

**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

Defendants

**REPLY TO DEFENDANT’S MEMORANDUM CONTRA PLAINTIFF’S  
REQUEST FOR LEAVE TO SERVE REQUESTS FOR ADMISSIONS UPON  
DEFENDANT**

The Defendant FDA is trying to convince this Court that this is just another case not unlike thousands of other cases. They suggest that the Plaintiff just has to wait their turn just like everybody else. They suggest the documents sought by Plaintiff are not ready at hand and have not been already compiled and reviewed as part of an internal investigation by Health and Human Services (HHS) or by the FDA, into its own affairs.

Putting aside the extraordinary situation present herein, which is that the FDA for the first time ever did not follow the advice of a hand picked panel of experts who overwhelmingly recommended approval of a treatment for a life threatening condition for which patients have no reasonable alternatives and that this effort was lead be a single individual from another FDA division, which was then followed by the death of almost 30,000 men who were never able to access the treatment, then it still makes a difference to this litigation whether this is really a stonewalling tactic or a legitimate FDA response. If the FDA has really done nothing itself to investigate this matter after all that has

occurred than that may be even a greater wrong. Doesn't this Court deserve the truth and to know if those documents are sitting on a desk ready to be sent yet not being sent only to stem the negative PR that it will cost the agency once the public obtains that knowledge. The FDA is well aware of the heightened scrutiny by the public as well as Congress of this matter and can ill afford release of such damning documents that will show the orchestration of the sabotage of Provenge and thus that due process was denied with the result being that a safe and effective treatment remains unavailable to the patients. *It's not that they lack the time and ability to produce them, only the desire.* The requests will be limited to a determination of whether the documents have already been located, reviewed and/or compiled by FDA insiders.

The FDA charges the requester for the cost of obtaining and providing the documents under a FOIA request and Plaintiff has already been charged for and paid for previous responses so the Defendants funding argument is a red herring. All costs are paid by the requester.

The FDA wants this Court to believe that despite the huge public outcry that followed the Provenge debacle that it is business as usual at the FDA and there is no public importance to the documents. A summary of just some of what occurred post Black Wednesday (May 9, 2007):

1. Hundreds of op editorial articles and/or press reports criticized the FDA action.
2. Physicians and medical journals were critical of the FDA.
3. Advocates marched in Washington D.C. protesting the decision.
4. Angry advocates met with Commissioner von Eschenbach.
5. Disappointed patients were interviewed on both the network and on cable news.

6. The public became aware and the FDA was notified about conflicts of interest and improper lobbying by two conflicted oncologists.
7. Thousands of letters of protest and e-mails were sent to Congress, the media and the FDA.
8. Dozens of members of both the House and Senate wrote to the FDA regarding their concerns over the FDA denial of Provenge on behalf of their constituents.
9. There was a protest demonstration in Chicago.
10. Continued world wide media coverage of the FDA actions.
11. A ½ page ad appeared in the Washington Post by Provenge advocates calling the FDA dysfunctional (later virtually admitted in a self assessment report by the FDA).
12. A Citizens Petition was filed with the FDA.
13. A law suit was initiated in Federal Court against the FDA.
14. Freedom of Information Act requests were submitted to the FDA.
15. A large rally/demonstration occurred in Rockville, Maryland, home of the FDA.
16. Further news coverage continued including peer reviewed journals calling for an investigation and which criticized the FDA for what they did to Provenge BLA process.
17. Other advocacy groups called for investigation and FDA reconsideration of Provenge.
18. The FOIA requests were attempted to be enforced in this Court in another related action prior to the complaint in this matter.

19. Three members of Congress sent a letter to the E & C committee calling for a Congressional Investigation of the Conflicts of interest that affected the FDA Provenge decision.
20. This FOIA Complaint was filed.
21. Another 8-10 House members joined the call for a Congressional hearing and investigation into the matter.
22. Additional members of Congress send letters of inquiry to the FDA for answers.
23. The Commissioner's office and CBER division respond to FOIA requests and thus confirm that the two conflicted AC members employed post AC lobbying strategies to hurt Provenge approval chances.
24. Continued media and internet articles critical of FDA and seeking transparency and accountability continue to appear across the country.
25. Continued advocacy by several different advocacy groups.
26. A group of physicians circulated a sign on petition that was submitted to Congress and copied to the FDA.
27. The world continued to seek answers from an FDA who will not provide the Information that is due under the Freedom of Information Act

AIPC affects one out of every six men and 80 patients a day die, yet the FDA believes this is just another FOIA request and that it can and should be processed in due course as they get to it. They want this Court to believe that they have given little to no thought at all to the request and that nobody in the FDA has investigated the matter since May of 2007. That even in the face of heightened Congressional and public scrutiny and the thousands of people who have sought the same answers that the FOIA request speaks to,

that this matter is of no public importance. Plaintiff, CareToLive patient members continue to die without ever having been able to access Provenge, yet the FDA treats this as an unimportant matter that lacks any need for urgency or priority treatment, much less normal compliance with the 20 day requirement of the Freedom of Information Act.

The Defendant can simply admit or deny 20 requests for admissions under oath and then the Court will know what the FDA really contends. The documents likely consist of less than 50 pages of letters and e-mails. Easily compiled documents probably already located and reviewed by FDA officials or in house counsel (they are probably all on one individual's computer and have already been reviewed in house). The FDA has either never done any internal investigation of this matter, which would be remarkable not to mention negligent given the circumstances, or they have and the information sought already at their finger tips just waiting for a court order to provide it in accordance with the clear mandate of the Freedom of Information Act. The requests for admission will be limited to the determination if any prior action has occurred relative to compiling and or reviewing the documents requested so as to ascertain whether the documents can be easily produced and/or have already been located and reviewed by FDA officials and are really just being withheld from the public.

WHEREFORE, this Court should grant leave for Plaintiff to submit a proper request for admissions seeking information on whether the documents have already been compiled and/or reviewed and/or are easily accessible non voluminous documents largely available at one easily accessible location within the FDA.

Respectfully submitted,

S/Kerry M. Donahue

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

**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.

S/Kerry M. Donahue