

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

CareToLive, et al.,

Plaintiff,

Case No. 2:07 CV 729

vs.

Judge Frost

Andrew von Eschenbach,  
in his capacity as Commissioner of the FDA et al.,

Magistrate Judge King

Defendants.

**MOTION FOR ORDER THAT FDA  
COMPLY WITH FREEDOM OF INFORMATION ACT**

Now comes Plaintiff, CareToLive, and moves this court for an order that Andrew von Eschenbach, as commissioner of the Food and Drug Administration, or appointed FOIA administrator for this area (Brenda S. Zimmer) comply with the Freedom of Information Request sent to them by counsel for Plaintiff on August 15, 2007 as set forth in the attached memorandum.

Respectfully submitted,

S/Kerry M. Donahue

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Kerry M. Donahue (0061105)  
TRIAL ATTORNEY  
*BELLINGER & DONAHUE*  
6295 Emerald Parkway  
Dublin, Ohio 43016  
Telephone: (614) 761-0402  
Facsimile: (614) 789-9866

## MEMORANDUM

On August 15, 2007 counsel for Plaintiff made a request for information under the Freedom of Information Act to the Food and Drug Administration (FDA). That request is attached hereto as “Exhibit A”. The Plaintiff’s have an absolute right to the information whether they are already Plaintiffs in a law suit or not.

While this matter could be filed as part of an amended complaint or separate complaint, considering the complexity of the underlying complaint a motion seemed more appropriate to bring this to the attention of the court, as it is related to this ongoing litigation. Plaintiffs believe the records should have been produced within 20 business days of August 16, 2007 which would have made them due September 14, 2007. The Plaintiffs had a right to this information under the FOIA under both section (a)(2)(D) and (a)(3)(A)

According to the Freedom of Information Act (FOIA):

5 U.S.C. 552

As Amended by Pub. L. No. 104-231

Sec. 552. Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying—

D) copies of all records, regardless of form or format, which have been released to any person under paragraph (3) and which, because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records; and

(E) a general index of the records referred to under subparagraph (D);

3) (A) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, 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.

(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter de novo, and may examine the contents of such agency records in camera to determine whether such records or any part thereof shall be withheld under any of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action. In addition to any other matters to which a court accords substantial weight, a court shall accord substantial weight to an affidavit of an agency concerning the agency's determination as to technical feasibility under paragraph (2)(C) and subsection (b) and reproducibility under paragraph (3)(B).

(E) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.

(F) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the withholding, the Special Counsel shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Special Counsel, after investigation and consideration of the evidence submitted, shall submit his findings and recommendations to the administrative authority of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Special Counsel recommends.

(G) In the event of noncompliance with the order of the court, the district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

(6)(A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall--

(i) determine within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefore, and of the right of such person to appeal to the head of the agency any adverse determination; and

While it may seem premature to file such a request, this is an emergency case and time is of the essence. In addition the Plaintiff believes the recent complaints of congress as to the non responsiveness of the FDA and the fact that similar other litigation to enforce compliance by the FDA to answer proper document requests have recently been filed by others, it is indicative that the current FDA is unlikely to provide them herein, in any kind of timely manner or to even recognize the emergency nature of this litigation.

The letters requested under FOIA were the three letters believed to have been written at the request and/or with the assistance of Richard Pazdur at the FDA. While Plaintiff has the version of the letters that the FDA leaked to “The Cancer Letter”, a non-peer publication, they only contain the body of the letter without the date, signature line, letterhead, or other identifying parts. In Exhibit A the Plaintiffs also requested the full letters along with any accompanying materials when received by the FDA and any materials that accompanied the “leaking” of the letter to outside sources. The accompanying documents will reveal how the FDA obtained the three letters and how all three of the letters were then each transmitted by the FDA to the very same news source.

This information is pertinent to the denial of due process to Plaintiffs in this matter and further ongoing daily due process denial. This is clear evidence of the conspiracy by

persons within and outside the FDA to deny due process to the Provenge BLA. This is simple and easily retrievable information that should have been produced by September 14, 2007.

The FDA already released at least part of these letters to the press in a timely fashion (to suit their needs) so there is simply no excuse to not timely provide the entire letters, along with the accompanying documents to Plaintiffs, as they properly requested under the FOIA.

WHEREFORE this court should order the immediate production of those documents requested in the Plaintiffs Exhibit A, since there has been no response forthcoming from the FDA.

Respectfully submitted,

S/Kerry M. Donahue

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TRIAL ATTORNEY  
*BELLINGER & DONAHUE*  
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**CERTIFICATE OF SERVICE**

It is understood that since this document was e-filed with the court that the clerk will transmit a copy by e-mail to all counsel of record in this matter.

S/Kerry M. Donahue

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