

**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,

Magistrate Judge King

Defendants.

PLAINTIFF'S MOTION FOR LEAVE TO FILE
2ND AMENDED COMPLAINT AND REPLY TO DEFENDANT'S
MEMORANDUM CONTRA PLAINTIFF'S MOTION TO ENFORCE
FOIA

Now comes Plaintiffs and hereby move this court for an order granting leave to amend the Plaintiffs first amended complaint as set forth in the attached memorandum of law and also offers the following as a Reply to Defendants Memorandum Contra Plaintiffs Motion to Enforce FOIA.

Respectfully submitted,

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MEMORANDUM

In an effort to conserve judicial resources, as well as party resources, the Plaintiffs brought to this courts attention the Defendant's violation of The Freedom of Information Act (FOIA), by way of motion, so as not have to amend and re file a rather weighty First Amended Complaint. Defendants are indeed correct such matter should be properly brought before this court by way of a Complaint so their assertion forces this request to so amend the Complaint.

The Defendants apparently prefer that the FOIA violation be part of the complaint rather than by motion in the already pending case. That now being made an issue to this Court, at Defendants request, Plaintiff could now either file a separate Complaint and then seek to consolidate it with this case, or seek leave to file an amended complaint to add the FOIA claim. Plaintiff has chosen to first seek leave to file an amended complaint.

The FOIA violation occurred after the filing of the First Amended Complaint as the FDA has 20 business days to produce the requested documents. The FDA has still not produced those documents and thus remains in violation of the FOIA. Such an amended complaint provides Plaintiff's even further argument that this court has jurisdiction over this matter as the FOIA itself provides authority to file a complaint against the government and grants this court jurisdiction to proceed on it.

It does not matter if there is a pending case or not. It is not relevant to a FOIA violation. Any United States citizen has an absolute right to documents under the FOIA whether they are involved in litigation against the government or not. Plaintiff's rights are no more and no less and Defendants rights are no more or no less, when there is an underlying Complaint. If this case was not pending the Plaintiffs still have a right to file an allegation of failure to comply with the FOIA.

The Freedom of Information Act was created to insure transparency in government. The government is supposed to be by the people, for the people. While the FDA operates by its own rules, in secrecy and without accountability to the public, it is not supposed to so act in that manner. In this case the FDA has taken it one step further and now fights public accountability even under a lawful FOIA request. The Defendants actions in this matter are even more blame worthy as they previously presented one posture and face to the public as to Provenge, only to take action, secretly, behind closed doors, in a fashion completely the opposite of what was expected from their head fake presentation they performed in the public eye. To date they have refused to explain the at least apparent injustice or provide a definitive rationale for the actions.

5 U.S.C.A. § 552

(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).

5 U.S.C.A. § 552

The claims are related as one of the core issues of this matter is the lack of accountability to the public from the FDA with regards to the apparent irrational Provenge decision.

Some excerpts from “Five Moral Imperatives of Government Regulation” by Peter Barton Hutt:

*.....The third principle is another easy one—public participation. Our country was founded on the democratic principle of participation. During the early years of government regulation this was not a central issue because the government was not regulating very much, its intrusiveness was not very noticeable, and therefore participation was not sought after. But as regulation has grown and real restrictions have affected all of us, public participation has become essential to legitimizing the regulatory process. **In my opinion, the most important statutes Congress has enacted in the past 100 years are the Freedom of Information Act, the Sunshine Act, and the Advisory Committee Act.** Without those the government would be doing business in private, not in public. They are important in part for appearance’s sake as well as for substance, but the potential for actually exposing government stupidity or wrongdoing under those laws is far greater than at any time in our past.*

Mr. Hutt practices in Covington's Washington, DC office, specializing in food and drug law. He began his law practice with the firm in 1960 and, except for four years as Chief Counsel for the FDA, has continued ever since as a longtime partner and now senior counsel. Since 1994, Mr. Hutt has taught at Harvard Law School, and he is the co-author of the leading food and drug law casebook used in law schools throughout the country. Mr. Hutt has won numerous accolades and has garnered recognition as a leader in his field. In April 2005, Mr. Hutt was presented the FDA Distinguished Alumni Award by FDA Commissioner Crawford. In May 2005, he received the Lifetime Achievement Award for research advocacy by the Foundation for Biomedical Research. *Business Week* referred to Mr. Hutt in June 2003 as the "unofficial dean of Washington food and drug lawyers." In naming Mr. Hutt in September 2005 as one of the eleven top food and drug lawyers, *Legal Times* described him as "the dean of the food-and-drug bar." He was named by *The Washingtonian* magazine as one of Washington's 50 best lawyers and as one of Washington's 100 most influential people; by *The National Law Journal* as one of the 40 best health care lawyers in the United States; and by *Global Counsel* as the best FDA regulatory specialist in Washington, DC.

The importance of compliance with the FOIA cannot be understated. The FDA seeks to continue to do what ever it wants, rules, regulations, congress and the public be damned.

This is not a new revelation and something that was expected in large part by some insightful members of Congress prior to the confirmation of Andrew von Eschenbach as FDA Commissioner. Attached hereto as “Exhibit A” is a part of the confirmation hearings and concerns as set forth by Senator Grassley regarding his long standing concerns over Andrew von Eschenbach failures to be forthright and responsive to the *public’s right to know*.

Fed.R.Civ.P. 15(a) states that after a responsive pleading is filed, a complaint may be amended only by leave of the court, and that “leave shall be freely given when justice so requires. The decision to grant or deny leave to “amend is within the discretion of the District Court.” *Foman v. Davis*, 371 U.S. 178, 182, 83 S.Ct. 227, 9 L.Ed.2d 222 (1962).

Although probably not applicable herein, under Rule 16(b), “once a scheduling order's deadline passes, a party must first show ‘good cause’ for the failure to seek leave to amend prior to the expiration of the deadline before a court will consider whether the amendment is proper under Rule 15(a).” *Hill v. Banks*, 85 Fed. Appx. 432, 433 (6th Cir.2003).

An amendment coming late in discovery should not be denied as a penalty to the moving party when the factual basis for the amendment

was not disclosed until late in discovery. *See MPT, Inc. v. Marathon Labels, Inc.*, 2005 U.S. Dist. LEXIS 29278 (N.D. Ohio, Nov. 23, 2005); *Discover Bank v. New Vision Financial, LLC*, 2005 WL 1865369 (S.D. Ohio, Aug. 1, 2005) (allowing leave to amend because a limited discovery extension confirmed suspicions sufficient in fact that new claims could be asserted in good faith). The *MPT, Inc.* court noted the defendant's admission “the bulk of time and expense spent on discovery related to the issue has been incurred” and also pointed to the “ample time” still available before the court's discovery deadline.

While Defendant does point out that the deadline for amended pleadings has expired, there is no argument on either side regarding “good cause” to determine the disposition of Plaintiffs' motion. (Def. Respon. to Pl.'s Mot. for Leave to Amend, p. 3; R. at 36).

Diligence of the moving party highlights the primary element in meeting 16(b)'s “good cause” standard; as explained by the 1983 Advisory Committee Notes, “the court may modify the schedule on a showing of good cause if it cannot reasonably be met despite the diligence of the party seeking the extension.” Prejudice to the party not seeking alteration to the scheduling order should be a factor, but the main focus should remain on the moving party's exercise of diligence. *See Andretti v. Borla Performance Indus., Inc.*, 426 F.3d 824, 830 (6th Cir. 2005). An assertion of “good cause” is likely meritorious when the moving party can show it “has been generally diligent, the need for more time was neither foreseeable nor its fault, and refusing to grant the continuance would create a substantial risk of unfairness to that party.” 3 *Moore's Federal Practice*, ¶ 16.14[1][c] at 16-72.1. Carelessness or oversight is ordinarily

incompatible with a finding of diligence. *See North Start Mut. Ins. Co. v. Zurich Ins. Co.*, 269 F.Supp.2d 1140, 1145 (D.Minn.2003) (“carelessness, inadvertence, or inattention” is not compatible with a finding of diligence so as to support modification of scheduling order deadlines); *see also Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 607-609 (9th Cir.1992).

The actual violation of FOIA itself did not arise until after the filing of the First Amended Complaint and standing was not an issue until it was raised by the Defendants in their motion to dismiss. Also, this case is in the early stages and it has been diligently prosecuted by Plaintiffs. There is no prejudice caused to Defendants by allowing the amendments to Plaintiff’s Complaint. There is good cause to allow the Plaintiffs amendments. Although rule 16 is addressed herein it is questionable whether it applies since the court has not ever set a *deadline for any further amendments* as part of an over all case schedule.

The Defendants have also raised the issue of standing in their pending motion to dismiss. As stated in Plaintiff’s Memorandum Contra the Defendant’s Motion to Dismiss, if the Court wants the Plaintiffs to restate the response to the Defendants raising of the issue of standing in the complaint itself, as opposed to incorporating it from the memorandum contra, it is requested that the court grant leave to amend the complaint to address the

standing assertions at the same time as the Plaintiff adds the FOIA count to the complaint, so as not to require two separate amendments.

WHEREFORE, this court should either issue an order that the FDA immediately comply with the FOIA request and/or grant leave to the Plaintiffs to make a separate claim for violation of the FOIA as part of a 2nd amended complaint and to allow the Plaintiff to add further standing language, if standing as set forth in the memorandum contra, is deemed by this Court to be necessary to be part of the complaint itself.

Respectfully submitted,

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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 this 27th day of October, 2007.

S/Kerry M. Donahue

Kerry M. Donahue