
CITIZEN PETITION
of
CareToLive,
a not for profit corporation
to the
FOOD AND DRUG ADMINISTRATION,
U.S. DEPT. OF HEALTH AND HUMAN SERVICES

***In re* Request for the Commissioner of Food and
Drugs to reconsider the failure to approve Proveng**

July 26, 2007

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July 26th 2007

Dockets Management Branch
Food and Drug Administration,
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

**Re : *In re* — Request for the Commissioner of Food and Drugs to reconsider
the failure to approve Provenge**

CITIZEN PETITION

A. ACTION REQUESTED

The undersigned submits this petition under Title 21 of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to reconsider the failure to approve Provenge.

B. STATEMENT OF GROUNDS

The agency needs to reverse its decision to deny immediate approval to Provenge, the BLA made by Dendreon in December 2006.

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The FDA invited the BLA and designated Provenge for fast track approval indicating that the FDA had enough data to decide if Provenge was safe and substantially proven to be effective.

You granted fast track approval with PDUFA date of May 15th 2007.

The Advisory Committee voted 17-0 that Provenge was safe and 13-4 that there was substantial evidence of efficacy.

Every year hundreds of thousands of Americans find themselves suffering from terminal diseases with no approved drugs capable of providing a cure or control of their disease.

The FDA knew this was the case for men with advanced prostate cancer.

The US Government has a moral and legal obligation to administer its regulation of drugs for life threatening and terminal diseases in a compassionate and timely manner, and in the best interests of all Americans, including those who have exhausted FDA-approved treatment options. It is a civil and human rights issue that adversely impacts Americans from all walks of life.

The FDA should have known this. And yet it denied these men their right to life, liberty and the pursuit of happiness.

At least two of the four no votes were by doctors who had both disclosed and undisclosed conflicts of interest. ONE DOCTOR, Dr. Howard Scher, received PAYOUTS by drug companies who are in direct competition with Dendreon's Provenge

During and after the Advisory Panel hearing, Dr. Scher, along with doctors Richard Pazdur and Maha Hussain conspired to have Provenge approval denied. Dr. Scher cashed in on wall street when the competing company he works for received \$440 million. That deal would not have happened if Provenge had properly been approved.

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From what we have heard, after threats and political activism from Dr. Pazdur, your agency in a last minute political kowtowing to Pazdur did give up the patients for money and politics. After the coup by Pazdur, Doctor Von Eschenbach relented in order not to be denied passage by congress of funding and other legislation of funding bills proceeding through congress.

You allowed non-voting Conflict of Interest doctors to participate, advocate against Provenge and even vote when the FDA regulation does not so allow.

The agency was not aware of all the conflicts, but now they are and the votes of the conflicted doctors Scher and Hussain should be stricken from the record.

The agency should not tell applicants that they have sufficient data for a decision, conduct studies, impanel an advisory committee and then sabotage the companies immunotherapy for political and monetary reasons.

The agency needs to stop allowing Pazdur to pre decide the outcomes of advisory meetings, stop denying applications arbitrarily and capriciously and stop trying to stack the deck with conflicted doctors who can't be objective.

The FDA should show that they have at least a little common sense when it comes to the risk benefit analysis when it comes to therapies for dying pateints.

Be honest, stop letting Pazdur scare you all, stop conflicts of interests. When you find you have been defrauded by a doctors false disclosures or lack of disclosures of conflicts (works for competitor to company seeking BLA) at least stop counting his illegal vote.

Stop COI's. Fire Pazdur, Sue Scher for fraud or turn it over to the SEC and DOJ. Scher works for Novacea and for ProQuest investments.

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C. ENVIRONMENTAL IMPACT STATEMENT

Not Applicable

D. ECONOMIC IMPACT

Unknown

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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