

FDA TURNS ITS BACK ON TED

Since the FDA denied approval to Provenge, 26,000 men have died from advanced prostate cancer without access to this life-extending drug. Although an FDA Advisory Committee of 17 experts found Provenge to be safe, and 13 experts found that there was substantial evidence of efficacy, the FDA denied approval to Provenge, leaving dying men without options.

On July 27, 2007, CareToLive filed a Citizens Petition that asked the FDA to reconsider their wrongful decision to deny these patients access to Provenge. Under U.S. Law the FDA had until January 24th to properly respond, which they failed to do. The CareToLive Petition has been supported by evidence sent to the FDA by hundreds of people. In addition, CDER refuses to release information mandated to us under the Freedom of Information Act.

What the FDA did with regards to Provenge was wrong; what they do now after they have been provided with the evidence that the denial of Provenge was done for the self-serving interests of certain FDA employees is inhumane.

Dear Friends,

My name is Ted Girgus. I have end stage prostate cancer that is becoming hormone refractory. Don't let the FDA treat me like a statistic.

I am a 64-year-old man who has been fighting this disease for 10 years. I have a wonderful wife who has been at my side



Ted Girgus with 3 of his 5 Sons

the entire time. I worry because I have four sons and genetically speaking, they have a very high probability of contracting this dreaded disease.

The FDA has decided that I am not a real person. They treat me like a statistic. One of 30,000 "statistics" that die every year from prostate cancer. We die a horrible death.

We know the Provenge story, we know the conflicts of interests associated with at least two members of the Advisory Committee ... NOW we have to make every lawmaker and citizen know about them.

Should I die before Provenge is approved, I leave you with this simple plea: don't let my sons die this way as well. Let them live in a world where people who see injustice stand up and say: "no more."

Make the FDA explain why

CareToLive is a not for profit corporation

This is OUR FDA

We need to take it back from certain FDA individuals with their own ambitions

FDA Approve Provenge Now!

More on this sordid affair at

www.CareToLive.com

thousands of men of all backgrounds have to die while they wait for more statistics.

After all, the Provenge Advisory Committee voted

17-0 that Provenge was safe and 13-4 that it demonstrated "substantial efficacy," the federally mandated standard.

My PSA levels terrifyingly have been going up for the last 7 months. My oncologist now has put me on pain killers, (oxycodone)

and has added a second hormone blocker to my treatment. He also restarted my monthly infusions, but must monitor my kidneys carefully because the Zometa infusions destroy kidney function. I have suffered memory loss, constant pain, incontinence and chemical castration. Compare this to the mild flu-like side effects from 3 infusions of Provenge over 30 days.

Give Provenge the "Approval" it should have received. Let men like me have an opportunity to receive this new treatment. I will not take chemotherapy and steroids. The side effects of chemo are horrendous and have proved to be of little or no value to prostate cancer patients. Why add to my agony?

If we must die, let us die with dignity.

God Bless You All.

Sincerely,
Ted Girgus