

Scott P. Bellinger  
Kerry M. Donahue\*  
\*Also admitted in Florida

---

**BELLINGER & DONAHUE**

Attorneys At Law

6295 Emerald Parkway  
Dublin, Ohio 43016  
Office 614-761-0402  
Fax 614-789-9866

---

July 17, 2008

The Honorable Leonard Green

Clerk of Court

Court of Appeals for the Sixth Judicial District of the United States

100 E. Fifth Street

Cincinnati, Ohio 45202-3988

Re: CareToLive v. von Eschenbach, Case no. 07-4465 (6<sup>th</sup> Circuit oral argument to be heard on July 29, 2008)

Dear Honorable Leonard Green,

Pursuant to Federal Rule of Appellate Procedure 28(j) on behalf of Appellant we submit the following two items

1) The press releases (3) from the FDA that accompanied the codification of 21 C.F.R. 601.3 as submitted by Appellee, attached and also seen here:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01859.html>

and

[http://www.fda.gov/cder/regulatory/complete\\_response\\_FR/default.htm](http://www.fda.gov/cder/regulatory/complete_response_FR/default.htm)

and

[http://www.fda.gov/cder/regulatory/complete\\_response\\_FR/qa.htm](http://www.fda.gov/cder/regulatory/complete_response_FR/qa.htm)

and

2) New case law rendered since the briefs were submitted, specifically as set forth on page 1 through 5 of the concurring opinion of Circuit Judge Tatel <http://pacer.cadc.uscourts.gov/common/opinions/200804/06-1343-1112979.pdf> as attached hereto which is supportive of the proposition set forth in Appellants brief that it was error for the lower Court to essentially treat the

matter as upon summary judgment, without at least considering the full APA record.

The District Court in this matter made its decision on both the requested injunctive relief and the averments of the complaint without considering the whole APA record in this matter. The need for greater transparency of FDA actions with regards to matters of such great public importance is imperative to the confidence of the Citizens in its government agencies. Transparency was denied in this case due to the treatment of the case by the lower Court when it failed to order production or consider the APA record, as discussed in the new Court decision attached. The District Court essentially dismissed the matter without even reviewing the CR letter sent to the applicant, which is a part of the APA record and which was offered to be made available to the Court by Appellee.

It is requested that the Clerk distribute this letter along with the attachments per Rule 28(j) to the panel.

Sincerely,

Kerry Donahue