

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

CareToLive,

Plaintiff,

Case No. 2:08 CV 0005

vs.

Judge Frost

The Food and Drug
Administration (FDA),
Commissioner Andrew von Eschenbach

Defendant.

**PLAINTIFF’S REPLY TO DEFENDANT’S MEMORANDUM IN
OPPOSITION PLAINTIFF’S MOTION FOR LEAVE TO CONDUCT
DISCOVERY UNDER CIVIL RULE 56(f)**

With all due respect, the Defendant FDA seems to want to have it both ways. On the one hand, they claim that Plaintiff’s request was “complex.” But on the other hand, to answer it, all they did was essentially ask Richard Pazdur (who was listed as a “cc” on the letters, which are in part, the object of the search) if he had any responsive documents; he simply declared that “no, he did not”. And that, apparently, began, and ended, the Agency’s search for the documents. When asked to produce an affidavit regarding the status of the sought-after documents, Dr. Pazdur simply wrote that while he had the requested communications in his possession at one

time, both in hardcopy and softcopy (on his computer), he had shredded and deleted them, respectively.

Richard Pazdur allegedly took this action despite the fact that he was named a Defendant in a lawsuit filed in July of 2007, and prior to that there was a pending decision to be made by the Center for Biologics Evaluation and Research (CBER) on May 8, 2007, regarding the subject matter of the communications. Richard Pazdur was intricately involved in the Provenge BLA process. However, it is Dr. Pazdur's position that he was not a *supervisor* of CBER, and so, because the documents were unimportant to him as a non- supervisor, he did not keep any of them. Further, by purposeful omission he does not discuss whether there were communications about, and/or with, those letters. The Court should be aware that Dr. Pazdur indeed was invited to be a part of the process of the evaluation of Provenge by CBER, and further, he did play a role in the review of the drug. Specifically, two oncologists who served as special government employees on the Provenge Advisory Committee (AC) meeting on March 29, 2007, were in fact consultants to Dr. Pazdur and to CDER. They were placed on the Advisory Committee as part of the panel of so-called experts at his request. Further, Dr. Pazdur was present at the AC hearing and was observed exchanging notes with one panelist (Dr. Maha Hussain), who did

participate both in the deliberations and in the decision-making process (i.e., vote) on Provenge. Thus, the statement of Richard Pazdur that the documents were not of interest to him does not ring sincere. Richard Pazdur would have this Court believe that when he received an important letter from a world-renowned oncologist, that not only was a consultant to him previously, but also, that he himself thought an appropriate expert for the panel...an oncologist with whom he had many years of experience working with and who was involved in numerous clinical trials involving drugs for prostate cancer, that he felt the letter was unimportant and should not be discussed or shared with anyone at CBER who was in fact making the final decision regarding the Provenge BLA. The fact is the letters, which were leaked to The Cancer Letter, a non-peer-reviewed newsletter published in Washington, DC, either before or shortly after they were delivered to their intended recipients at the FDA, created an overnight firestorm. It is an understatement to say they were immediately controversial! For a special government employee and especially for an AC panelist to further lobby the FDA after the AC hearing had ended, is virtually unheard of. (CTL can find no precedent for this action.) Much of the controversy came from the recognition and discovery of the fact that Richard Pazdur had selected oncologist Howard Scher, who had substantial unreported conflicts of

interest (COIs) involving Novacea, Inc. (for whom he was conducting Phase III trials of a competing prostate cancer drug, Asentar) and ProQuest Investments, an investment firm in Princeton, NJ (for whom he was on the Scientific Advisory Board, an officer, and a member of the Board of Directors; ProQuest Investments owned 8+% of Novacea, Inc., stock at the time of the Provenge AC and the founder of ProQuest Investments, Mr. Jay Moorin, was on the Novacea Board of Directors at the time of the Provenge AC). None of these COIs were revealed in Dr. Scher's request for a waiver that was submitted to CBER prior to his being allowed to participate in the Provenge AC. Clearly, the approval of Provenge was not in Dr. Scher's best interest, and his election to the Provenge AC by Dr. Pazdur, who would have known of his involvement with Novacea, was seriously flawed.

Dr. Pazdur *knew* these documents and the communications surrounding them were and would be important from the moment he received them. They were from fellow oncologists that he knew very well. He had specifically selected them for the AC on the basis that he knew they were likely to be critical of Provenge because this new immunological treatment would represent a "new standard of care" for victims of prostate cancer...one that would turn patients away from the current oncologist administered chemotherapeutic treatment of the day (Taxotere) and make it

more difficult for the large pharmaceutical houses to run trials over which he and CDER held sway. (Recall that the approval of Provenge was in the hands of CBER, not CDER...that alone presented a threat to Richard Pazdur's dominance within the FDA regarding the oversight and approval of cancer drugs.) Richard Pazdur has not shied away from the proclamation that he is the "cancer czar". He was intent on derailing Provenge as a power play within the Agency, once his division CDER had been denied control over the drug's approval. There is every reason, therefore, for Richard Pazdur to obfuscate and delay the search for, and the release of, the sought after documents.

Despite the fact that the FDA told this Court that the search of this matter was complex and that it would take 15 months to complete, the total amount of search time was essentially zero. In Defendants Memorandum in Opposition they state that they provided "detailed declarations describing the agency's thorough searches for documents responsive". The Plaintiff does not see any such "detailed declarations" describing *the search*.

Attached hereto and incorporated by reference thereto, as "Exhibit A" is the breakdown of the time and cost for the search conducted by the FDA. Attached hereto as "Exhibit B" and incorporated by reference thereto, is the invoice that was sent the next week asking Plaintiff, CareToLive to send in

40 cents to pay for the search. Yes, they spent 44 cents of the taxpayers' money to send it. Specifically, the invoice to CareToLive states that the total cost for reproduction, search time, review time, microfiche and other, totaled 40 cents. It is in bad faith that first, the Agency deceives the Court by designating a request as "complex" and then, responds so simply 15 months later by providing a single document, said document having previously been provided to Plaintiff from Janet Woodcock's files long ago. Was not the fact that Richard Pazdur allegedly had attempted to destroy both the hard- and soft copies of the sought after documents not known months and months ago...if the intent of the FOIA office was simply to ask him for the documents verbally, would not a simple phone call to him have sufficed, with a simply letter to the Court provided in response to the CTL request for the documents? The bounds of the delays and deception delivered unto both CTL and the Court on the part of the FDA defy credulity.

All of this is even more surprising when one considers that an internal investigation into the Provenge fiasco should have been initiated two years ago. The FDA by not conducting or not making known publicly that it investigated any of the allegations, made not just by CareToLive but by many others nationwide, have continued to lose credibility with the public over the last several years. That scrutiny is even more heightened now in

light of the success of the IMPACT trial showing definitively that Provenge is a safe and effective treatment for late stage prostate cancer sufferers. It is an even greater transgression that the irregularities in the process concerning Provenge served to insure the delay of access to Provenge by patients, for more than 2 1/2 years, in spite of the recommendation by the AC for approval in March 2007. In fact, according to the Energy and Commerce Committee of the House, headed up by representatives Dingell and Pallone, the FDA told inquiring members of Congress that they did in fact conduct an investigation (this was in January 2008). Yet, nobody conducting the investigation ever spoke to the “Cancer Czar” about what happened and what documents he might or might not have relative to the Provenge BLA and communications with Dr. Scher and Dr. Hussain? None of the DOJ attorneys or any of FDA’s in house counsel, or anyone else ever questioned him about communications sought so publicly by CareToLive?

While there were ongoing demonstrations in Washington, Chicago, Rockville, and later across the Country regarding the treatment of Provenge as well as the leaked letters and while there were Congressman inquiring of top FDA officials about their handling of the Provenge matter, and under the eyes of the media (where Richard Pazdur was responding in press interviews) and while the FDA was suffering through a PR nightmare,

Richard Pazdur was determining the importance of communications among himself and the two oncologists that CTL alleges assisted him to delay Provenge for 2-1/2 years, he was making the decision they were unimportant and he should destroy them? Nobody in the FDA ever investigated the event until the FOIA office talked to Richard Pazdur in April 2009?

Between this pending case and the Case of CareToLive vs. FDA, Howard Scher, and Richard Pazdur, no less than 15 attorneys have been involved on Defendants behalf. Just the recent response to Plaintiffs motion indicates the involvement of 5 attorneys. Given the level of attention within the Government, the number of lawyers and other personnel involved, and the time and expense to which the Agency, the Court, and CTL have gone, it is in bad faith that now, we learn the Agency simply, does nothing but ask a party to the previous litigation if they have any responsive documents? None of the 15 attorneys involved in this matter over the last 2 years ever talked to Richard Pazdur and asked him about the matter over the course of litigation in two cases? That this Court has to be involved when in-house counsel or the in-house investigative arm of a huge Federal Agency would not take reasonable action, should be considered by this Court as yet another example of bad faith. Has no one within the Agency ever investigated any of the claims made in two lawsuits filed against the Agency? Has no one within the

Agency investigated, even though dozens of Congressman inquired of them about the situation and three Congressman (later joined by at least 15 more) called for an investigation.

While the FDA's memorandum sets forth that the Agency took steps to search, Plaintiff fails to see evidence of any reasonable *search*.

The FDA's Nancy Sager says:

18. Dr. Pazdur did not have any responsive documents. Dr. Woodcock's staff conducted a search of her files, and they were able to locate only one responsive document, a letter dated April 4, 2007 from Dr. Howard Scher to Dr. Andrew von Eschenbach.

That is all it says about Richard Pazdur's response? It does not say that anyone conducted a search of Richard Pazdur's files or his computer for correspondence and the means of communication of said correspondence. There was no search of hard drives, back up systems, Internet servers, or any other probing inquiry or actual real search.

Richard Pazdur was served with a complaint against him in early August 2007. So, too, the FDA and Commissioner were served. The FDA and Richard Pazdur knew that there was pending litigation regarding this matter long ago. The letters previously provided by CBER indicated they were in fact sent to Richard Pazdur. The FDA clearly knew and should have conducted such an inquiry long before this FOIA Complaint was filed in January 2008. Yet their response was to classify it as "complex." Is the

government still asserting it was complex, or have they changed their mind on that issue? Was the fact that they designated it “complex” to begin with an attempt to be deceptive to this Court? This is how CBER handled the CareToLive request directed to them:

CBER, DFOI forwarded the request to ALFOI on September 14, 2007. The request was processed in ALFOI's Fast Track. Requests in the Fast Track can be answered with readily available documents that do not need to be redacted. 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).

Plaintiffs request was placed in the Fast Track because *many of the documents that were responsive to Plaintiffs request had been assembled and reviewed for a previous document request.*

The ALFOI employee who conducted the initial search for responsive documents is no longer employed by the agency. However, based on the administrative record in the file, it appears that ALFOI searched for records in CBER's 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, components that were reasonably expected to have correspondence related to Provenge.

The ALFOI staff gathered and reviewed all potentially responsive documents to determine whether they were actually responsive to Plaintiffs' FOIA request and to determine whether any documents or portions thereof were exempt from disclosure. ALFOI identified twelve documents that were responsive to Plaintiffs request, and determined that these documents did not contain any information that fell within an exemption to the FOIA.

By Beth Brockner Ryan. Emphasis added.

Each of the letters previously turned over by Commissioner von Eschenbach and Dr. Goodman that were sent by Dr. Scher and Dr. Hussain were sent with other correspondence attached to them or with a personal message or note introducing the letter. These letters were not sent to the chief antagonist of Provenge by Dr. Scher and Dr. Hussain without some kind of e-mail introduction and comments and/or an acknowledgment of receipt by Richard Pazdur. Ultimately, the CDER FOIA office response provided to the Plaintiff was merely to send one of the same letters previously provided to Plaintiff. This clearly qualified this as a FOIA request that should have been processed as a fast track. That it was not, was the first demonstration of bad faith. With a history of bad faith now before this Court this Court is justified in at least doubting the factual accuracy and/or completeness of the FDA search and response to the FOIA request. The inept handling of the matter, for whatever ultimate purpose, by the FDA, requires that the Court now order the Agency to perform an additional, more thorough search and response. Though Richard Pazdur may have thought he deleted the e-mails from his government-owned computer, the fact is, all he did was erase their file names from his computer's directory. The sought-after e-mails may or may not still be on his hard drive. (This is tantamount to

taking a name plate of a company off the list of the first floor of a building; the space above may or may not still be occupied by the company named on the name plate.) Regardless, whether or not the e-mails are found on Richard Pazdur's government-owned computer, the fact is, all Government agencies are required to retain electronic (and other forms of documents) for specified periods of time. It would be a relatively simple matter for an information technology (IT) technician or forensic computer expert to search the Agency's e-mail server as well as its Storage Area Network (SAN) e-mail servers using keyword searches (including misspellings of keywords found in other documents written, for example, by Dr. Scher). Such searches would rapidly produce the sought after e-mail documents and their attachments. This is done everyday, in Government agencies in Washington, D.C., and across the country. This, in fact, is what the FDA FOIA office should have done in the first place if it truly had any intent whatsoever in responding to the will and intent of Congress and the Court.

As stated by the FDA's Frederick Sadler:

On October 10, 2007 DFOI forwarded Plaintiffs request to the DIDP in CDER. DFOI did so, because after consultation with CBER it appeared likely that CDER was also likely to have the requested correspondence.

Richard Pazdur did not completely deny having the letters but he also knew long ago he was either directly addressed or cc'd on them and all

the other listed persons including the commissioner had received theirs with attached comments and conversation regarding same.

The FDA's Nancy Sager said this way back on Feb 13, 2008:

Any requests that are not considered simple are placed in the Complex Track.

For requests in the Complex Track, DIDP may need to search, or contact individuals and *direct them to search, numerous agency files*. After the search has been carried out and the documents have been sent to DIDP, DIDP conducts a preliminary review of the records collected to verify that they are responsive to the request.

However, if DIDP anticipates that a FOIA request in the Complex Track will require *extensive searches for numerous documents in different locations, then multiple individuals in DIDP are assigned to the request. Complex requests that require this level of staffing often involve voluminous records and frequently necessitate extensive time for searching and redaction in order to prepare the records for release. Furthermore, such requests often require substantive input from supervisory staff to determine both the scope of the search and the ultimate releasability of the records.*

27. There are three primary types of organizational and work process changes that have helped DIDP reduced its backlog: (i) *using new information technology systems to increase efficiency;*

In 2001, CDER implemented a new filing system for NDA documents known as the Division Files System ("DFS"), and DIDP integrated this filing system into its document retrieval function. The use of this system was expanded in September 2006 to include abbreviated new drug application ("ANDA") documents. DFS eliminates the paper document search for certain documents and instead *allows electronic searches*. This capability has reduced the time required to search for documents needed to process FOIA requests.

DIDP determined that this request did not meet the criteria for the Simple Track (because it requested documents that were not readily

available and would require a search and possible redaction) and therefore assigned it to the Complex Track.

The Agency clearly has the ability to do a more extensive search of the computer and the Agency's servers as well as the system back up, as required by the law, the latter being required so that the FDA does not lose important documents. The decision of the Agency to look no further than a simple request to Dr. Pazdur, in light of the admissions that he once had correspondence and deleted it along with the means of communication of the correspondence, requires that the Agency conduct the complex search that it promised this Court twice it needed to conduct.

The Agency cannot now say that, "oops", it did not mean that a complex search was needed, and now a simple search is all they will deliver. The Agency cannot and should not be allowed to refuse to have an IT person attempt to recover the communications or to determine the date of destruction. This Court cannot allow the FDA to skirt the intent and purpose behind the Freedom of Information Act by dishonestly designating something complex that they knew is not, in order to get an additional 15 months to respond and then 15 months later say "well, gee, that complex search really was very simple as we are not really even going to conduct a

“search.” The Plaintiff cannot completely respond to the Agency motion without evidence that is exclusively in the hands of the Defendant.

Defendant FDA’s complains that such a search as requested by Plaintiff would be too costly. Plaintiff does not understand this contention because *it is the Plaintiff and not the Defendant that must pay the cost of the search. It does not cost the Defendant anything!* All costs of FOIA searches are to be billed to Plaintiff. This is what they have done with all other FOIA requests. They are supposed to bill for the time spent which they did (See Exhibit A and B). That the Agency would trot out this lame, illegitimate excuse as to why they did not perform the search ordered by the Court, lays bare the bad faith that is being perpetrated by the Defendant in this case.

Other than the expense, which is a non-starter, the FDA fails to explain to this Court the bases for their actions in not conducting a more thorough search of the agencies e-mail computer records (e-mail servers and SAN servers), central back up system, or just Richard Pazdur’s hard drive on the computer that at least admittedly previously contained the desired correspondence and probably still does contain the desired correspondence. Judicial review is frustrated when the Agency will not disclose why it cannot take additional action to retrieve the correspondence. This Court has the right to have this information, especially considering the previous

classification of Plaintiff's request as "complex" and to demand further review and explanation from the Agency as to why it cannot conduct the requested search and why it did not over the past 2 years.

Courts do allow discovery in these matters when any of the following might apply: (1) *when agency action is not adequately explained in the record before the court*; (2) when looking to determine whether the agency considered all relevant factors; (3) *when a record is incomplete*; (4) when a case is so complex that a court needs more evidence to enable it to understand the issues; (5) when evidence arising after the agency action shows whether the decision was correct or not; (6) in certain NEPA cases; (7) in preliminary injunction cases; and (8) *when an agency acts in bad faith*. See, e.g., [*Davis Mountains Trans-Pecos Heritage Assn v. U.S. Air Force*, 249 F. Supp. 2d 763, 776 \(N.D. Tex. 2003\)](#) (Cummings, J.); [*Amfac*, 143 F. Supp. 2d at 11](#); see also Frank B. Cross, NEPA Law and Litigation § 4:36 (2007).

Further, a different situation is presented when analyzing the completeness of the record and the good faith behind a decision - these can only be grasped by looking beyond the record itself. See [*Amfac*, 143 F. Supp. 2d at 12](#); see also [*Bar MK Ranches*, 994 F.2d at 740](#). For example, courts have held that plaintiffs are entitled to an opportunity to determine

whether any other documents that are properly part of the administrative record have been withheld. See [*Pension Benefit Guar. Corp. v. LTV Steel Corp.*, 119 F.R.D. 339, 341 \(S.D.N.Y. 1988\)](#). Courts also have permitted litigants to supplement the administrative record with additional material that explains the administrative officials' basis for their actions. See *id.*

"Thus, in these circumstances, the only way a non-agency party can demonstrate to a court the need for extra-record judicial review is to first obtain discovery from the agency." [*Amfac*, 143 F. Supp. 2d at 12](#). In other words, an adequate record can sometimes only be determined "by looking outside the [record] to see what the agency may have ignored." [*Davis*, 249 F. Supp. 2d at 776](#) (citing [*County of Suffolk v. Sec'y of the Interior*, 562 F.2d 1368,1384 \(2d Cir. 1977\)](#)). In those cases, the administrative record may be "supplemented, if necessary, by affidavits, depositions, or other proof of an explanatory nature." [*Davis*, 249 F. Supp. 2d at 776](#). "The new material, however, should be explanatory of the decision makers' action at the time it occurred. No new rationalizations for the agency's decision should be included." *Id.* (citation omitted). The Agency decided to designate Plaintiff's FOIA request as complex, then spent zero search time on it and declared that the computer copies of the correspondence have been destroyed by an individual within the FDA that had been named a Defendant

in litigation that included the FDA. Although on notice that the documents might be in unwilling hands, the Agency did nothing to verify the veracity or the accuracy of what was claimed to them by the person expected to be exposed by the information.

This is clearly a case where the FDA has been guilty of having "swept stubborn problems or serious criticism . . . under the rug," so discovery may be permissible. *Id.* The agencies "search" was clearly inadequate. See [id. at 1385](#).

The Plaintiff has in fact provided good reason that discovery or an order from the Court that the proper search be completed immediately should be ordered or allowed. A proper search or small amount of discovery will uncover the e-mails and/or may at least indicate the date of destruction. Simple questions posed to Dr. Pazdur also would indicate the content and determine why he might have thought it appropriate to destroy letters sent to him by expert oncologists (who are consultants to him) that had taken the time to write highly scientific papers regarding a treatment that was being evaluated by the FDA at the time he received them (Decision made May 8, 2007). Richard Pazdur would have received the letters in mid-April 2007, while the FDA was considering approval of Provenge. Discovery will allow the Plaintiff to compile more information on the existence and location of

the documents. Discovery will allow Plaintiff to present further evidence of bad faith on the part of Defendant to this Court.

A party must provide good reason to believe that discovery will uncover evidence relevant to the court's decision to look beyond the record. *See id.* [Amfac, 143 Fupp. 2d at 12](#) (citations omitted). As indicated in Plaintiff's motion, even if the Court just for now allows Plaintiff leave for a short period of time, Plaintiff can obtain an affidavit and CV from an IT expert who can present further evidence to this Court that suggests that the e-mails are still retrievable from government agencies computers, their e-mail, or their backup (SAN) e-mail servers.

The Freedom of Information Act indicates:

FOIA 5 USCS § 552

(3) (A) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, and except as provided in subparagraph (E), each agency, upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

(B) In making any record available to a person under this paragraph, an agency shall provide the record in any form or format requested by the person if the record is readily reproducible by the Agency in that form or format. *Each agency shall make reasonable efforts to maintain its records in forms or formats that are reproducible for purposes of this section.*

(C) In responding under this paragraph to a request for records, an *agency shall make reasonable efforts to search for the records in*

electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information system.

(D) For purposes of this paragraph, the term "search" means to review, manually or by automated means, agency records for the purpose of locating those records which are responsive to a request.

The Freedom of Information Act itself says that (B) the agency should make reasonable efforts to maintain its records (C) shall make reasonable efforts to search for the records in electronic form or format, and (D) that search means to review manually or by *automated means*.

The FDA and the Federal Government in general has recently given much lip service to becoming more transparent, but this is a prime example where they allow individual employees not to release documents that they do not want released. Thus, the Government speaks of becoming more transparent but increasingly their actions are to be less transparent.

In foot notes/annotations to 5 USCS § 552

Congress finds that—

"(1) the Freedom of Information Act was signed into law on July 4, 1966, because the American people believe that--

"(A) our constitutional democracy, our system of self-government, and our commitment to popular sovereignty depends upon the consent of the governed;

"(B) such consent is not meaningful unless it is informed consent; and

"(C) as Justice Black noted in his concurring opinion in [Barr v. Matteo \(360 U.S. 564 \(1959\)\)](#), 'The effective functioning of a free government like ours depends largely on the force of an informed public opinion. This calls for the widest possible understanding of the quality of government service rendered by all elective or appointed public officials or employees.';

"(2) the American people firmly believe that our system of government must itself be governed by a presumption of openness;

"(3) the Freedom of Information Act establishes a 'strong presumption in favor of disclosure' as noted by the United States Supreme Court in [United States Department of State v. Ray \(502 U.S. 164 \(1991\)\)](#), a presumption that applies to all agencies governed by that Act;

"(4) 'disclosure, not secrecy, is the dominant objective of the Act,' as noted by the United States Supreme Court in [Department of Air Force v. Rose \(425 U.S. 352 \(1976\)\)](#);

"(5) in practice, the Freedom of Information Act has not always lived up to the ideals of that Act; and

"(6) Congress should regularly review [section 552 of title 5, United States Code](#) (commonly referred to as the Freedom of Information Act), in order to determine whether further changes and improvements are necessary to ensure that the Government remains open and accessible to the American people and is always based not upon the 'need to know' but upon the fundamental 'right to know'.".

Since Congress designed FOIA to pierce veil of administrative secrecy and to open agency action to light of public scrutiny, FOIA has strong presumption in favor of disclosure. BPA Watch (DOE/OHA, 7/11/08) Case No. TFA-0260. annotation to **5 USCS § 552**

Freedom of Information Act ([5 USCS § 552](#)) is broadly conceived, *seeks to permit access to official information long shielded unnecessarily from public view, attempts to create judicially enforceable public right to secure such information from possibly unwilling official hands*, and attempts to provide workable formula which balances and protects all interests. [EPA v Mink \(1973\) 410 US 73, 93 S Ct 827, 35 L Ed 2d 119, 4 Env't Rep Cas 1913, 1 Media L R 2448, 3 ELR 20057](#) (superseded by statute on other grounds as stated in [Phillippi v CIA \(1976, App DC\) 178 US App DC 243, 546 F2d 1009, 2 Media L R 1208](#)) and (superseded by statute on other grounds as stated in [Brandon v Eckard \(1977, App DC\) 187 US App DC 28, 569 F2d 683, 3 Media L R 1731](#)) and (superseded by statute on other grounds as stated in [CNA Fin. Corp. v Donovan \(1987, App DC\) 265 US App DC 248, 830 F2d 1132, 44 BNA FEP Cas 1648, 34 CCF P 75389, 44 CCH EPD P 37424](#)) and (superseded by statute on other grounds as stated in [Halpern v FBI \(1999, CA2 NY\) 181 F3d 279, 187 ALR5th 495](#)). Emphasis added

Richard Pazdur would be an *unwilling official hand* and the purposes of the FOIA are undermined by allowing him to completely control the response.

The policy of the Freedom of Information Act requires that disclosure requirements be construed broadly. [Bristol-Myers Co. v Federal Trade Com. \(1970, App DC\) 138 US App DC 22, 424 F2d 935, 1970 CCH Trade Cases P 73120, cert den \(1970\) 400 US 824, 91 S Ct 46, 27 L Ed 2d 52.](#)

The primary purpose of Freedom of Information Act ([5 USCS § 552](#)), which provides generally for disclosure of agency records and information, is to open administrative processes to scrutiny of press and general public.

[Renegotiation Bd. v Bannerkraft Clothing Co. \(1974\) 415 US 1, 39 L Ed 2d](#)

[123, 94 S Ct 1028](#). Purpose of Freedom of Information Act is to pierce veil of administrative secrecy and open agency action to light of public scrutiny. [Wis. Project On Nuclear Arms Control v United States DOC \(2003, App DC\) 354 US App DC 373, 317 F3d 275](#), reh, en banc, den (2003, App DC) [2003 US App LEXIS 11339](#).

Basic purpose of Freedom of Information Act ([5 USCS § 552](#)) is to insure informed citizenry, which is vital to functioning of democratic society, and is needed to check against corruption and to hold governors accountable to governed. [Westchester General Hospital, Inc. v Department of Health, Education & Welfare \(1979, MD Fla\) 464 F Supp 236](#). Interests must be balanced, yet place emphasis on fullest responsible disclosure. [Dep't of the Air Force v Rose \(1976\) 425 US 352, 48 L Ed 2d 11, 96 S Ct 1592, 1 Media L R 2509](#).

Freedom of Information Act ([5 USCS § 552](#)) establishes general philosophy of full agency disclosure unless information is exempted under clearly delineated statutory language. [Kent Corp. v NLRB \(1976, CA5\) 530 F2d 612, 92 BNA LRRM 2152, 78 CCH LC P 11385, cert den \(1976\) 429 US 920, 97 S Ct 316, 50 L Ed 2d 287, 93 BNA LRRM 2570, 79 CCH LC P 11697](#). Under Freedom of Information Act ([5 USCS § 552](#)) disclosure is

general rule unless material comes within a statutory exemption. [Kreindler v Department of Navy \(1973, SD NY\) 363 F Supp 611.](#)

Disclosure of material in government files has now become the rule, not the exception; Freedom of Information Act, [5 USCS § 552](#), was intended to increase public access to such records through imposition of liberal disclosure requirements limited only by specific, narrowly constructed exemptions and does not authorize withholding of any information except as specifically stated. [Stokes v Brennan \(1973, CA5 Ga\) 476 F2d 699, 22 ALR Fed 317.](#)

[5 USCS § 552](#) does not authorize withholding of information or limit availability of records to public except as specifically stated. [Wellman Industries, Inc. v NLRB \(1974, CA4\) 490 F2d 427, 85 BNA LRRM 2260, 73 CCH LC P 14249, cert den \(1974\) 419 US 834, 95 S Ct 61, 42 L Ed 2d 61, 87 BNA LRRM 2398.](#)

Congress did not intend to confer on District Courts general power to deny relief on equitable grounds apart from exemptions in [5 USCS § 552](#) itself. [Soucie v David \(1971, App DC\) 145 US App DC 144, 448 F2d 1067, 2 Env't Rep Cas 1626, 1 Media L R 2435, 1 ELR 20147.](#) Federal courts have no equitable jurisdiction to approve withholding of information not specifically exempt from disclosure under [5 USCS § 552\(b\)](#). [Getman v](#)

[NLRB \(1971, App DC\) 146 US App DC 209, 450 F2d 670, 78 BNA LRRM 2101, 66 CCH LC P 12010, 16 ALR Fed 499.](#) Freedom of Information Act authorizes suits both to compel disclosure and to *scrutinize governmental Agency's decision to disclose.* [Burroughs Corp. v Schlesinger \(1975, ED Va\) 403 F Supp 633, 22 CCF P 80027.](#)

Richard Pazdur was invited to participate in the CBER review of the Provenge BLA. Richard Pazdur attended the meeting and participated, yet he was never introduced or officially recognized. At a break in the meeting, he passed notes back and forth with Dr. Husain. After the AC meeting, Drs. Scher and Hussain took the unusual step to write two letters to the FDA decision makers, including Richard Pazdur, critical of Provenge, which letters were both leaked to the same newsletter publication. The notes exchanged at the AC between Richard Pazdur and Maha Hussain should be publicly disclosed, even without request, just as should other communications with the AC panel. Dr. Alison Martin of the NCI who helped Dr. Scher write his letter, and on whose Government computer version 3 of the “Scher” letter was located, used to work in the same FDA division with Richard Pazdur. Per the Federal Advisory Committee Act, the Agency is generally obligated under [5 USCS Appx 10\(b\)](#) to make available for public inspection and copying all materials that *were made available to*

or prepared for or by an advisory committee, and, except for materials Agency reasonably believes to be exempt from disclosure pursuant to FOIA, member of public need not request disclosure in order for FACA materials to be made available. [Food Chem. News v Department of Health & Human Servs. \(1992, App DC\) 299 US App DC 25, 980 F2d 1468, 21 Media L R 1057.](#) In hindsight, now that the Provenge IMPACT trial has been successfully completed, we know that the denial of due process to Provenge caused a safe and effective treatment for late stage prostate cancer patients to be denied to these patients for 2-½ years. For many, approval will come too late.

That the Federal Public Records Law or Information Act, through which plaintiff seeks to obtain information denied him by agencies of the United States, was intended to require disclosure of government records to any person on proper application is clear, and in considering the issues raised under a motion for summary judgment should be liberally construed to carry out the express purpose of the act, which is discussed by Judge Croake in [Consumers Union of United States, Inc. v. Veterans Administration, D.C., 301 F. Supp. 796, at 799.](#)

"Consumer Union's request for VA records came in the wake of the passage of the Freedom of Information Act. The key portion of that Act, now codified, is as follows:

* * * each agency, on request for identifiable records made in accordance with published rules stating the time, place, fees to the extent authorized by statute, and procedure to be followed, shall make the records promptly available to any person. * * *

The purpose of the Act, seen in the statutory language and the

legislative history, was to reverse the self-protective attitude of the agencies under which they had found that the public interest required, for example, that the names of unsuccessful contract bidders be kept from the public. The Act made disclosure the general rule and permitted only information specifically exempted to be withheld; it required the agency to carry the burden of sustaining its decision to withhold information in a de novo equity proceeding in a district court. Disclosure is thus the guiding star for this court in construing the Act. Because portions of the Act are patently ambiguous, its illumination will be most useful."

And so, in considering this matter under a motion for summary judgment, unless the material sought cannot be described as a "record" required to be produced within the meaning of the Act, or if a record, does not fall within the numerous exemption provisions of the Act, then as to such a specific record, the motion must be denied.

Under [Federal Rules of Civil Procedure 56\(d\)](#), the Court is authorized to ascertain what material facts exist without substantial controversy and what material facts are actually and in good faith controverted. An order may then be made specifying facts that appear without substantial controversy and directing such further proceedings in the action as are just.

Because the term "records" is not defined in the Act, the Court is initially put to the task of deciding which of the items requested by plaintiff may be so classified within the contemplation of the statute. It is unfortunate that attention was not given to this point when the law was enacted since the positive provisions of the Act are all but smothered by some nine broad and generalized statements providing for many exemptions.

Efforts have been made to classify the material which may be considered as a record under the Act, e.g., the General Services Administration adopted the following definition in [41 C.F.R. 105-60.104\(a\)](#):

"(a) Records. The term 'records' means all books, papers, maps, photographs, or other documentary materials, regardless of physical form or characteristics, made or received by GSA in pursuance of

Federal law or in connection with the transaction of public business and preserved or appropriate for preservation as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of GSA or because of the informational value of data contained therein."

.....

Then, paragraph (b) of the section states:

"(b) Availability. The term 'availability' signifies the right of the public to obtain information, purchase materials, and inspect and copy records and other pertinent information."

If these regulations were designed to be a clarification of what was intended by the term "record," a failure of purpose must be registered. Nor do the declarations of the General Services Administration subtract from the confusion. The Attorney General's memorandum on the Public Information Section of the Administrative Procedure Act offers little help but simply quotes [44 U.S.C. § 366](#), now [44 U.S.C. § 3301](#), stating what material is included by the term "records," and specifically excluding "library and museum material made or acquired and preserved solely for reference or exhibition purposes * * *." Just what constitutes "library and museum material" is not designated or defined.

[44 U.S.C. § 3301](#) offers some illumination when it declares that the word "records" includes all books, papers, maps, photographs, *or other documentary materials*, regardless of form or characteristics. (Emphasis added.) But again comes the question, what are "documentary materials"? In Jones on Evidence, 5th Ed., Vol. 3, p. 1043, § 535, is found this helpful statement:

"For all practical purposes the term 'document' may be considered as synonymous with 'writing.' A document has been defined as 'any substance having any matter expressed or described upon it by marks capable of being read.' A writing or document, in addition to handwritten or printed or typewritten instruments, which first come to mind, should include inscribed chattels, photographic or other mechanical reproductions and sound recordings -- even though in the

case of sound recordings the inscribed marks may not be visible to the eye and may be read only with the use of mechanical devices."

This Court must assume that since no better definition of the term, "record," is provided by legislative enactment, executive order or controlling judicial determination, reliance may be placed on a dictionary of respected ancestry for a reasonably accurate meaning of the word. In Webster's New International Dictionary, this definition appears:

"That which is written or transcribed to perpetuate knowledge of acts or events; also, that on which such record is made, as a monument; a memorial."

Again, in Webster's New Collegiate Dictionary, the word record is defined as,

"That which is written to perpetuate a knowledge of events * * * that on which such a record is made, a monument."

A record is intended to serve as evidence of something written, said or done. Thus, under any reasonable calculation of what is intended to be covered by the congressional enactment referred to as the Information Act, it seems clear that the provisions of [5 U.S.C. § 552](#), under which plaintiff seeks relief, limits the authority of a district court to enjoin an Agency from withholding *records* and to order production of any Agency *records* improperly held from complainant.

Fact that Agency may no longer be in physical possession of record is not determinative; if Agency notes what records given request is directed towards, knows where those records are located and is able to produce them,

[5 USCS § 552](#) requires that it do so. [Tax Reform Research Group v IRS \(1976, DC Dist Col\) 419 F Supp 415, 76-2 USTC P 9558, 38 AFTR 2d 5601.](#)

It is clear that neither a word search, or an electronic search, or a server search, or a hard drive search, nor a back up search was conducted by the FDA over the 1-½ year period it took to conduct the search and respond.

That the documents are in a centrally located backup storage location, or part of internal or external server records, does not exempt them from being turned over. The fact that documents have been placed in storage does not make them exempt from disclosure pursuant to FOIA. The Advocate (DOE/OHA, 5/20/92) Case No. LFA-0198 (annotation/comment to FOIA). The Agency has not provided sufficient detail for this Court to evaluate if they do or do not have the documents. If Defendant will not conduct a proper search the Court should allow the Plaintiffs forensic computer expert to retrieve the documents. There is a clear factual dispute as to whether the documents exist and are retrievable. The FDA does not say they are not available, just that such a search would be expensive (although Plaintiff pays). When discovery requests are granted, the scope is "usually limited to the adequacy of the Agency's search and similar matters." [Voniche, 412 F. Supp. 2d at 71.](#) See [Schrecker v. United States Dep't of Justice, 217 F. Supp.](#)

[2d 29, 35 \(D.D.C. 2002\)](#) . An exception to limiting the scope of discovery is made if the plaintiff has made a sufficient showing that the Agency acted in bad faith.

It is significant that in a related case, the Plaintiff asked that the FDA be ordered to preserve evidence back in August 2007. It is significant that the FDA gives no details to how it conducted the search. It is significant that the FDA classified the requested search as complex and then did no real search. It is significant that the affidavit by Richard Pazdur is evasive and lacks specificity and it is significant that we know there are responsive documents that at least were on an FDA computer at one time.

When discovery requests are granted, the scope is "usually limited to the adequacy of the Agency's search and similar matters." [Voniche, 412 F. Supp. 2d at 71](#). It is a simple matter to determine the extent of the search that could have been done and if in fact it was done. To date, by the FDA response, it appears that a proper search was never done.

COMPUTER FORENSIC EXPERT

The FDA clearly wasted a lot of both Plaintiffs and this Courts time when it fought over providing documents to Plaintiff, designated the request “complex” then provided a non responsive answer that failed to indicate a full and proper search was conducted. The FDA has violated the Freedom of

Information Act and demonstrated bad faith in classifying, searching, and in responding to the request. The documents the Plaintiff seeks are likely still in the possession of the FDA. Attached hereto as “Exhibit C” and incorporated by reference thereto is information from a computer forensic expert that sets forth how electronic information and the retrieval of electronic information works. The Plaintiff is at this moment discussing with an expert, with an extremely impressive resume, his retention to provide an expert affidavit consistent with the facts set forth in Exhibit C (with more specifics) that will make it clear to this Court that the information sought by CareToLive is most likely still retrievable and in the possession of the FDA. If the opinion of the Plaintiff’s expert would be helpful to this Court in determining whether the Court should grant the relief requested in Plaintiff’s motion, then Plaintiff seeks leave of one week to obtain and provide that affidavit by way of supplement to this response.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This reply was filed by e-transmission and is understood to be served on all parties by the courts electronic notification system this 16th day of June 2009.

S/Kerry M. Donahue