

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

FILED
JAMES BONINI
CLERK

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U.S. DISTRICT COURT
SOUTHERN DIST. OHIO
EAST. DIV. COLUMBUS

CareToLive,
a not for profit corporation,
6295 Emerald Parkway
Dublin, Ohio 43016

Plaintiff,

vs.

The Food and Drug Administration (FDA),
Commissioner Andrew von Eschenbach
1401 Rockville Pike
Rockville, MD 200852-1448

Defendants

Case No **2 : 08 CV 0005**

Judge **JUDGE WATSON**

~~MAGISTRATE JUDGE KEMP~~

**COMPLAINT FOR VIOLATION OF
FREEDOM OF INFORMATION ACT**

Now comes Plaintiff CareToLive, a not for profit corporation and advocacy group organized and incorporated under the laws of and in Ohio, and hereby asserts the following causes of action against the Defendant, Food and Drug Administration (FDA), commissioner Andrew von Eschenbach.

COUNT I

VIOLATION OF FREEDOM OF INFORMATION ACT

1. This Court has jurisdiction under the Freedom of Information Act (FOIA) 5 U.S.C.A. § 552.
2. On behalf of Plaintiff CareToLive (CTL), counsel sent a FOIA request for documents to the FDA on August 15, 2007.
3. The FDA, FOIA office (CBER division), confirmed receipt of the request on September 11, 2007.

4. On November 6, 2007 the Center for Biologics Evaluation and Research (CBER) sent responsive documents to Plaintiff.
5. Responsive documents from Center of Drug Evaluation and Research (CDER) and the Commissioners office, have yet to be received, although the CBER Office confirms that those divisions have had the request and have been “working on their response”, for what is now a substantial amount of time past 20 days (this was stated to Plaintiff by the CBER FOIA office in mid November).
6. The documents received from CBER while possibly or even likely all the responsive documents that CBER had in its possession, were clearly not all the FDA documents relative or responsive to the Plaintiff’s request.
7. A call to the CBER FOIA office in November by Plaintiff, resulted in Plaintiff being advised by that office that the response was not complete because the FDA FOIA Office had also properly sent the request for production to the Center of Drug Evaluation and Research (CDER) which includes the Office of Oncologic Drugs (OOD) and the Commissioner’s office and that “OOD was working on a response, as was the office of the Commissioner Andrew von Eschenbach”.
8. The CBER FOIA division of the FDA was helpful and responsive and provided the information sought which they had access to.
9. The CDER division, as well as the Commissioner’s office has not been forthcoming with easily accessible documents and appear to be stonewalling for reasons that may include the fact that three members of Congress have called for a Congressional hearing of the underlying matter, for which the FOIA request, if

properly responded to, might provide evidence helpful to that investigation of the underlying wrongful actions of the FDA.

10. Under FOIA, both CDER and the Commissioners office needed to provide the documents within 20 business days of August 15, 2007, or arguably, at least 20 days from September 11, 2007.
11. CDER and the Commissioners Office has not complied and produced the documents with 20 business days as required by FOIA.
12. It is going on 5 months since the FOIA request was both faxed and mailed to the FDA and 4 months since the date the FDA confirmed receipt.
13. Plaintiff has still not received the responsive documents and has received no written communication (response) from the Commissioners Office or CDER.
14. Several calls by Plaintiff to the CDER FOIA Office of the FDA including a call on December 27, 2007 resulted in the response from Defendant that Plaintiffs would just have to wait in line and that no documents should be expected soon.
15. That response completely ignores the requirements of 5 U.S.C.A. § 552.
16. The actual documents received from the CBER division of the FDA show that letters and e-mails were sent to commissioner von Eschenbach as well as Richard Pazdur head of OOD within CDER.
17. That there are documents responsive to the request possessed by CDER and the Commissioners office is undeniable unless the documents have been destroyed in which case FDA (FOIA), IT employees can recover them.
18. Since there is a fear that some e-mails and hard copies of documents may have disappeared (communications sent to OOD head Richard Pazdur) and may need

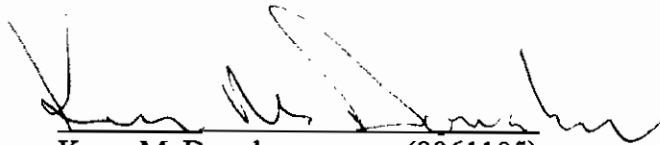
to be retrieved by an IT person, the order to produce must include a review by IT of the computer hard drive and/or server (IP) of OOD head Richard Pazdur.

19. The Freedom of Information Act provides that the Plaintiff is entitled to fees and sanctions for enforcement.

20. The Plaintiff's FOIA request has been designated file number 07-8316 by the FDA and has not been responded to by the Commissioner, or Richard Pazdur of CDER/OOD.

WHEREFORE, Plaintiff requests an order compelling immediate production of the requested documents as well as an award of fees and sanctions to Plaintiff.

Respectfully submitted,



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