

August 25, 2007

In regards to: Southern District of Ohio, Case No. 2:07 CV 729, CareToLive v. FDA, et al.

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Dear _____,

AS you are aware from my previous correspondence I seek answers tot he following questions which will enable me to later craft and affidavit for you. Again this process is less intrusive then depositions and attendance at court hearings and I would like to avoid as much inconvenience to you as possible by doing it this way. I have even enclosed a self addressed stamped envelope for return of the responses. Time is of the essence in this matter.

Thank you for taking the time out of your busy schedule to answer our questions regarding the advisory panel meeting reviewing the Provenge (sipuleucel-T) BLA on March 29, 2007 and the before and after events surrounding that meeting.

1. Briefly indicate your professional background that may have caused the FDA to seek you out as an expert panel member in this matter.

2. Did you thoroughly review all the data submitted by Dendreon Corporation prior to the advisory panel meeting?

3. Did you answer yes to both the questions posed by the FDA: a)Is the treatment safe, and b) Is there substantial evidence of efficacy. Why did you vote that way?

4. Did anyone inside or outside the FDA try to influence your vote negatively prior to the meeting, at the meeting or after the meeting. If so who and what did they do or say?

5. Did Dr. Richard Pazdur do anything that indicated to you that he wanted Provenge not to be approved?

6. Did Dr. Pazdur seem to have an anti Provenge agenda. If yes did you see him lobbying any of the other advisors?

7. Do you have any knowledge that Dr. Pazdur was angry that OOD and/or CDER was not the departments handling this immunotherapy review?
8. Attached hereto are three letter (Exhibit A, Exhibit B, and Exhibit C) purportedly written by Dr. Scher, Dr. Hussain and Dr. Fleming. Have you sen these letter previously? Who Wrote them? Did the writers have help by others to write them? If yes do you know who helped to write them?
9. What is your opinion of the substance of the letters?
10. Do you believe the letters were proper? Why or why not?
11. Did you think about wrting a responsive letter. Why or why not.
12. Do you think what was said about CBER (that they are lesser qualified to review cancer treatments and/or immunotherapies is true? Please explain.
13. Were there post advisory meetings between you and the FDA or employees at the FDA? If yes were you pressured to take negative action towards Provenge? How long after the advisory meeting were the closed door meetings. Who was there and what non-proprietary information was discussed?
14. Have you spoken to Dr. Scher, Dr. Hussain or Dr. Fleming since the attached letters were written.
15. Do you know who leaked the letters (exhibit A. B and C) to the "Cancer Letter"?
16. In your opinion do you believe the letters were written with the intent to leak them?
17. Do you know if Pazdur was involved in the letters being written or leaked outside the agency?

18. Do you know why the agency asked one question re efficacy then changed it to another question? Do you know why this was done, who's idea it was to do try to ask a different question? If yes who and why?
19. Were any of the Doctors confused as to the question as far as you know?
20. Is there anything in the attached letters that would have changed your opinion at if you had seen them prior to the panel meeting? Is there anything in them that changes you opinion regarding Provenge now.
21. Is it your expert opinion that Provenge should be approved or conditionally approved for immediate marketing and sale based on the science.
22. Did you believe that discussions between Hussain and Pazdur or Pazdur and Scher or Pazdr and others were improper in the context of the advisory meeting? Did you see Maha Hussain taking notes during a meeting break whail talking to Pazdur? Was ther any other things tat you consider strange or abnormal for an advisory meeting. Of so, what?
23. Is it true that "adjuvant chemotherapy trials have been dismal failures due to lack of enrollment" and enrollment in the now ongoing trials by Taxotere maker Sanofi-Aventis would, he says, "dry up to nothing" if Provenge was approved.
24. Do you have knowledge or believe that an "adjuvant Provenge trial was essentially designed and ready to go upon FDA approval, and the oncology academic community would have been very well aware of that...and the lead investigators on an adjuvant Provenge trial would have been mostly urologists."

25. Do you believe there is a strong desire within the prostate oncology community to not rock the boat in order to ensure these adjuvant trials are enrolled.
26. Do you believe that a cancer treatment should be approved or denied based on a belief that it may or may not become the standard of care.
27. Do you believe Dr. Pazdur recruited Doctors to the advisory meeting who he believed would be negative towards Provenge.
28. Have you hear Dr. Padur or anyone else with personal knowledge say that Dr. Pazdur swore or otherwise stated that no cancer therapy would ever be approved that did not go through CDER.
29. What information if any do you have about the threatened demonstration by Dr. Pazdur and or CDER on or about May 15, 2007.
30. Is it fair to say that approval of Provenge would potentially represent a major complication to successful enrollment of Taxotere's adjuvant trials? If so, how would you characterize the threat to prostate oncologists, and to the prostate oncologist community if Provenge became the standard of care?
31. Were you aware of any internal FDA politics that resulted in the surprise and unprecedented decision by the FDA to overrule the AC panel?
32. Do you think the following is a fair statement: "Consciously or otherwise, prostate oncologists will do most anything, or rationalize most any behavior, to prevent anything from interfering with the successful enrollment of these trials?"
33. Do you know if the CR letter written to Dendreon was changed or written in haste. If yes what do you believe happened?
34. Was there a decision within the FDA to issue a conditional approval Provenge which decision was later changed?
35. Were you aware that Dr Richard Pazdur's request for Office of Oncologic Drug (OOD) review of Provenge was denied by senior FDA

officials? Or that a request by Dr Pazdur to have a joint ODAC/CTGT panel was also denied by senior FDA officials? If yes, do you know which officials denied that request?

36. Did you know that Dr Pazdur's request to have the right to place ODAC members on the CTGT panel was mostly denied by senior FDA officials, who later compromised by allowing Dr Pazdur to compile a list from which either CBER or CTGT management would choose two people? If yes, do you know which senior FDA officials were opposed to having ODAC members on the CTGT panel? Which officials compromised?
37. One Science question: Provenge has shown an improvement in PSADT in ADPC (D9905- PSADT is considered to be one of the best predictors of clinical outcome in patients with PSA recurrence following primary therapy). Provenge has shown an improvement in PSADT in ADPC when used with Avastin (P-16). Provenge has shown an improvement in PSADT in ADPC when used with hormonal therapy (P-11). Provenge has shown an improvement in SURVIVAL when used in HRPC (9901 and 9902a). Provenge has shown an improvement in prostate cancer specific survival in HRPC (9901 and 9902a- An analysis of prostate-cancer-specific survival showed a median survival of 35.2 months for patients randomized to PROVENGE compared to 23.5 months for patients randomized to placebo, a difference of 11.7 months and a 50 percent reduction in prostate cancer-specific mortality (p-value = 0.002; HR = 2.04).). Provenge has shown an improvement in survival in HRPC when used in combination with Taxotere (9901 and 9902a- The analysis was conducted by evaluating the integrated data from the Phase 3 Studies D9901 and D9902A to assess the influence of PROVENGE on clinical outcome in patients who received docetaxel chemotherapy after primary treatment with PROVENGE. Specifically, the analysis evaluated survival data from 82 patients who received docetaxel chemotherapy following initial treatment with either PROVENGE or placebo. The median survival

observed in the PROVENGE treated patients who subsequently received docetaxel was 34.5 months compared to 25.4 months for patients randomized to receive placebo who went on to receive docetaxel, a difference of 9.1 months (HR = 1.90; p-value = 0.023). Approximately 68 percent of the patients randomized to receive placebo also subsequently participated in a cross-over salvage protocol that allowed them to receive active cellular immunotherapy with APC8015F, a version of PROVENGE generated from cryopreserved cells. The median survival was 25.7 months for patients who received APC8015F followed by docetaxel. In contrast, the median survival was 20.2 months for patients who received placebo only and subsequent treatment with docetaxel, a 14.3 month difference compared to 34.5 month median survival seen in the patients who received initial treatment with PROVENGE followed by docetaxel. These three groups appeared to be well balanced based on their baseline prognostic factors, using an independently validated predictive nomogram (Halabi, et al. Prognostic model for predicting survival in men with HRPC: Journal of Clinical Oncology, 2003; 21(7):1232-7) (The abstract, titled "Advanced Prostate Cancer Patients who Receive Sipuleucel-T followed by Docetaxel Have Prolonged Survival" (#605), written by Daniel P. Petrylak, M.D., associate professor of medicine at New York-Presbyterian Hospital at the Columbia University Medical Center).

38. Based upon the entire data set for Provenge, taking into account the evidence of efficacy shown in the Phase II and Phase III trials, the 9905, P-16, P-11, the 9901 and 9902a, the stimulation index data, the CD54 data, the strong trend towards delaying time to tumor progression and the stellar survival results, that have never been achieved in AIPC, of 9901 and the combined data of 9901 and 9902a, which were originally designed to be combined, do you feel that Provenge showed substantial evidence of efficacy?

39. Do you feel justice to the cancer community was served by delaying the approval of Provenge

40. Is there anything that I have not asked you that you would like to comment on. If yes please do so here

Sincerely

Kerry M. Donahue

Counsel for CareToLive, a not for profit corporation