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FDA IGNORES PATIENTS LIKE STEPHEN STUDY

CareToLive Loses Another Member — Part II

4/23/08 Care To Live brings you week #4 of our campaign which will continue until the FDA acts in a humane manner.

1 in 6 men get prostate cancer. 83 American men die of it every day. Provenge was voted 17-0 Safe and 13-4 Efficacious by an FDA panel of experts.

On behalf of our patient members like Stephen H. Study, we filed a Citizens Petition on July 27, 2007 asking the FDA to reconsider the failure to approve Provenge and by law they were to have properly responded in January. To date they have not properly

responded.

The FDA ignores our Petition while our members continue to die painful deaths. Why can't the FDA Commissioner consider the patients and take some action? We want better, safer treatments NOW!

In Week #3, CareToLive member Stephen Study, wrote a letter sharing the sad story of how the FDA refused to help his father, Stephen H. Study, who recently lost his battle with prostate cancer. Stephen begged for help for his father but the uncaring FDA Commissioner turned his back.

Stephen's father's urologist, Dr. Jacobsen, was hoping for Provenge's approval in May 2007, as he wanted to start him on it immediately. Instead the FDA denied approval in an unprecedented act for a treatment that was voted so overwhelmingly safe and effective by an FDA Advisory Panel, when no viable options are available.

Stephen described it: "By now we were running out of time and began working on getting Dad into a study in Manila to receive a treatment pioneered by Sangretech. In September we flew to California in hopes of joining a group going to Manila in November where this treatment was being administered. They told us Dad was in bad shape and to immediately book a flight to Manila, which we did. I took Dad back to Manila for his final treatment and he recovered in a Manila hospital for two days and then three days in the hotel. Then we began an arduous trip home.

We landed in San Francisco and Dad was in such pain that he was lying on the floor of the concourse curled up in a fetal position while we waited for our connecting flight. It was the

most heartbreaking thing I had ever experienced, to see Dad reduced to this indignity, in order

(CBER's Development of Safe and Effective Tumor Vaccines and Gene Therapy products). Again he was met with silence.

Stephen wrote to FDA Consumer Affairs and finally received a response. He was told that while the majority of the panelists were for Provenge, several vocal panelists were not.

This shows that the FDA was siding with Drs. Scher and Husain, the "letter leakers", (see the CareToLive website) two oncologists who had numerous conflicts of interest and who did not work with immunotherapies. Both these biased Doctors voted Provenge safe so what really was the harm, other than to the personal agenda of these conflicted doctors? The FDA could have given Provenge conditional approval subject to monitoring data from ongoing trials, making Provenge available to patients like Mr. Study.

Stephen responded to FDA Consumer Affairs telling her of Dr. Jacobsen's assessment and pointed her to Abigail Alliance's research, but he never heard from her again.

Stephen tried his Representative, Jim Marshall. Next he tried Ron Paul who sent a response that he would send a letter off to the FDA. Since then, numerous other members of Congress have voiced their concern and sent letters of inquiry to the FDA, but mostly received uninformative form letters back. Stephen's Dad passed away on March 27, 2008 at age 66.



CareToLive Outside the FDA 4/16/08 to get treatment for a disease. Finally, we arrived home after an exhausting, painful month."

Before it got to this stage, Stephen D. tried feverishly to work with the FDA. He began e-mailing and faxing FDA staff and Congress asking for help.

He wrote to FDA Commissioner Dr. Andrew von Eschenbach and emphasized the safety profile of Provenge. "It seems clear that safety is not the issue here," Stephen said. Dr. von Eschenbach never bothered to reply. The same letter went to Ms. Shone (CBER's office of vaccines), Dr. Celia Witten (FDA Spokesperson at the Advisory Panel Hearing who emphasized the panel look at the survival), and Dr. Raj K. Puri

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 See you next week #5 in the Chevy Chase/Bethesda Gazette

FDA Approve Provenge Now!

More on this sordid affair at

www.CareToLive.com