH and rerouted Platsky's FOIA request to CDRH.

(Kotler Decl. ¶¶ 9–10.)

In early January 2013, CDRH conducted searches for information responsive to Platsky's

FOIA request. Declarations submitted by the FDA detail the search terms used and databases

searched. During this time, a CDRH subdivision was conducting an active investigation of the

physician responsible for Platsky's study and was initiating an inspection of the physician's

studies at his medical office. (Holzerland Decl. ¶ 14.) This FDA subdivision believed the release of records related to the inspection could reasonably be expected to interfere with law enforcement proceedings. (*Id.*) CDRH therefore recommended that the FDA deny Platsky's FOIA request pursuant to FOIA Exemption 7(A), *see* 5 U.S.C. § 552(b)(7)(A), which authorizes agencies to withhold certain records where disclosure could reasonably be expected to interfere with enforcement proceedings. (Def.'s 56.1 Stmt. ¶¶ 18–19.) Thus, by letter dated January 17, 2013, the FDA denied Platsky's FOIA request pursuant to Exemption 7(A). (Def.'s 56.1 Stmt. ¶ 20; Compl. Ex. 5, ECF No. 1 at pp. 9–11.)

Platsky administratively appealed the FDA's denial of his FOIA request in February 2013. (Def.'s 56.1 Stmt. ¶ 21; Compl. Ex. 6, ECF No. 1 at p. 12.) He then resubmitted his FOIA request in June 2013. (Def.'s 56.1 Stmt. ¶ 23; Compl. Ex. 8, ECF No. 1 at p. 14.) After receiving Platsky's resubmitted request, the FDA identified what it thought were responsive documents and thus sent Platsky a warning letter that had resulted from the investigation noted above. (Holzerland Decl. ¶¶ 21–22.) After receiving a copy of the warning letter, Platsky wrote to the FDA to note that the warning letter involved a different device than the device at issue in his complaint and thus was not responsive to his FOIA request. (Holzerland Decl. ¶ 23; Compl. Ex. 11, ECF No. 1 at p. 19.) The FDA then confirmed that that investigation involved a different device and wrote back to Platsky informing him that no other potentially responsive records were found. (Holzerland Decl. ¶¶ 24–25.) Platsky again administratively appealed, and the FDA again informed Platsky that it found no responsive documents and that any documents withheld under FOIA exemption 7(A) were related to a different investigation and therefore not responsive to his requests. (Def.'s 56.1 Stmt. ¶ 31–32; Compl. Ex. 13, ECF No. 1 at p. 21.)

-3-

After Platsky filed this action in November 2013, the FDA performed additional searches. (Def.'s 56.1 Stmt. ¶ 34.) Around this time, the FDA discovered that no record existed to show that CDRH ever received from CDER Platsky's April 2012 complaint about the TRUS device procedure. (Def.'s 56.1 Stmt. ¶ 43.) CDRH thereafter conducted an investigation of Platsky's complaint and sent him the records from that investigation on March 4, 2014. (Def.'s 56.1 Stmt. ¶ 43–44.) Platsky admits he received these documents. (Mem. Opp'n ¶ 43, ECF No. 19.)

2. FDA declarations

The FDA submitted declarations from Dana Walters, Donna Engleman, Sarah Kotler, and William Holzerland. The Court briefly summarizes these declarations.

Dana Walters is a Public Health Analyst for CDER, the FDA division that processes and investigates complaints related to drug studies. (Walters Decl. ¶ 1, 5, ECF No. 20-5.) Walters is the individual who spoke with Platsky in April 2012 and forwarded his complaint to CDRH in May 2012. (*Id.* at ¶¶ 11, 14.) Her declaration describes how CDER tracks complaints and the database used for this function, the Office of Scientific Investigations ("OSI") Inspection Tracking Database. (*Id.* at ¶¶ 6–10.) Walters's declaration describes the search terms she used to search the OSI Inspection Tracking database. (*Id.* at ¶ 17.)

Donna Engleman is Chief of the FDA's Allegations of Regulatory Misconduct Branch ("ARMB"). (Engleman Decl. ¶ 1, ECF No. 20-6.) Engleman bases her declaration upon her "personal knowledge and official records available to [her] in [her] capacity as Chief of ARMB." (*Id.* at ¶ 3.) Engleman states that she is "personally familiar with Henry Platsky's FOIA requests" related to the complaint he lodged with the FDA in April 2012. (*Id.* at ¶ 4.) Her declaration describes the databases, physical files, and Microsoft Outlook folders likely to

-4-

contain responsive records. (*See id.* at ¶¶ 7–8.) Her declaration details the search terms used to search the relevant databases and describes her search of the physical records, which focused on complaints received from May to August 2012. (*Id.* at ¶ 9.) Engleman's declaration summarizes her search efforts by stating she "searched all places likely to contain responsive records under ARMB's possession or control" and notes that no potentially responsive records were located. (*Id.* at ¶ 10.)

Sarah Kotler is the Deputy Director of the FDA's Division of Freedom of Information. (Kotler Decl. ¶ 1, ECF No. 20-7.) She draws her information from her "personal knowledge and records available to [her] in her official capacity" and notes that she is "personally familiar with FDA's handling of the FOIA requests submitted by Henry Platsky . . . dated July 2, 2012 . . . and dated June 23, 2013." (*Id.* at ¶ 3.) Kotler's declaration describes the FDA's general process for handling FOIA requests and details the steps taken in response to Platsky's requests. (*See id.* ¶¶ 5-7, 9-25.)

William Holzerland is the Director of CDRH's Division of Information Disclosure ("CDRH-DID"). (Holzerland Decl. ¶ 1, ECF No. 20-8.) Holzerland's statement is based on his "personal knowledge and official records available to [him] in [his] capacity as Director of CDRH-DID." (*Id.* at ¶ 3.) Holzerland is "personally familiar" with Platsky's FOIA requests. (*Id.*) Holzerland's declaration describes CDRH-DID's general process for handling FOIA requests and how CDRH-DID handled Platsky's FOIA requests. (*Id.* at ¶¶ 5–39.) Holzerland's declaration describes the various searches performed in response to Platsky's FOIA requests, including the databases searched and the search terms used. Holzerland summarizes the search by stating that CDRH "searched all places likely to contain responsive records" but located no records responsive to Platsky's requests. (*Id.* at ¶ 39.)

-5-

3. Procedural History

Platsky filed this FOIA action against the FDA on November 6, 2013, seeking an order directing the FDA to release the report on its investigation of his April 2012 complaint. (ECF No. 1.) On March 26, 2014, this Court granted the FDA's request to move for summary judgment pursuant to Federal Rule of Civil Procedure 56. (ECF No. 16.) The FDA filed the fully-briefed motion on May 30, 2014, arguing that it conducted full and complete searches reasonably calculated to locate responsive records. In his opposition, Platsky contends that contradictions in the FDA's submissions constitute evidence of "chicanery" and that fact issues preclude summary judgment.

LEGAL STANDARD

"FOIA cases are generally and most appropriately resolved on motions for summary judgment." *Families for Freedom v. U.S. Customs & Border Prot.*, 797 F. Supp. 2d 375, 385 (S.D.N.Y. 2011). As in other contexts, summary judgment is appropriate in a FOIA case only if the record "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "'In ruling on a motion for summary judgment, a court must resolve all ambiguities and draw all factual inferences in favor of the nonmoving party." *Families for Freedom*, 797 F. Supp. 2d at 385 (quoting *McClellan v. Smith*, 439 F.3d 137, 144 (2d Cir. 2006)).

A federal agency responding to a FOIA request must "(1) conduct an adequate search using reasonable efforts, (2) provide the information requested, unless it falls within a FOIA Exemption, and (3) provide any information that can reasonably be segregated from the exempt information." *Bloomberg L.P. v. Bd. of Governors of Fed. Reserve Sys.*, 649 F. Supp. 2d 262, 270 (S.D.N.Y. 2009) (citing 5 U.S.C. §§ 552(a)(3), 552(b)), *aff*³d, 601 F.3d 143 (2d Cir. 2010).

-6-

The agency bears the burden of showing it conducted an adequate search for responsive records. *Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 812 (2d Cir. 1994). "Once the agency satisfies its burden of showing that it conducted an adequate search, the burden shifts to the plaintiff to make a showing of bad faith sufficient to impugn the agency's showing." *Bloomberg*, 649 F. Supp. 2d at 271. The plaintiff cannot rebut this presumption with purely unsubstantiated claims. *Grand Cent. P'ship, Inc. v. Cuomo*, 166 F.3d 473, 489 (2d Cir. 1999) (citations omitted). However, "[*p*]*ro se* litigants are permitted special latitude in responding to a summary judgment motion." *Doolittle v. U.S. Dep't of Justice, Drug Enforcement Agency*, 142 F. Supp. 2d 281, 284 (N.D.N.Y. 2001) (citation and internal quotation marks omitted).

The agency may meet its burden to show the adequacy of the search through affidavits or declarations that demonstrate that its search was "reasonably calculated to uncover all relevant documents." *Bloomberg*, 649 F. Supp. 2d at 271. "Reasonableness does not demand perfection, and a reasonable search need not uncover every document extant." *Id.* (citing *Grand Cent. P'ship*, 166 F.3d at 489). To satisfy this burden, the affidavits or declarations must be "relatively detailed and nonconclusory, and . . . submitted in good faith." *Grand Cent. P'ship*, 166 F.3d at 488–89 (2d Cir. 1999) (quoting *SafeCard Servs., Inc. v. S.E.C.*, 926 F.2d 1197, 1200 (D.C. Cir. 1991)). "[T]he court may rely on [a] reasonably detailed affidavit setting forth the search terms and the type of search performed, and averring that all files likely to contain. responsive materials (if such records exist) were searched." *Peeler v. U.S. Dep't of Justice*, No. 11CV1370 (RNC), 2013 WL 5448515, at *3 (D. Conn. Sept. 30, 2013) (quoting *Valencia-Lucena v. U.S. Coast Guard*, 180 F.3d 321, 326 (D.C. Cir. 1999)); *see also Dinsio v. F.B.I.*, 445 F. Supp. 2d 305, 312 (W.D.N.Y. 2006) ("Such an affidavit 'should, at a minimum, describe in reasonable detail the scope and method by which the search was conducted." (citing *Maynard v*.

C.I.A., 986 F.2d 547, 559 (1st Cir. 1993))). "Affidavits submitted by an agency are 'accorded a presumption of good faith."" *Carney*, 19 F.3d at 812 (citation omitted).

Courts will deny summary judgment "where the agency's response raises serious doubts as to the completeness of the agency's search, where the agency's response is patently incomplete, or where the agency's response is for some other reason unsatisfactory." *Nat'l Day Laborer Org. Network v. U.S. Immigration & Customs Enforcement Agency*, 877 F. Supp. 2d 87, 96 (S.D.N.Y. 2012) (citation and internal quotation marks omitted).

DISCUSSION

The FDA moves for summary judgment on the ground that its search was adequate. The FDA argues that the declarations it submitted, which set forth the FDA's general practices and procedures for processing FOIA requests and the actions taken in response to Platsky's requests, satisfy its burden to demonstrate an adequate search. As described above, the FDA's declarations set forth in reasonable detail the scope of the search, and the search terms and methods the FDA employed shows the agency's search was reasonably calculated to discover documents responsive to Platsky's FOIA request. Furthermore, the Engleman and Holzerland declarations aver that all places likely to contain responsive records have been searched. The FDA has thus satisfied its burden of showing it conducted an adequate search for responsive records. *See Peeler*, 2013 WL 5448515, at *5 (finding DEA attorney's declaration summarizing DEA's policies and practices and detailing steps agency took to comply with plaintiff's FOIA request sufficient to demonstrate an adequate search).

Platsky contends that a letter he received from the FDA's New York District office in September 2012 contradicts the FDA's statement that its inquiries into his FOIA request did not begin until December 2012 and thus constitutes evidence of the FDA's "chicanery." (Mem.

-8-

Opp'n 4–5, ECF No. 19.) As the FDA notes, however, the FDA's Rule 56.1 Statement does not state that its investigation did not begin until December 2012. Instead, the FDA's Rule 56.1 Statement indicates that Platsky's July 2012 FOIA request was routed to a certain FDA subdivision in December 2012 for further processing. (Def.'s 56.1 Stmt. ¶ 11.) Contrary to Platsky's contention, this letter does not contradict the FDA's explanation of its handling of Platsky's request and does not constitute evidence of "chicanery." Rather, the FDA's declarations detail how it processed Platsky's complaint during the time period at issue.

Platsky also argues that the explanation for what he describes as a five-month delay in the FDA's processing of his FOIA request was that the FDA "bureaucratically subject[ed] [the report of the investigation into Platsky's April 2012 TRUS procedure complaint he believes already existed in June 2012] . . . to oblivion within [the FDA]'s labyrinth of divisions." (Mem. Opp'n 3–4, ECF No. 19.) Platsky's speculation does not suffice to show the FDA's search was inadequate or that the FDA acted in bad faith. As noted above, the FDA's declarations detail the routing and processing of Platsky's complaint and FOIA requests during this time period. Moreover, any mix-ups that may have contributed to any delay do not suffice to show the FDA's search was inadequate or that the FDA acted in bad faith. *See Garcia v. U.S. Dep't of Justice, Office of Info. & Privacy*, 181 F. Supp. 2d 356, 367 (S.D.N.Y. 2002) (mere "mix-up[s] and . . . technical failings [by the agency] support neither the allegation that [the agency's] search procedures were inadequate, nor an inference that it acted in bad faith" (citation omitted)).

Platsky next argues that fact issues exist to preclude summary judgment. (Mem. Opp'n 2, ECF No. 19.) Specifically, Platsky argues that whether his April 2012 complaint about the TRUS procedure was forwarded to a certain FDA subdivision is a fact issue that requires discovery. (*Id.*) But whether Platsky's complaint was forwarded to a certain FDA subdivision is

-9-

not at issue. The question raised by Platsky's case is whether the FDA complied with FOIA and adequately searched for responsive records. *See Bloomberg*, 649 F. Supp. 2d at 270 (explaining that a federal agency responding to a FOIA request must "(1) conduct an adequate search using reasonable efforts, (2) provide the information requested, unless it falls within a FOIA Exemption, and (3) provide any information that can reasonably be segregated from the exempt information.") Thus, whether Platsky's original complaint was forwarded to a certain FDA subdivision is immaterial and does not preclude summary judgment. *See Quarles v. Gen. Motors Corp.*, 758 F.2d 839, 840 (2d Cir. 1985) ("[T]he mere existence of factual issues—where those issues are not material to the claims before the court—will not suffice to defeat a motion for summary judgment.").

Finally, Platsky argues that during a June 2012 telephone call with Dana Walters, "Ms. Walters told [Platsky] that [he] could receive a copy of the report on the investigation of [his] complaint by making a[] FOIA request to the FDA." (Mem. Opp'n 3, ECF No. 19.) Platsky continues: "Why again did Ms. Walters tell me there was a report responsive to my complaint when she now asserts implicitly that there never was one?! Further why would Ms. Wa[1]ters suggest that I Make a[] FOIA request for a non-existent report?!" (*Id.*) Walters's statement, as recounted by Platsky, does not require the conclusion that a report in fact existed. Her statement that Platsky "could receive a copy of the report on the investigation of [his] complaint by making a FOIA request" can naturally be read to mean that a FOIA request would be the proper method by which to seek a copy of a report, if one existed. This Court, however, must construe the evidence in the light most favorable to Platsky, the nonmovant. *See Families for Freedom*, 797 F. Supp. 2d at 385.

Even assuming Walters told Platsky a report existed at the time of the June 2012 call, Platsky still fails to defeat the FDA's motion for summary judgment. The factual question raised here is whether the FDA's search "was reasonably calculated to discover the requested documents, not whether it actually uncovered every document extant." *See Peeler*, 2013 WL 5448515, at *4 (citation omitted). Under this standard, even if a report did exist and the FDA failed to locate it, this alone would not suffice to create a genuine issue of material fact as to the adequacy of the search. *See id.* (finding fact that plaintiff possessed documents DEA's search failed to find did not preclude summary judgment); *Schoenman v. F.B.I.*, 763 F. Supp. 2d 173, 204 (D.D.C. 2011) ("Because the adequacy of a FOIA search is generally determined not by the fruits of the search, but by the appropriateness of the methods used to carry out the search, the [mere] fact that a particular document was not found does not demonstrate the inadequacy of a search." (internal citations and quotation marks omitted)).

In his opposition, Platsky states that he "hope[s] to solve the mystery of what happened to [his] inquiry to the FDA about the TRUS procedure." (Mem. Opp'n 5, ECF No. 19.) This case presents complicated facts compounded by the FDA's apparent mistakes in not investigating Platsky's April 2012 complaint until early 2014 and erroneously sending Platsky FOIA responses based on an investigation outside the scope of Platsky's FOIA requests. But any mixups by the FDA do not invalidate what the FDA has otherwise shown was an adequate search, *see Garcia*, 181 F. Supp. 2d at 367, and the FDA's submissions clarify what became of Platsky's April 2012 complaint. Platsky has not submitted evidence sufficient to rebut the presumption of good faith accorded to the FDA's declarations, and nothing about these declarations or the FDA's response hints that the FDA's response was incomplete or for any reason unsatisfactory. The FDA is therefore entitled to summary judgment.

Case 1:13-cv-06250-SLT-RLM Document 21 Filed 12/24/14 Page 12 of 12 PageID #: 181

CONCLUSION

For the reasons set forth above, the Defendant's motion is granted. The Clerk of Court is respectfully requested to close the case.

SO ORDERED.

/s/ Sandra L. Townes

SANDRA L. TOWNES United States District Judge

Dated: December 23, 2014 Brooklyn, New York