

No. 09-4084

In the  
**United States Court of Appeals**  
for the Sixth Circuit

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**CARETOLIVE,**  
*Plaintiff-Appellant,*  
v.

**FOOD AND DRUG ADMINISTRATION,**  
*Defendant-Appellee.*

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On Appeal from the United States District Court  
for the Southern District of Ohio  
No. 2:08-cv-00005 (Frost, J.)

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**BRIEF FOR DEFENDANT-APPELLEE FOOD AND DRUG  
ADMINISTRATION**

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**STATEMENT REGARDING ORAL ARGUMENT**

The Food and Drug Administration believes the facts and legal arguments are adequately presented in the briefs and record, and that oral argument would not aid the deliberative process. FDA therefore submits that this appeal meets the criteria of Rule 34 of the Rules of the Sixth Circuit for submission without oral argument.

**STATEMENT OF JURISDICTION**

On January 2, 2008, CareToLive invoked the district court's federal question jurisdiction by filing its complaint under the Freedom of Information Act, [5 U.S.C. § 552](#). (R. 2, Complaint, ¶ 1).

On August 14, 2009, CareToLive timely appealed from the June 23, 2009 Judgment of the District Court for the Southern District of Ohio granting FDA's motion for summary judgment and denying CareToLive's motion for discovery. (R. 42, Notice of Appeal; R. 40, Order; R. 41, Judgment.) This Court has jurisdiction over CareToLive's appeal because [28 U.S.C. § 1291](#) provides the courts of appeals with jurisdiction over appeals from all final decisions of the district courts.

**ISSUES PRESENTED FOR REVIEW**

I. Whether the district court properly granted summary judgment to FDA, based on its determination that the agency's declarations established the adequacy of FDA's search in response to CareToLive's FOIA request and that CareToLive failed to present evidence to impugn those declarations.

II. Whether the district court abused its discretion in denying CareToLive's request for discovery, when CareToLive failed to present evidence that FDA had acted in bad faith in responding to its FOIA request.

**STATEMENT OF THE CASE**

In January 2008, CareToLive filed its complaint against the FDA, seeking the immediate production of documents responsive to its September 11, 2007 FOIA request. (R. 2, Complaint.) FDA responded to the complaint in February 2008 with a Motion to Stay Proceedings, which the district court conditionally granted. (R. 12, Order, pp. 16–17.)

On May 18, 2009, FDA produced the last of its responsive

documents to CareToLive and filed a motion for summary judgment. (R. 29.) In its motion, FDA argued that it was entitled to summary judgment because the agency had conducted a reasonable and adequate search and had produced all responsive documents to CareToLive's FOIA request. (*Id.*) In support of its motion, FDA filed detailed declarations from supervisors of three FOIA divisions within the agency to show the steps that were taken to locate records in every agency office that was likely to have documents responsive to CareToLive's narrow request. (*Id.* Exhs. A, B, C.)

CareToLive responded to FDA's motion with a request for discovery under Federal Rule of Civil Procedure 56(f). (R. 34, Pl's. Mot. in Part'l. Opp. to Summ. J. and for Leave to Conduct Disc.) Although CareToLive argued that it was entitled to discovery because FDA had acted in bad faith in responding to the FOIA request, CareToLive did not provide any evidence to rebut the agency's declarations showing that an adequate document search had been conducted. (*See id.*) In addition, CareToLive failed to provide an adequate declaration setting forth its basis for requesting discovery, as required by Federal Rule of

Civil Procedure 56. (*See id.*)

On June 23, 2009, the district court granted FDA's motion for summary judgment and denied CareToLive's motion for discovery. (R. 40, Order; R. 41, Judgment.)

## **STATEMENT OF FACTS**

### **A. CareToLive's FOIA Request.**

On September 11, 2007, FDA's Division of Freedom of Information ("DFOI") received a FOIA request from Bellinger & Donahue, attorneys for CareToLive, dated August 15, 2007.<sup>1</sup> (R. 29-1, Def.'s Mot. for Summ. J., Exhibit A, Declaration of Frederick J. Sadler ("Sadler Decl."), ¶ 9.)

CareToLive's request sought:

A copy of all letters written to the FDA (or prepared by the FDA) and purported to be from Dr. Scher, Dr. Hussain and Doctor Fleming in between March 29th 2007 and April 30th of 2007, regarding the BLA [Biologics License Application] submitted for Provenge also known as Sipuleucel-T including the envelope or other means of communication whereby the

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<sup>1</sup> The delay between the date of the FOIA request and receipt by DFOI occurred because CareToLive improperly sent the request to the agency's Cincinnati District Office rather than to DFOI. Per [21 C.F.R. § 20.40\(a\)](#), all FOIA requests must be received by DFOI in order to be processed. The request was ultimately forwarded from the Cincinnati District Office to DFOI on or around September 11, 2007. (Sadler Decl. ¶9 & n.1.)

FDA received such letters and a copy of any record of those letters then being disclosed to any media or other persons or specifically a publication called “The Cancer Letter,” including the means of communication to the Cancer Letter of the Scher, Hussain and Fleming letters from the FDA or its employees to outside persons, publications or companies.

(*Id.*) DFOI referred the request to the Access Litigation and Freedom of Information Branch (“ALFOI”) of FDA’s Center for Biologics Evaluation and Research (“CBER”) on September 14, 2007, because the request sought documents relating to Provenge, an unapproved biological product regulated by CBER. (*Id.* ¶ 12; *see also* R. 29-2, Def.’s Mot. for Summ. J., Exhibit B, Declaration of Beth Brockner-Ryan (“Brockner-Ryan Decl.”), ¶¶ 10–11.) On November 6, 2007, CBER released all responsive documents, without any redactions, to CareToLive. (Brockner-Ryan Decl. ¶ 14; Sadler Decl. ¶ 12.)

DFOI also forwarded the request to the Office of the Executive Secretariat (“Exec. Sec.”) and the Immediate Office of the Commissioner (“Immediate Office”), both of which maintain agency correspondence files, in FDA’s Office of the Commissioner. (Sadler Decl. ¶ 13.) Exec. Sec. responded to CareToLive, through DFOI, on January 24, 2008, indicating that no responsive records had been located. (*Id.* ¶ 14.) The

Immediate Office, through DFOI, produced responsive documents, without any redactions, to CareToLive on February 26, 2008. (*Id.* ¶ 15.)

On October 10, 2007, DFOI forwarded CareToLive's request to the Division of Information Disclosure Policy ("DIDP") in FDA's Center for Drug Evaluation and Research ("CDER"). (Sadler Decl. ¶ 16; *see also* R. 29-3, Def.'s Mot. for Summ. J., Exhibit C, Declaration of Nancy A. Sager ("Sager Decl.") ¶ 11.) DFOI did so because, after consultation with CBER, it appeared that CDER was also likely to have records relating to Provenge. (*Id.*) Because DIDP uses a "first-in, first-out" queue system to process all requests for documents, and there were many requests for documents ahead of CareToLive's FOIA request, DIDP could not process CareToLive's request within the time required by the FOIA. (Sager Decl. ¶ 13.)

## **B. CareToLive's Litigation Under the FOIA.**

When CareToLive became aware that DIDP would not produce documents within FOIA's time frame, it filed its Complaint in January 2008, seeking the immediate production of all documents responsive to its request. (R. 2.) In response to CareToLive's lawsuit, FDA filed a

Motion to Stay Proceedings for twenty months to allow FDA to continue processing FOIA requests submitted before CareToLive's request. (R. 10.)

In May 2008, the district court conditionally granted the agency's Motion to Stay Proceedings. The court ordered DIDP to provide it with an update on the progress of the FOIA request in the queue on December 1, 2008, and informed the agency that it would have to produce all responsive documents no later than May 18, 2009. (R. 23, Order, pp. 16–17.) On December 1, 2008, DIDP informed the district court that CareToLive's request was still on track to rise to the top of the queue in October 2009, but DIDP would pull the request earlier and provide CareToLive with all responsive documents on or before May 18, 2009 as required by the Court's order. (R. 25, Def.'s Supplemental Decl.)

Following a search of all relevant CDER offices, DIDP produced one additional responsive document, without any redactions, to CareToLive on May 18, 2009. (Sager Decl. ¶¶ 17–20.) On that same day, FDA filed its motion for summary judgment, in which it argued

that it had produced all documents responsive to CareToLive's FOIA request, and thus there was no longer any relief that the court could provide to CareToLive. (R. 29, Def.'s Mot. for Summ. J.) FDA's supporting declarations, submitted by the heads of three agency FOIA divisions, described in detail the adequacy of the agency's search for responsive documents. (*Id.*)

In addition, FDA included the declaration of Dr. Richard Pazdur, Supervisory Medical Officer in CDER's Office of Oncology. (R. 29-4, Exhibit D, Declaration of Dr. Richard Pazdur ("Pazdur Decl.")). CareToLive had named Dr. Pazdur, in its Opposition to FDA's Motion to Stay Proceedings, as an employee that it believed had numerous responsive documents. (R. 18, Pl.'s Resp. to Def.'s Mot. to Stay Proceedings, pp. 2-3, 15.) In fact, Dr. Pazdur had only possessed copies of documents already produced to CareToLive, and he had destroyed those copies soon after receiving them in May 2007. (Pazdur Decl. ¶ 7.)

CareToLive's response to FDA's motion for summary judgment included a request for discovery under Federal Rule of Civil Procedure 56. (R. 34, Pl.'s Mot. in Part'l. Opp. to Summ. J. and for Leave to

Conduct Disc.) CareToLive argued that discovery was necessary because the agency had acted in bad faith by not using an IT expert to search Dr. Pazdur's computer for additional correspondence and the date of deletion of the 2007 letters. (*Id.* pp. 6–11.) Although Rule 56(f) requires a party opposing a summary judgment motion to “show by affidavit that, for specified reasons, it cannot present facts essential to justify its opposition” without discovery, CareToLive did not submit an affidavit. Instead, CareToLive submitted a one-paragraph “Affidavit By Counsel for CareToLive” that stated as follows in its entirety:

Now comes Counsel for CareToLive under Federal Rule of Civil Procedure 56(f) and swears under oath and asserts to this Court that CareToLive is unable by affidavit to provide proof to this Court of the existence of the requested FOIA correspondence on the computer of FDA employee Richard Pazdur at this time without the relief and/or discovery requested herein. With any or all of the relief requested in the Rule 56(f) motion the Plaintiff is confident it can show that the FDA FOIA response was not complete.

Sworn to by me this 6th day of June 2009.

s/Kerry M. Donahue  
Kerry M. Donahue

(*Id.* p. 22.) This “affidavit” was neither sworn to under penalty of perjury before a notary public nor was it signed under penalty of

perjury pursuant to 28 U.S.C. § 1746.<sup>2</sup> (*Id.*)

Moreover, CareToLive did not state any specific facts in support of its assertion of bad faith. (*See* R. 34.) Instead, CareToLive ignored the declarations submitted by FOIA supervisors detailing the agency's search and focused on discrediting the declaration submitted by Dr. Richard Pazdur. (*Id.* pp. 6–11.) Without providing any factual support, CareToLive alleged that “it would make sense that” there was additional correspondence between Dr. Pazdur and Drs. Hussain and Scher as they served together on the same Advisory Committee, and because Dr. Pazdur was a “leader of the opposition” against the approval of the biologic Provenge. (*Id.* p. 7.) CareToLive also tried to uphold its conspiracy theory by asserting—again without providing any factual support—that Dr. Pazdur lied about the approximate date that he deleted and shredded the responsive letters because he “would or should have” known in early April 2007 that these letters were generating, at least in CareToLive's view, “worldwide” controversy

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<sup>2</sup> Although the one-paragraph statement by CareToLive's counsel was clearly not an affidavit, this brief will refer to it as an affidavit for ease of identification. Such reference is in no way a concession that counsel's statement was in fact an affidavit.

among cancer patients and advocates, and were likely to be the subject of litigation. (*Id.* p. 9.)

**C. The District Court’s Decision.**

On June 23, 2009, the district court granted summary judgment for FDA and denied CareToLive’s motion for discovery. (R. 40, Order.) The court found that the declarations submitted by FDA “unquestionably established” that the agency had performed an adequate and reasonable search pursuant to CareToLive’s FOIA request, and that all responsive documents had been produced. (*Id.* p. 6.) The court also found that CareToLive did not present any evidence to undermine the agency’s declarations. (*Id.*) Consequently, according to the Court, FDA was entitled to summary judgment under FOIA. (*Id.*)

Although the court stated that CareToLive’s request for discovery is properly denied on the basis of the inadequate Rule 56 affidavit alone, the court found that CareToLive’s failure to provide anything other than “factually inaccurate statements and conspiracy theories” to rebut FDA’s declarations made discovery unnecessary even if the

affidavit were sufficient. (*Id.* p. 10.) In particular, the court noted that CareToLive had not disputed that the documents destroyed by Dr. Pazdur were duplicates, and FOIA “does not require a party to account for documents, so long as it reasonably attempted to locate them.” (*Id.* at p. 8) (citing [West v. Spellings](#), 539 F. Supp. 2d 55, 62 (D.D.C. 2008)). According to the Court, the agency was “simply not required to hire an IT expert to search for a copy of a document that had already been produced.” (*Id.* pp. 7–8.) Thus, the court held that CareToLive had failed to show that FDA acted in bad faith in performing its search and was therefore not entitled to discovery. (*Id.* at p. 12.)

### **STANDARD OF REVIEW**

The Sixth Circuit reviews a district court’s grant of summary judgment in a FOIA proceeding de novo, viewing the evidence in the light most favorable to the party opposing the motion. [Rugiero v. U.S. Dep’t of Justice](#), 257 F.3d 534, 543 (6th Cir. 2001) (upholding summary judgment on adequacy of search where no responsive records located); *see also* [Detroit Free Press, Inc. v. Dep’t of Justice](#), 73 F.3d 93, 95 (6th Cir. 1996). “Summary judgment is proper if ‘the pleadings, depositions,

answers to interrogatories, and admissions on file, together with the affidavits show there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law.” [Rugiero](#), 257 F.3d at 543; *accord* Fed. R. Civ. P. 56(c). “Entry of summary judgment is appropriate ‘against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.’” [Rugiero](#), 257 F.3d at 543 (quoting [Celotex Corp. v. Catrett](#), 477 U.S. 317, 322 (1986)).

In the Sixth Circuit, “the scope of discovery is within the sound discretion of the trial court,” and a “ruling by the trial court limiting or denying discovery will not be cause for reversal unless an abuse of discretion is shown.” [S.S. v. E. Ky. Univ.](#), 532 F.3d 445, 451 (6th Cir. 2008). “An abuse of discretion exists when the reviewing court is firmly convinced that a mistake has been made.” *Id.* (citing [Bush v. Rauch](#), 38 F.3d 842, 848 (6th Cir. 1994)).

### **SUMMARY OF ARGUMENT**

The district court’s judgment should be affirmed because FDA

conducted an adequate search in response to CareToLive's FOIA request. The district court also acted well within its discretion in denying CareToLive's request for discovery.

In declarations from the heads of three FOIA divisions within the agency, FDA unquestionably established that it conducted a search that was reasonably calculated to uncover the documents that CareToLive requested. FDA also submitted a declaration from Dr. Richard Pazdur, an employee that CareToLive believed to have many responsive documents, stating that all he ever had were copies of the letters that had already been produced to CareToLive by other agency divisions, and that he had destroyed his copies within a month of receiving them.

CareToLive did not provide any evidence to question the adequacy of FDA's search. Instead, CareToLive speculated that Dr. Pazdur lied in his declaration about both the existence of additional documents and the date that he destroyed his copies of the letters produced to CareToLive, purportedly because he wanted to hide his participation in a claimed conspiracy to derail the approval of

Provenge. Such baseless speculation cannot rebut the factually established reasonableness of FDA's search. Thus, this Court should affirm the district court's grant of summary judgment to FDA.

The district court also properly denied discovery to CareToLive. CareToLive did not file an adequate affidavit in support of its request for discovery, as required by Federal Rule of Civil Procedure 56(f). CareToLive's affidavit was only one paragraph and did not include either factual support for its claim of agency wrongdoing or an explanation of what material facts it hoped to uncover with the requested discovery. The district court correctly noted that CareToLive's request for discovery failed on this basis alone.

But the district court also correctly concluded that CareToLive did not need discovery regardless of its affidavit. CareToLive had hinged its request on its unfounded allegations and conspiracy theories about the veracity of Dr. Pazdur's declaration, and its belief that additional documents "must" be out there. As CareToLive did not present any evidence to support its claim that the agency had acted in bad faith, the district court acted well within its discretion in denying

the request for discovery.

## ARGUMENT

### **I. The District Court Properly Granted Summary Judgment to FDA Based on Its Determination That FDA Conducted an Adequate Search That Led to the Production of All Responsive Documents.**

#### **A. An Agency's Search for Documents Must Be Reasonable and Can Be Sufficiently Proven Through Detailed Declarations.**

In response to a FOIA request, an agency “must make a good faith effort to conduct a search for the requested records using methods reasonably expected to produce the requested information” and that is “tailored to the nature of the request.” [Rugiero](#), 257 F.3d at 547. The question of adequacy “focuses on the agency’s search, not on whether additional documents exist that might satisfy the request.” [Rugiero](#), 257 F.3d at 547 (citing [Steinburg v. U.S. Dep’t of Justice](#), 23 F.3d 548, 551 (D.C. Cir. 1994)). Indeed, the search standards under the FOIA do not place upon an agency the requirement that it prove that all responsive documents have been located. [Nation Magazine v. U.S. Customs Serv.](#), 71 F.3d 885, 892 n.7 (D.C. Cir. 1995); *see also* [Rugiero](#), 257 F.3d at 547. As a result, an agency is not required to search every

division or field office in response to a FOIA request when responsive documents are likely to be located in a few places. Marks v. Dep't of Justice, 578 F.2d 261, 263 (9th Cir. 1978). In short, “adequacy is measured by the reasonableness of the effort in light of the specific request.” Meeropol v. Meese, 790 F.2d 942, 956 (D.C. Cir. 1986).

It is the agency's burden to establish the adequacy of its search, and in discharging this burden, “the agency may rely on affidavits or declarations that provide reasonable detail of the scope of the search.” Rugiero, 257 F.3d at 547 (citing Bennett v. DEA, 55 F. Supp. 2d 36, 39 (D.D.C. 1999)). These declarations need not “set forth with meticulous documentation the details of an epic search for the requested records.” Perry v. Block, 684 F.2d 121, 127 (D.C. Cir. 1982). “Rather, in the absence of countervailing evidence or apparent inconsistency of proof, affidavits that explain in reasonable detail the scope and method of the search conducted by the agency will suffice to demonstrate compliance with the obligations imposed by the FOIA.” *Id.*; see also Rugiero, 257 F.3d at 547 (quoting Bennett v. DEA, 55 F. Supp. 2d 36, 39 (D.D.C. 1999)). Furthermore, a requester cannot rebut agency affidavits

regarding the adequacy of the search with purely speculative claims.

[\*SafeCard Servs., Inc. v. SEC\*](#), 926 F.2d 1197, 1200 (D.C. Cir. 1991).

**B. FDA’s Search Was Adequate.**

The district court correctly found that FDA “unquestionably established” that it conducted a reasonable and thorough search for all documents responsive to CareToLive’s request. (See R. 40, Order, p. 8.) The scope of the search is defined by the scope of the request. See [\*Rugiero\*](#), 257 F.3d at 547; see also [\*Kowalczyk v. Dep’t of Justice\*](#), 73 F.3d 386, 388–89 (D.C. Cir. 1996). CareToLive’s request was narrow, seeking only copies of correspondence between FDA and three individuals, and possibly “media or other persons,” during a one-month period. (See Sadler Decl. ¶ 9.) As required by FOIA, FDA forwarded CareToLive’s FOIA request to every office in the agency that would be reasonably likely to have responsive documents, and these offices followed strict procedures in conducting their searches to ensure that they found and produced all responsive documents.

**1. DFOI’s Role in the Search for CareToLive’s Requested Documents.**

Under FDA’s regulations at [21 C.F.R. § 20.40\(a\)](#), all requests for

FDA records must be made in writing to DFOI. (Sadler Decl. ¶ 5.)

When a FOIA request is received by DFOI, a Freedom of Information technician (“FOI technician”) scans the request into a PDF format, logs and uploads the request into the Agency Information Management Systems (“AIMS”), which stores and tracks all agency FOIA requests, and assigns the request a reference number. (*Id.* ¶ 6.) Once a FOIA request is logged in, DFOI sends a letter to the requester acknowledging FDA’s receipt of the request. (*Id.* ¶ 8.) The FOI technician then forwards the request to the FDA office(s) which, based on a preliminary review of the request, is (are) most likely to possess responsive records. (*Id.* ¶ 7.)

DFOI received CareToLive’s request on September 11, 2007, and on that same day, a FOI technician logged it into AIMS, assigned it a reference number, and sent an acknowledgment letter to CareToLive. (*Id.* ¶¶ 9–11.) On September 14, 2007, DFOI referred CareToLive’s request to CBER’s ALFOI because the request sought documents relating to Provenge, an unapproved biological product regulated by CBER. (*Id.* ¶ 12.) ALFOI’s search for documents is discussed in detail

below.

DFOI also forwarded CareToLive's request to Exec. Sec. and the Immediate Office in FDA's Office of the Commissioner because the request sought agency correspondence, and both Exec. Sec. and the Immediate Office maintain certain agency correspondence in their files. (*Id.* ¶ 13.) Both offices searched their official agency correspondence files and reported their findings to DFOI. Exec. Sec. responded to CareToLive, through DFOI, on January 24, 2008, indicating that no responsive records had been located. (*Id.* ¶ 14.) On February 26, 2008, DFOI, on behalf of the Immediate Office, produced responsive documents, without any redactions, to CareToLive. (*Id.* ¶ 15.)

On October 10, 2007, DFOI forwarded CareToLive's request to DIDP in CDER. (*Id.* ¶ 16.) Both DFOI and ALFOI had determined that it was likely that CDER had copies of the requested correspondence, as the addressees on the letters from Dr. Scher, Hussain, and Fleming included CDER employees. (*Id.*; *see also* Sager Decl. ¶ 11.)

**2. CBER's Role in the Search for CareToLive's Requested Documents.**

Similar to DFOI, CBER's ALFOI has a detailed procedure that it follows when processing FOIA requests. Once ALFOI receives a FOIA request from DFOI, it places each request in one (or more) of seven queues of pending requests, based on the complexity and subject matter of the requested documents. (Brockner-Ryan Decl. ¶ 7.) ALFOI's queues consist of the Fast, Simple, 510k, Counter-Terrorism-Related, Influenza, Adverse Event, and Complex Tracks. (*Id.*) Generally, requests in each queue are assigned to reviewers for processing on a first-in, first-out basis. (*Id.*)

For any request, independent of the queue under which it is processed, ALFOI may need to contact individuals in several CBER offices and direct them to search their files for responsive documents. (*Id.* ¶ 8.) ALFOI then gathers all documents and conducts a preliminary review of the records collected to verify that they are responsive. (*Id.*) This is generally followed by a line-by-line, word-by-word review of the responsive documents to determine whether any FOIA exemptions apply. (*Id.*) Any exempt material is then redacted.

(*Id.*) Finally, the employee assigned to the request prepares copies of the responsive documents for delivery to the requester. (*Id.* ¶ 9.)

CareToLive's request, received by ALFOI on September 14, 2007, was processed in ALFOI's Fast Track. (*Id.* ¶¶ 11–12.) Requests in the Fast Track can be answered with readily available documents that do not need to be redacted. (*Id.* ¶ 12.) Requests are placed in this track usually because they seek documents that previously were reviewed and redacted (typically in response to a previous document request) or information that is publicly available (often from documents that were reviewed, redacted and placed on FDA's website). (*Id.*) CareToLive's request was placed in the Fast Track because many of the documents that were responsive to CareToLive's request had been assembled and reviewed for a previous document request. (*Id.*) The ALFOI employee who conducted the initial search for responsive documents is no longer employed by the agency. (*Id.* ¶ 13.) Based on the agency's administrative record, however, it appeared that ALFOI searched for records in the Office of Cellular, Tissue and Gene Therapies, the Office of Communication, Outreach, and Development, the Immediate Office

of the Director, and the Office of Management, Division of Scientific Advisors and Consultants, all of which were likely to have the requested correspondence. (*Id.*)

The ALFOI staff gathered and reviewed all potentially responsive documents to determine whether they were actually responsive to CareToLive's FOIA request and to determine whether any documents or portions thereof were exempt from disclosure. (*Id.* ¶ 14.) ALFOI identified twelve documents that were responsive to CareToLive's request, and determined that these documents did not contain any information that fell within an exemption to the FOIA. (*Id.*) ALFOI provided the responsive documents, without any redactions, to the requesters in a letter dated November 6, 2007. (*Id.* ¶ 15.)

### **3. CDER's Role in the Search for CareToLive's Requested Documents.**

CDER's DIDP also follows established procedures in responding to FOIA requests. Upon receiving a request, DIDP considers all requests that can be answered quickly with readily available documents, and that require no redacting as "simple" requests, which generally are processed on a fast track (the "Simple Track"), as opposed

to “complex” requests, which follow a slower processing track (the “Complex Track”)<sup>3</sup>. (Sager Decl. ¶ 8.) DIDP staff generally processes Simple and Complex Tracks requests in queues, on a first-in, first-out basis.

For requests in the Complex Track, DIDP may need to search, or contact individuals and direct them to search, numerous agency files. (*Id.* ¶ 10.) After the search has been carried out and the documents have been sent to DIDP, it conducts a preliminary review of the records collected to verify that they are responsive to the request. (*Id.*) DIDP then conducts a page-by-page, line-by-line review of the responsive documents to determine whether any records can be released and whether any FOIA exemptions apply. (*Id.*) Any exempt material is redacted. (*Id.*) Frequently, a team leader conducts a quality control review to ensure that the responsive documents have been properly prepared for public disclosure. (*Id.*) This review ensures that the

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<sup>3</sup> Simple requests do not require DIDP personnel to redact documents, generally because: 1) DIDP has already reviewed and redacted the responsive documents; 2) the documents requested are publicly available; or 3) it is apparent from the face of the request that the documents do not exist in CDER’s records. (*Id.* ¶ 9.)

FOIA exemptions have been properly applied, that no releasable material will be withheld, and that no material meriting protection will be released. (*Id.*) Finally, copies of the responsive documents are prepared and delivered to the requester. (*Id.*)

Here, when DIDP received CareToLive's FOIA request in October 2007, it assigned the request to the Complex Track because it requested documents that were not readily available and that would require a search and possible redaction. (*Id.* ¶ 12.) DIDP was unable to process CareToLive's request any further, however, because so many other requests for documents were ahead of CareToLive's request in the Complex Track queue. (*Id.* ¶ 13.) At the time it received CareToLive's request, DIDP estimated that the request would not rise to the top of the Complex Track for processing until October 2009. (*Id.*)

When CareToLive was advised of this delay, it filed its Complaint against FDA seeking the immediate production of all documents responsive to its FOIA request. (*Id.*) As discussed above, the district court granted FDA's subsequent Motion to Stay Proceedings on May 22, 2008 (R. 23, Order.) On December 1, 2008, as required by the

Court's order, DIDP filed a declaration stating that it would provide CareToLive with all responsive documents on or before May 18, 2009. (Sager Decl. ¶ 15.)

DIDP pulled CareToLive's request from the Complex Track queue in mid-April 2009. (*Id.* ¶ 16.) A DIDP employee reviewed the documents produced by CBER's ALFOI in response to CareToLive's request in order to identify individuals in CDER who might have responsive documents. (*Id.* ¶ 17.) The DIDP employee identified two CDER employees to which the CBER documents had been addressed or copied, and were therefore likely to have responsive documents: Dr. Janet Woodcock, the Director of CDER, and Dr. Richard Pazdur, a Supervisory Medical Officer in CDER's Office of Oncology. (*Id.*) As discussed in detail below, Dr. Pazdur did not have any responsive documents. (*Id.* ¶ 18.) Dr. Woodcock's staff conducted a search of her files, and they were able to locate only one responsive document, a copy of the letter dated April 4, 2007 from Dr. Howard Scher to Dr. Andrew von Eschenbach. (*Id.*) The DIDP employee determined that the letter did not contain any information that fell within an exemption to the

FOIA. (*Id.* ¶ 19.) The letter, without any redactions, was produced to CareToLive on May18, 2009. (*Id.*)

In an abundance of caution, the DIDP employee also searched: (i) the CDER electronic databases containing application information on drugs and therapeutic biological products; and (ii) CDER's document room, where CDER stores paper application files for drug and therapeutic biological products, even though CDER ordinarily would not maintain any electronic or paper application files for a vaccine such as Provenge. (*Id.* ¶ 20.) The DIDP employee did not find any responsive documents in CDER's electronic or paper application archives. (*Id.*)

As described above, FDA conducted a search reasonably calculated to locate all documents responsive to CareToLive's FOIA request. Even CareToLive conceded that its request is "a very simple, basic, and easy request," and that FDA's search included every conceivable office and individual that may have had responsive documents. (R. 18, Pl.'s Opp'n to Def.'s Mot. for Stay, p. 6.)

Based on the evidence presented in the declarations provided by

FDA, the district court correctly determined that FDA had conducted a reasonable search and that all responsive documents had been produced, and that summary judgment should be entered on behalf of FDA.

**C. Dr. Pazdur Only Had Copies of Documents Already Produced to CareToLive.**

Throughout its litigation with FDA, CareToLive repeatedly asserted in its briefs that Dr. Richard Pazdur, a Supervisory Medical Officer in CDER's Office of Oncology, had numerous documents that were responsive to its FOIA request. (*See* R. 18, Pl.'s Resp. to Def.'s Mot. for Stay, pp. 2–3, 15 (stating repeatedly that Dr. Pazdur's computer contains files that were responsive to CareToLive's request, including some that reveal his "improper involvement in the conspiracy to sabotage Provenge"); *see also* R. 34, Pl.'s Mot. in Part'l. Opp. to Summ. J. and for Leave to Conduct Disc., p. 7 (claiming that it would "make sense" that Dr. Pazdur had additional correspondence other than the letters already produced to CareToLive between them when Dr. Pazdur was a "leader of the opposition" against the approval of Provenge).) But CareToLive failed to provide any factual support for

its assertions.

Dr. Pazdur is an addressee of Dr. Maha Hussain's April 27, 2007 letter to numerous FDA employees. (Pazdur Decl. ¶ 5.) He is also listed as a "cc" recipient on the April 5, 2007 letters from Dr. Howard Scher to Dr. Janet Woodcock, Director of CDER, Dr. Celia Witten, Director of CBER, and Andrew von Eschenbach, Commissioner of FDA. (*Id.*) CareToLive received copies of these letters in CBER's response to its FOIA request. (Brockner-Ryan Decl., Attach. 2.)

Dr. Pazdur searched both his paper and computer files and could not locate any documents responsive to CareToLive's request. (*Id.* ¶ 6.) Dr. Pazdur recalled receiving both hard copies and electronic copies of the letters from Drs. Hussain and Scher in April 2007. (*Id.* ¶ 7.) But because these letters related to a specific regulatory application conducted by a different FDA Center (CBER), did not fall under his direct regulatory supervision, and did not require a response from him, Dr. Pazdur shredded the hard copies of these letters and deleted any electronic copies. (*Id.*) The documents were shredded and deleted within a month of receipt. (*Id.*) In fact, Dr. Pazdur does not keep

personal copies of any regulatory communications. (*Id.* ¶ 8.) Official copies of regulatory correspondence are kept in the official regulatory document room of the specific center assigned to an application. (*Id.*)

Contrary to CareToLive’s suspicions, Dr. Pazdur never disclosed the letters of Drs. Hussain and Scher to “any individuals outside of the FDA, or any media outlet, including a publication called ‘The Cancer Letter.’” (*Id.* ¶ 9.) In addition, he did not write any portion of the letters that Drs. Scher, Hussain, or Fleming sent to the FDA. (*Id.* ¶ 10.) He also never received a copy of a letter from Dr. Thomas Fleming to the FDA regarding Provenge. (*Id.* ¶ 11.) In short, Dr. Pazdur never possessed any documents responsive to CareToLive’s FOIA request other than copies of the letters produced by CBER to CareToLive in 2008. As noted by the district court, CareToLive did “not dispute that the correspondences that Dr. Pazdur admits were destroyed are duplicates of the documents already produced to [CareToLive] by FDA.” (R. 40, Order, p. 7.)

**D. CareToLive Failed to Provide Any Evidence to Rebut the Adequacy of the Agency’s Search.**

CareToLive fashioned its response to FDA’s Motion for Summary

Judgment as a “partial opposition” and a request for discovery, claiming that it could not fully respond to the arguments in FDA’s motion without being allowed to search Dr. Pazdur’s computer. (R. 34, pp. 21–22.) But in its “partial” response, as the district court noted, CareToLive claimed that FDA’s search was inadequate because CDER’s “complex” search yielded only one document that had already been produced, and because the agency did not use an IT expert to search Dr. Pazdur’s computer for additional 2007 correspondence and to determine the date that Dr. Pazdur destroyed his copies of the 2007 correspondence. (R. 40, Order; *see also* Appellant’s Br., pp. 16, 18.) Both of these claims stem from CareToLive’s baseless speculation that Dr. Pazdur had additional correspondence from Drs. Hussain and Scher, and that he purposefully destroyed this correspondence to avoid producing it to CareToLive. (*See* Appellant’s Br., pp. 18–21.) Neither of these unsupported arguments constitute evidence to rebut the agency’s declarations detailing the reasonable and thorough search. *See [SafeCard Servs., Inc. v. SEC](#)*, 926 F.2d 1197, 1200 (D.C. Cir. 1991) (holding that “speculative claims” are insufficient to rebut agency declarations detailing an adequate search).

As the district court noted, CDER's producing only one document which was already produced is not evidence that the agency conducted an inadequate search. (R. 40, Order, p. 7.) Although CareToLive has repeatedly claimed that it was unreasonable for a "complex" search that lasted "twenty months" to produce only a copy of a produced document, any FOIA request that seeks documents that must be reviewed and possibly redacted is placed in the "Complex Track" queue. (R. 10, Def.'s Mot. to Stay Proceedings, Exh. B, Declaration of Nancy Sager ¶ 11; *see also* Appellant's Br., pp. 19–21.) Thus, a FOIA request need not consist of hard-to-find or large quantities of documents to fall into the Complex Track and to be processed only when it rises to the top of that Track's queue. (R. 10, Def.'s Mot. to Stay Proceedings, Exh. B, Declaration of Nancy Sager ¶ 29.) For CareToLive's request, FDA did not claim that the agency needed twenty months to *complete* the search; rather, FDA stated that the request was not scheduled to rise to the top of the Complex Track queue until October 2009, and it had to be pulled from the queue in order to comply with the Court's May 22, 2008 order. (R. 25, FDA's Supplemental Decl. ¶¶ 6–7; *see also* Appellant's Br., pp. 18–20, 31–32.) Moreover, as discussed in detail

above, the search conducted by the DIDP staff member assigned to CareToLive's request involved identifying employees with relevant documents, and searching files, databases, and document rooms, and did not consist of "essentially ask[ing] employee Richard Pazdur . . . if he had any responsive documents." (Sager Decl. ¶¶ 18–20; *see also* Appellant's Br., p. 22.)

FDA did not use an IT expert to search Dr. Pazdur's computer because he had only copies of documents already produced to CareToLive and had destroyed those copies within a month of receipt. (Pazdur Decl. ¶ 7.) CareToLive never disputed that the documents that Dr. Pazdur destroyed were copies of documents already produced, but it repeatedly made baseless allegations that Dr. Pazdur lied in his declaration and that there "must have been" additional correspondence between Dr. Pazdur and Drs. Hussain and Scher because Dr. Pazdur was "intent on derailing Provenge as part of a power play within his division." (R. 34, Pl.'s Mot. in Part'l. Opp. to Summ. J. and for Leave to Conduct Disc.; *see also* Appellant's Br., pp. 24–28.) A requester cannot rebut agency affidavits regarding the adequacy of an agency's search with purely speculative claims, as CareToLive attempted to do here.

SafeCard Servs., 926 F.2d at 1200. As the district court correctly reasoned, “FOIA ‘does not require [Defendant] to account for [the documents], so long as it reasonably attempted to locate them.’” (R. 40, Order, p. 8 (citing West, 539 F. Supp. 2d at 62)). Thus, the district court properly determined that FDA was “simply not required to hire an IT expert to search for a copy of a document that has already been produced.” (*Id.* p. 8.)

The district court correctly concluded that CareToLive’s arguments “do not establish ‘countervailing evidence’ nor do they indicate an ‘apparent inconsistency of proof’ provided by [FDA] in its declarations.” (*Id.* p. 8) (citing Rugiero, 257 F.3d at 547)). FDA’s declarations unquestionably established that the agency performed a reasonable search and produced all responsive documents, and this Court should therefore affirm the district court’s grant of summary judgment.

**II. The District Court Did Not Abuse Its Discretion in Denying CareToLive's Request for Discovery.**

**A. To Justify Discovery in FOIA Summary Judgment Cases, a Plaintiff Must Allege Specific Facts Showing That the Agency Acted in Bad Faith.**

To forestall summary judgment by requesting the opportunity to conduct discovery under Federal Rule of Civil Procedure 56(f), the party making the request must “file an affidavit or motion explaining what material facts [the party] hopes to uncover by the requested discovery.” *Cardinal v. Metrish*, 564 F.3d 794, 797-98 (6th Cir. 2009); *see also Taylor Acquisitions, L.L.C. v. City of Taylor*, No. 07-2242, 2009 WL 415993, at \*8 (6th Cir. Feb. 19, 2009) (finding that an affidavit that “contains only general and conclusory statements or lacks any details or specificity is insufficient under Rule 56(f)”).

In FOIA cases, courts generally do not permit discovery and routinely enter summary judgment where the defendant agency has shown that it conducted a reasonable search and that all responsive documents have been produced. *See e.g., Rugiero*, 257 F.3d at 544 (noting that, “procedurally, district courts typically dispose of FOIA cases on summary judgment before a plaintiff can conduct discovery”);

see also [GMRI, Inc. v. EEOC](#), 149 F.3d 449, 451 (6th Cir. 1998) (upholding grant of summary judgment where agency had turned over all records responsive to plaintiff's request). Thus, to justify discovery in a FOIA matter where the defending agency has moved for summary judgment and submitted detailed declarations to show that it conducted a reasonable search that led to the production of all responsive documents, the plaintiff must make "a showing of bad faith on the part of the agency sufficient to impugn the agency's affidavits or declarations." [Carney v. U.S. Dep't of Justice](#), 19 F.3d 807, 812 (2d Cir. 1994). Moreover, "conclusory allegations that other, undisclosed records 'must' exist somewhere, that they are within defendants' control, and that defendants must have therefore conducted an inadequate search, or that they are deliberately concealing the records" are insufficient to show bad faith on the part of the agency. [Dinsio v. FBI](#), No. 05-CV-6159L, 2007 WL 2362253, at \*3 (W.D.N.Y. Aug. 16, 2007).

**B. CareToLive's Affidavit in Support of Its Rule 56(f) Motion for Discovery Was Inadequate.**

To obtain discovery under Rule 56(f), the party opposing the

motion for summary judgment must show “by affidavit that, for specified reasons, it cannot present facts essential to justify its opposition.” As the district court correctly found, the affidavit submitted by CareToLive in support of its Rule 56(f) motion was inadequate on its face. (R. 40, Order, p. 9.) The affidavit consisted of one paragraph and merely stated that CareToLive was “unable by affidavit to provide proof to this Court of the existence of the requested FOIA correspondence on the computer of FDA employee Richard Pazdur at this time without the relief and/or discovery requested herein.” (*Id.*) The affidavit was not sworn to under penalty of perjury before a notary public nor was it signed under penalty of perjury pursuant to [28 U.S.C. § 1746](#). (*Id.*) It did not set forth any factual basis for the implication, found in the referenced “Request for Relief,” that FDA acted in bad faith by failing to hire an IT expert to examine Richard Pazdur’s computer. (*Id.* pp. 21–22.)

CareToLive’s affidavit was patently insufficient to impugn FDA’s detailed declarations describing the searches conducted for documents responsive to CareToLive’s FOIA request. See [Carney](#), 19 F.3d at 812. As Rule 56(f) requires a party opposing a summary judgment motion to

“show by affidavit” that discovery is necessary to learn material facts, the district court correctly held that CareToLive’s inadequate affidavit alone was a sufficient ground for denying its request for discovery.

**C. CareToLive Failed to Show Bad Faith.**

Regardless of the sufficiency of the affidavit, the district court concluded that CareToLive had not shown that discovery was necessary in this action because it failed to “make a showing of bad faith on the part of the agency.” (R. 40, p. 11) (citing *Carney*, 19 F.3d at 812)). According to the district court, to support its claim that the agency acted in bad faith, CareToLive offered only “factually inaccurate statements and conspiracy theories which completely ignore[d] the evidence.” (*Id.*). Indeed, as discussed above, CareToLive accused Dr. Pazdur of lying about the existence of additional documents, and the agency of acting in bad faith, based on nothing more than its assertions that “certainly there was accompanying communications [to the 2007 letters] because all the other e-mailed employees in FDA including the FDA Commissioner did in fact have such communications” and Dr. Pazdur’s “communications would have been greater seeing that the letters were sent” by oncologists that he “specifically selected . . . on the

basis that he knew they were likely to be critical of Provenge.”

(Appellant’s Br., pp. 24, 27.)

Furthermore, despite CareToLive’s claim that it did “not know” the date that Dr. Pazdur deleted and shredded the 2007 letters, Dr. Pazdur stated in his declaration that he recalled destroying the documents “within a month of receipt.” (Pazdur Decl. ¶ 7.)

CareToLive’s repeated assertions that it “suspect[s]” that “the alleged destruction may have occurred during pending litigation by CareToLive against the FDA and Richard Pazdur” and that “it was also likely that the destruction . . . was clandestine and for the purpose of hiding the truth” were not enough to impugn Dr. Pazdur’s testimony, signed under penalty of perjury pursuant to [28 U.S.C. § 1746](#).

(Appellant’s Br., pp. 19–21, 28, 39; *see also* Pazdur Decl.) There was no need for CareToLive to conduct discovery to determine when Dr. Pazdur destroyed the documents because it had already received that information.

CareToLive’s “conclusory allegations that other, undisclosed records ‘must’ exist somewhere, that they are within the defendants’ control, and that defendants must therefore have conducted an

inadequate search, or that they are deliberately concealing the records, are not enough to make such a showing [of bad faith].” *Dinsio*, 2007 WL 2362252, at \*3. In fact, CareToLive’s Appellant Brief consists of baseless attacks without citation to any record evidence or indeed anything at all. CareToLive “believes” Dr. Pazdur “is the FDA” and that he previously “leaked” confidential information, describing an elaborate conspiracy theory in which Dr. Pazdur defeated the approval of Provenge to save his “dominance within FDA.” (Appellant’s Br., pp. 23, 26, 27.) As CareToLive’s “arguments fall woefully short of showing bad faith and, indeed, are completely at odds with the evidence” presented in FDA’s declarations, the district court correctly denied discovery, and this Court should uphold that decision. (R. 40, Order, p. 12.)

**CONCLUSION**

For the reasons stated above, this Court should affirm the district court's judgment.

Respectfully Submitted,

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**CERTIFICATE OF COMPLIANCE**

I hereby certify that the foregoing brief complies with the type-volume limitation provided in Rule 32(a)(7)(C)(i) of the Federal Rules of Appellate Procedure. The foregoing brief contains 7,380 words of Century Schoolbook (14 pt) proportional type. WordPerfect X3 is the word-processing software that I used to prepare this brief.

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**DESIGNATION OF RELEVANT  
DISTRICT COURT DOCUMENTS**

Pursuant to Sixth Circuit Rule 30(b), Appellee Food and Drug Administration states that Plaintiff CareToLive has already designated all of the relevant parts of the district court record.

**CERTIFICATE OF SERVICE**

I hereby certify that on February 4, 2010, I filed the foregoing Brief of Defendant-Appellee Food and Drug Administration using the CM/ECF system, which will provide notification to Mr. Kerry M. Donahue at bedonwahoo@aol.com.

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