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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,

In response to the Government's, (Appellee's), Federal Rule 28(j) letter the Plaintiff, CareToLive (Appellant), offers no objection but does submit its own Rule 28(j) letter by separate letter being sent contemporaneously. The reason will be better understood in light of the press release issued by the FDA in conjunction with the announcement of the codification of the "CR Letter" more properly referred to as the "we don't ever make final decision's rule/mechanism", enacted by the FDA in an effort to avoid oversight, accountability and transparency.

Although the Appellee failed to indicate the reason they believe the codification assists their case or which section they believe is significant to a decision of this Court as set forth in Rule 28(j), Appellant is in favor of its submission as they believe it along with the FDA press release assists the Appellant's argument regarding whether the FDA action or inaction constituted a final reviewable action. The rule was already being applied to biologics applications prior to the recent codification and is mostly newly applicable to non-biologic New Drug Applications (NDA's) which will now also refer to "Approvable Letters" (App) as "Complete Response" (CR) Letters. The FDA's past and recent practice is to always send App's, now always CR Letters, whether it's a new drug application or a biologic application being considered, and to never issue any denials. Most CR letters while withstandable by big pharmaceutical companies will financially devastate small companies including small biotech companies. The FDA rule

was promulgated and codified so as to protect the big pharmaceutical companies that fund the FDA and hinder their competition.

It is requested that the Clerk distribute this letter along with the separate Rule 28(j) being filed by Appellant to the panel.

Sincerely,

Kerry Donahue