

Care To Live

a not for profit corporation

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FDA SAYS “WAIT” TO DYING MEN !!! WE ASK “WHY” ???

Care To Live, a not for profit corporation and advocacy group for prostate cancer patients, seeks transparency and accountability from the FDA as to why they disregarded the advice of their hand selected Congressionally mandated Advisory Panel of experts, who, on March 29, 2007 overwhelmingly voted that Provenge immunotherapy is both safe and effective. Without cause or explanation, and in an unprecedented action, the FDA denied licensure.

WHY DID THE FDA IGNORE THE ADVICE OF ITS OWN ADVISORY PANEL?

1 in 6 men get prostate cancer. 83 American men die from it every day. The FDA has not approved a treatment for stage IV prostate cancer in over 43 years.

WHAT IS THE FDA WAITING FOR?

Over a year has passed, and 31,000 American men have died without hope since the FDA denied the licensure of Provenge, an immunotherapy that the FDA's advisory panel unanimously voted (17-0) was safe and overwhelmingly voted (13-4) effective. This is a noninvasive, non-toxic, immune system building treatment, which works by employing your own body's healthy immune system cells to fight the cancer.

WHY WON'T THE FDA ALLOW DYING PATIENTS ACCESS TO THIS LIFE SAVING THERAPY?

Since Provenge is undeniably safe, and prolongs survival of patients with advanced prostate cancer, the FDA should have at least given Provenge conditional approval subject to further review of the data from the ongoing 500 patient “IMPACT” trial. If the FDA had taken this action Provenge would be available NOW to treat tens of thousands of patients who have no viable alternative (except for Taxotere, a chemotherapy with horrific side effects, including death).

WHY IS THE FDA KILLING THESE PATIENTS?

There have been huge and unprecedented irregularities associated with every step of Provenge's movement through the review process. Anyone with a minimum of curiosity about even one of these events, or in a position of responsible oversight would start asking questions about the same.

WHY HASN'T FDA COMMISSIONER ANDREW VON ESCHENBACH INVESTIGATED THESE GROSS IRREGULARITIES?

CareToLive has filed a Citizens Petition asking the FDA to reconsider its inexplicable decision of May 8, 2007 to withhold marketing approval for Provenge and instead insist on waiting for additional trial results to reinforce efficacy data substantiating survival which is already in hand from two previous trials. Additionally, to date, the FDA has failed to follow Federal regulation to properly respond to CareToLive's petition seeking immediate access to Provenge for patients. The FDA wants more “data” while patients including CareToLive members continue to die.

WHAT DOES THE FDA HAVE TO HIDE?

We are seeking immediate access to Provenge for all men with end stage prostate cancer.

If you agree with us that this lifesaving therapy should not be denied to dying prostate cancer patients, please join our efforts by contacting the FDA and your congressman and demand they approve Provenge NOW !!!

For more information visit www.CareToLive.com

PROVENGE FACTS:

Provenge is an active immunotherapy that works by activating the body's own immune system through extraction of the patient's own dendritic cells (a special immune system cell which "turns on" the rest of the immune system), exposure of the dendritic cells to prostate cancer antigens to energize them, and reinfusion of the activated dendritic cells into the patient. It is a patient-specific treatment, utilizing the patient's own cells to target cancer cells INSTEAD Of toxic chemicals that indiscriminately kill every type of cell in the patient's body in the hope that all of the cancer cells will also be killed.

Provenge has already gone through two phase III trials (9901 and 9902A). These trials were the basis of the original biologic license application (BLA) for Provenge. Survival data from 9901 over three years showed substantial evidence of Provenge's efficacy, with a p-value of 0.01 and a hazard ratio of 1.7. The median survival for the treatment arm was 25.9 months vs 21.4 months for the control arm. At 3 years, 34% treated patients were still alive vs. 11% control patients. The second smaller trial, 9902a, failed to achieve statistical significance but again showed median survival benefit 19 months vs. 15.4 months and 32% vs 21% survival rates at 3 years.

Provenge was overwhelmingly recommended for approval by the FDA's own advisory committee on March 29th, 2007 by a unanimous 17-0 vote as to its safety and a 13-4 vote as to its efficacy. Voting on the efficacy question had to be clarified because the panel was originally asked to vote to determine whether Provenge "was efficacious" instead of the legislatively mandated question "Is there substantial evidence of efficacy".

WHY WAS THE WRONG QUESTION INSERTED INTO THE BRIEFING DOCUMENTS TO BEGIN WITH? WAS THIS MORE THAN JUST A TYPOGRAPHICAL ERROR? WHY DID THE FDA DECIDE TO IGNORE THE OVERWHELMING ADVICE OF ITS ADVISORY COMMITTEE, AND NOT APPROVE PROVENGE LAST YEAR?

Of the 4 "No" votes on efficacy, two were cast by Dr. Howard Scher (of Memorial Sloan Kettering) and Dr. Maha Hussain. Subsequent to the Advisory Committee meeting, several undisclosed conflicts of interest by each of these panel members have been discovered, including 17 previously undisclosed COI's for Dr. Howard Scher. Most egregious was Dr. Scher's failure to disclose his role as lead investigator for a rival prostate cancer treatment then in Phase III trials, Novacea's Asentar. Subsequent to the FDA's notice that it was not approving Provenge licensure, Novacea finalized a deal with Schering-Plough to develop and market Asentar. Schering-Plough made an upfront payment of \$60 million to Novacea, with the total value of the deal estimated at \$500 million. How willing would Schering-Plough have been to enter into a partnership with Novacea and make a huge upfront payment for a prostate cancer treatment still in trials if Provenge had been approved by the FDA and gone to market in mid 2007? It is important to note that Dr. Scher was not only the lead investigator for the Asentar trial, he also was a scientific advisor to, and an investor in Proquest Investments, who held a substantial minority stake in Novacea at the time.

THIS REPRESENTS A SERIOUS CONFLICT OF INTEREST ON DR. SCHER'S PART WHICH, HE FAILED TO DISCLOSE WHY? AND WHY HAS THE FDA SO FAR FAILED TO INVESTIGATE THIS ISSUE?

Subsequent to the Advisory Committee hearing, but prior to the FDA's notice of non-approval, three "internal" FDA memos objecting to Provenge approval were "leaked" to a non-peer review newsletter, "The Cancer Letter", at roughly 1-2 week intervals. The first two of these letters were authored by none other than Dr. Howard Scher and Dr. Maha Hussain, two of the "no" votes on the Advisory Committee, and the two AC panel members who had UNDISCLOSED conflicts of interest. It is even more curious that each of the "internal" memos started with a lengthy preamble establishing each author's professional bona fides. Why do that for what is supposedly an internal piece of correspondence? The lengthy preambles make it clear that these letters were written to be leaked externally in an effort by certain parties within the FDA to subvert Provenge approval.

WE ARE STILL WAITING ON THE FDA TO INVESTIGATE THE SOURCE OF THE LEAKED INTERNAL CORRESPONDENCE.

The FDA also refuses to respond to the CareToLive Freedom of Information Act (FOIA) request, which they know would prove that a few FDA insiders, who cared more about serving their own interests, rather than the best interest of the patients, purposely sabotaged Provenge. By this we mean specifically Dr. Richard Pazdur, head of the FDA CDER division. Previous FOIA requests have turned up drafts of Dr. Scher's "leaked" letter on the computer of the National Cancer Institute's Dr. Alison Martin. The final copy of Dr. Scher's letter, as found on Dr. Martin's computer, was written on Memorial Sloan Kettering's own letterhead. What does Memorial Sloan Kettering have to say about Dr. Scher's use of their letterhead to advance his agenda of sabotaging approval of Provenge, a rival to a drug which he was lead investigator of, and which he had an indirect financial interest in its success.

We believe that Dr. Pazdur has taken a leading role in a conspiracy within the FDA to foment against approval of Provenge. We note that review of the Provenge licensure application was not even assigned to Dr. Pazdur's FDA CDER division - as a biologic (not a drug), it was assigned to CBER, another division entirely that does not report to Dr. Pazdur.

WHY IS DR. PAZDUR EVEN INVOLVED IN THIS SITUATION, BECAUSE REVIEW OF PROVENGE IS NOT EVEN WITHIN HIS DIVISION'S PURVIEW?