

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

CARETOLIVE,
a not-for-profit corp.,
Plaintiff,

Civil No. 2:08-CV-00005

JUDGE FROST

v.

MAGISTRATE JUDGE KING

U.S. FOOD and DRUG
ADMINISTRATION,
Defendant.

**PLAINTIFF'S MOTION FOR LEAVE TO SUBMIT TWENTY
REQUESTS FOR ADMISSION TO DEFENDANT FDA**

Now comes Plaintiff and moves this Court for leave to conduct limited discovery by allowing the submission of twenty (20) requests for admission to the Defendant FDA, in accordance with Federal Rule of Civil Procedure 36 as more fully set forth in the attached memorandum.

Respectfully submitted,

S/Kerry M. Donahue

Kerry M. Donahue
6295 Emerald Parkway
Dublin, Ohio 43016

MEMORANDUM

In both this case and the related case the FDA is comfortable in asserting no bad faith or wrong doing on their part related to the Provenge debacle. cThey are confident in their assertions because they know that most of the proof of wrong doing lies within the FDA. As long as the Courts will never allow any discovery and the FDA (CDER division) will not respond to the FOIA request then they are correct that they may never have to be held accountable for their actions.

Without any discovery the Plaintiff is in a catch 22. If this Court will not allow discovery, the bad faith of the FDA cannot be demonstrated to this Court. The unprecedented nature of the CTL versus FDA matter renders the case law that has been developed to allow non compliance of the law by the FDA not meaningful. The unique circumstances that exist in this important matter is that for the first time ever the FDA has capriciously denied access to a safe and effective therapy for late stage cancer patients with no viable alternative other than death. For the first time ever known, certain FDA insiders were able to subvert the new drug approval process to serve their own misguided ambitions and now those same individuals are being allowed to subvert the Freedom of Information Act to avoid evidence of their misconduct coming to the attention of the public. If the unique facts herein are compared to those facts in the other cases, this Court will see that this case is not so easily assumed to be factually like any other FOIA case. The reasons why this case is unprecedented is always relevant because the FDA has

never acted as irresponsibly as it has with regards to dying prostate cancer patients right to access Provenge. Never has the nature of a bureaucracy itself been displayed in such an unflattering manner. The inability of the bureaucracy to act in a humane manner has resulted in the frustrations and the resulting inability of dying men to get simple answers from the FDA, as to the reasons why they are being denied a therapy voted unanimously by 17 hand selected FDA experts to be safe. The coldness and inhumanity of the FDA is apparent from their refusal to treat this matter as one of life and death and without concern for the suffering patients that manifests itself in their announcement to this Court that this matter is not urgent and therefore not deserving of at least priority placement in the supposed production line of FOIA responses.

If this Court does not allow a few simple depositions then the Court should at least allow the Plaintiff the right to test the assertions made by the FDA by submitting twenty (20) simple requests for admission to be propounded to the FDA to be answered within 30 days in accordance with Civil Rule of Procedure 34.

This simple discovery device, which will minimally inconvenience the Defendant, will allow the Plaintiff to demonstrate that the documents requested have already been identified, their whereabouts are known and/or that they are being withheld by individuals within the FDA as intentional legal strategy.

While Congress has decided not to honor the request of three Congressman (supported by even more members of Congress) to hold hearings into the Provenge

matter to date, if they had the CDER FOIA response that position might very likely change, and the FDA knows it, because they have seen the responsive documents and refuse to release them to Plaintiff. The FDA's fear is that the Congressional decision can change at any time and that release of the CDER documents might contribute to that change. They also fear that the evidence could be used if there is a possible remand in the CTL vs. FDA case. The documents will allow the world to understand that the FDA wrongdoing has caused needless suffering among mankind. The FOIA response will cause embarrassment to the FDA that will precede a public outcry for badly needed FDA reform.

Wherefore the Plaintiff requests that this Court grant leave to allow the Plaintiff to serve twenty (20) requests for admissions regarding the FOIA requests to the FDA.

Respectfully submitted,

S/Kerry M. Donahue

Kerry M. Donahue
6295 Emerald Parkway
Dublin, Ohio 43016

CERTIFICATE OF SERVICE

This motion for leave has been e-filed and thus sent to all parties of record by the Clerk's e-filing system.

Kerry M. Donahue

