

Care To Live

a not for profit corporation

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FOR IMMEDIATE RELEASE

United States Court of Appeals — CareToLive v. FDA — Notice of Oral Argument

CareToLive, a not for profit corporation representing end stage prostate cancer patients who are seeking access to the safe and effective immunotherapy Provenge which the FDA denied approval of on May 8, 2007, received notification on June 2, 2008, that the United States Court of Appeals has scheduled oral argument on July 29, 2008 at 1:30 PM before a three-judge panel of the Sixth Circuit in Cincinnati, Ohio.

Attorney Kerry Donahue, who is representing CareToLive, seeks transparency and accountability from the FDA, as to why it disregarded the advice of its hand selected, Congressionally mandated Advisory Committee of experts, who voted Provenge unanimously safe and overwhelmingly effective. With no scientific basis the FDA denied licensure, which was an unprecedented action since no alternative viable treatment options exist. We are seeking immediate access to Provenge for all men with end stage prostate cancer.

CareToLive filed a Citizens Petition with the FDA over 10 months ago, asking it to reconsider the wrongful denial of Provenge. The FDA failed to follow Federal regulation and to this day it has not bothered to properly respond to our Petition seeking immediate access to Provenge for these desperate men.

CareToLive filed a lawsuit on July 30, 2007, which the US District Court, Southern District of Ohio, Eastern Division, dismissed based on ripeness, finality and sovereign immunity, essentially stating that since the FDA did not deny Provenge licensure, but merely failed to approve it, the court could do nothing. It makes no difference to the CareToLive members who have since passed away, as well as those currently seeking access to the Provenge immunotherapy, whether the FDA merely “failed to approve” or “denied licensure”, as they both amount to the same thing, a rapid, premature death. Some men who were able to access Provenge in the trials, are living as long as 7 years later.

The FDA has also refused to respond to the CareToLive Freedom of Information Act request, which it knows would prove that a few FDA insiders, who cared more about serving their own self interests, rather than the best interest of the patients, purposely sabotaged Provenge.

“This is a giant step for prostate cancer sufferers!” CareToLive Spokesperson, Mike Kearney, said. “1 in 6 men will get prostate cancer in their lifetime. By allowing oral arguments, the court is saying that CareToLive can present argument to the three Federal Judges on behalf of prostate cancer patients who seek Provenge, that the lower court decision was a mistake, and that the lives of the 30,000 American men who will die from end stage prostate cancer every year, matters.”

We thank our many members and supporters who have been in this battle with us, and mostly we thank our sick who are waging this war on a daily basis. To you we say, please try to hold on.

Notice of Oral Argument: http://caretolive.com/US_Court_of_Appeals_CTL_vs_FDA_06-02-08.pdf

CareToLive’s Appeal: <http://caretolive.com/CareToLiveAppeal7Final.pdf>

CareToLive Reply Brief: http://caretolive.com/CTL_Reply_Brief_03-05-08.pdf

CareToLive Legal Filings: <http://caretolive.com/lawsuit-news/>

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