

**IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

CareToLive, a not for profit corporation
C/O Statutory Agent
6295 Emerald Parkway
Dublin, Ohio 43016

Plaintiff,

Case No. (Civil) 2:07 CV 00729

vs.

Judge Frost

Andrew von Eschenbach, in his
official capacity as Commissioner
Food and Drug Administration,
14-71 Parklawn Building
5600 Rockville, MD 20857

Magistrate Judge King

Defendant,

and

Mike Leavitt, in his capacity as
Secretary of the U.S. Department of
Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201

Defendant,

and

Richard Pazdur, in his capacity as an employee
of the FDA and in his own individual capacity
14-71 Parklawn Building
5600 Rockville, MD 20857

Defendant,

and

Howard Scher, in both his individual capacity and
as a special government employee, FDA.
1275 York Avenue
New York, NY 10021

Defendant.

COMPLAINT

Now comes CareToLive, a not for profit corporation, formed under the laws of the State of Ohio, an association of prostate cancer patients, cancer patients, patient families, doctors, investors and advocates, and on behalf of themselves and its membership, doctors on behalf of their patients, and all other androgen independent prostate cancer patients (hereinafter “Plaintiffs”), and hereby aver the following claims and causes of action against the Defendants, Andrew von Eschenbach, in his official capacity as Commissioner Food and Drug Administration, Mike Leavitt, in his capacity as Secretary of the U.S. Department of Health and Human Services, Richard Pazdur, in his capacity as an employee of the FDA and in his own individual capacity, Howard Scher, in both his individual capacity and as a special government employee, FDA (hereinafter collectively referred to as “Defendants”).

JURISDICTION AND VENUE

1. The court has jurisdiction over this action under 28 U.S.C. 1331, in that the action arises under the laws of the United States, including but not limited to 21 U.S.C. § 355(d), 28 U.S.C. § 2201(a) (Declaratory Judgment Act) as well as under the Administrative Procedures Act (APA), 5 U.S.C. 702 & 704 and under the United States and State Common Law of Torts, and under the United States Constitution for the violation of the patients constitutionally protected right to due process that arises due to the Defendants complete denial and refusal to follow FDA regulations and protocol when the Defendants arbitrarily and capriciously decided to deny approval of Sipuleucel-T (hereinafter referred to under its marketing name of “Provenge”) on May 9, 2007, which action has deprived Provenge to the patients who need it now.

2. Venue is appropriate as CareToLive is an Ohio not for profit corporation, its statutory agent is in Ohio, many Plaintiff members are in Ohio, prostate cancer patients are living and dying in Ohio and patients families and doctors in Ohio want this treatment for their family, friends and patients. Every man in this country has a one in six chance to get prostate cancer, Plaintiffs include them all.. Defendants are the government (FDA) and government employees, as well as individuals who reside in various States and there is no real property involved.

THE PARTIES

3. The Plaintiffs are cancer patients individually, doctors seeking help for their patients , families seeking help for their loved ones, current, past and future prostate cancer patients, potential prostate cancer patients and a not for profit corporation, CareToLive, who's members are made up of representatives of each of the classes of individuals set forth above, and who seek to advance the right to life of prostate cancer patients, who could have or would have benefited from Provenge, both past, present, and future who have an absolute right to fight for their lives and choose to live and enjoy a continued quality of life that access to an undeniably safe immunotherapy, Provenge, (which has done all that is required of it to obtain government approval, but which cannot get fair and due process) may provide, and who otherwise seek to immediately enjoin the Defendants from denying, for even one more day, the marketing and distribution of Provenge, to them.
4. Andrew von Eschenbach is the commissioner of the Food and Drug Administration (hereinafter "FDA") and this action is brought against him in his official capacity.

5. Mike Leavitt, in his official capacity as Secretary of the U.S. Department of Health and Human Services, which agency violated the oversight duties it has with regards to the FDA and did allow a complete breakdown of procedural due process within the FDA, and did allow FDA employees to abuse their authorities by taking various actions within the FDA including a complete lack of supervision which has allowed Defendant Richard Pazdur to lead a political coup d'etat within the FDA; has failed to investigate leaks from within the FDA to hedge funds, stockbrokers and others, failed to investigate the improper use of federal employees for non-agency business matters and did allow federal employees to facilitate their own personal agendas within the FDA, and in doing so did deplete government resources.
6. Dr. Richard Pazdur, is the head of the FDA's Office of Oncologic Drug Division (OOD) who both as an employee of the FDA and while exceeding the scope of his employment, did intentionally violate Federal Regulations and US law by improperly controlling the make up of FDA advisory committees, applying improper pressure on advisory committee members and other FDA employees and did participate in purposely denying due process to the BLA for Provenge, filed by Dendreon Corporation (a third party who is attempting to provide aid to dying patients), in an effort to achieve a pre determined outcome and did knowingly deny patients due process by the actively ensuring an arbitrary and capricious decision to deny approval of Provenge, to the detriment of patients.
7. Dr. Howard Scher is a special government employee of the FDA and acting in his capacity as an employee and advisor did make false representations regarding Provenge, both before and after the FDA advisory meeting in an effort to mislead the

FDA, doctors, patients and investors, and further did fail to disclose all conflicts of interest that would have placed the FDA on notice that his own personal interests provided him additional reasons to cause a desired decision that the Provenge BLA not be immediately approved for marketing and use by dying patients and further did exceed the scope of his employment (acting in his individual capacity), when he did unlawfully use his position in violation of federal law and regulations and did undertake to act while failing to disclose all conflicts of interest, did then make knowing misrepresentations to the press in a further post meeting effort to derail the imminent approval of Provenge, in a manner that has callously deprived cancer patients of a safe and effective immunotherapy.

THE FACTS

DEFENDANT FDA HISTORY

8. In contrast to ancient principles that dying men may try to save themselves from dying, regulation of access to new drugs has a history in this country that is of recent origin. Prior to 1906, there was essentially no drug regulation in the United States. In that year Congress enacted the Pure Food and Drug Act (“1906 Act”), Pub.L. No. 59-384, 34 Stat. 768 (repealed 1938), which prohibited misbranded and adulterated foods or drugs from entering interstate commerce, and prohibited false and misleading labeling. For a small number of particularly dangerous drugs, the 1906 Act required the labels to identify the drug's ingredients and quantities. The statute also authorized the Bureau of Chemistry, a predecessor of the FDA, to seize nonconforming goods and to recommend federal prosecution of those who violated the 1906 Act. The 1906

Act did not, however, limit individual access to new drugs or regulate therapeutic claims by drug manufacturers.

9. A patient still could obtain access to any new drug for medicinal use, even if the drug had no therapeutic benefit, albeit subject to the controls placed on narcotics in 1914 by the Harrison Narcotic Act.
10. The 1938 Act did not, however, require drug manufacturers to receive affirmative FDA approval before marketing the drug. Rather, an NDA became automatically effective within a time frame set by the FDA unless the FDA determined that the drug was unsafe and barred its commercial distribution. It was not until 1951, in the Durham-Humphrey Amendment, that Congress created the category of prescription drugs, i.e., drugs that are unsafe for self-medication but which can be used while under a doctor's supervision. Act of Oct. 25, 1951, 65 Stat. 648 (1951) (codified at 21 U.S.C. § 353(b)). Only in 1962 did Congress require drug manufacturers to provide empirical evidence of the effectiveness of a drug as opposed to merely the drug's safety.
11. The Kefauver-Harris Amendments transformed drug regulation and the approval process in several respects. First, the Amendments required the FDA to review a new drug for both safety and effectiveness and specified that to demonstrate effectiveness manufacturers were required to submit data from “adequate and well-controlled investigations.” 21 U.S.C. § 355(d).

BRIEF HISTORY OF PROSTATE CANCER

12. Prostate cancer is the most common non-skin cancer in the United States and the third most common cancer worldwide. More than one million men in the United States

- have prostate cancer, with an estimated 232,000 new cases of prostate cancer diagnosed each year. More than 30,000 men die each year of the disease.
13. Prostate cancer is the third most common cancer in men, globally with half a million new cases each year, almost 10% of all cancers in men.
 14. One in six American men will be diagnosed with prostate cancer.
 15. A man is 35% more likely to develop prostate cancer than a woman is to develop breast cancer.
 16. In 2007, more than 234,000 American men will be diagnosed with prostate cancer. That's one new case every 2.25 minutes. In 2007, more than 27,000 American men will die from prostate cancer. That's one death every 19 minutes.
 17. Approximately 2 million American men currently have prostate cancer.
 18. A non-smoking man is more likely to develop prostate cancer than he is to develop lung/bronchus, colon, rectal, bladder, melanoma, lymphoma and kidney cancer combined.

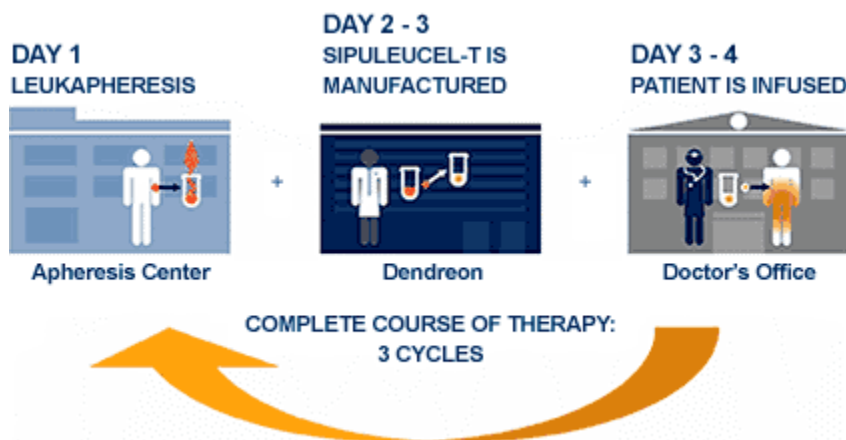
HISTORY OF PROVENGE

19. Provenge is manufactured by Dendreon Corporation.
20. Dendreon is at the forefront of introducing the first in a new class of active cellular immunotherapies (ACIs). The goal of active cellular immunotherapy is to turn the immune system "back on" to elicit a specific and long-lasting response against cancer.
21. Provenge is Dendreon's lead ACI candidate and is designed to treat asymptomatic, metastatic, androgen-independent prostate cancer.

22. The process uses the patient's naïve and untrained human immune system cells and through steps proprietary to Dendreon, trains those cells to re-engage the patients own immune system to fight prostate cancer.
23. The immune system is the complex group of organs and cells that defends the body against infections and other diseases. Cancer develops when cells in the body begin to grow out of control. Normal cells grow divide, and die. Instead of dying cancer cells continue to grow and form new abnormal cells. Cancer cells often travel to other parts of the body where they grow and replace normal tissue. This spreading process is called metastasis. When cancer spreads or metastasizes it is still named after the body part where it started. For example if prostate cancer spreads to the bones it is still prostate cancer, not bone cancer.
24. If approved, Provenge could fill a gap in the treatment continuum for the thousands of men with asymptomatic, metastatic androgen-independent prostate cancer. When first diagnosed with prostate cancer, most men have their prostate removed or irradiated as an initial treatment. After a period ranging from months to years prostate cancer will return in nearly all men who do not die of some other disease first. After this initial treatment failure, drugs are given to block the body's production of androgens (i.e. testosterone) as prostate cancer cells need androgens to grow. All men who do not die of some other cause first, progress to the third and final stage of prostate cancer, androgen-independent or hormone refractory prostate cancer. Androgen-independent or hormone-refractor are substantially interchangeable terms for prostate cancer cells that no longer respond to hormone

therapy. Provenge is intended for this patient population, a population that has already failed two different kinds of therapy.

25. The treatment: Antigen presenting cells (APCs) are obtained from the patient via leukapheresis a blood collection process that isolates a patient's white blood cells. The patients APCs are then transported to a cell-processing center where they are co-cultured with a recombinant fusion protein containing prostatic acid phosphatase (PAP). PAP is found on prostate cancer cells and serves as the therapeutic target for Provenge. The activated, antigen-loaded APCs (now Sipuleucel-T or Provenge) are then delivered to the physician's office (infusion site) for infusion into the patient. Provenge is then infused into the patient, where it can potentially stimulate an immune system response against prostate cancer cells. The infusion is a 30-60 minute process. The process is performed 3 times over the course of a six week period, upon which treatment is completed.



26. Dendreon has completed two Phase 3 clinical trials of Provenge for the treatment of metastatic androgen-independent (hormone refractory) prostate cancer. The results were published in the July 2006 issue of the Journal of Clinical Oncology. Prior to

- the initiation of these two Phase III trials, a Phase I and Phase II trial were completed. A third Phase III trial was completed in men who had only failed initial surgery. Two additional Phase II trials were completed in men who had failed surgery, one using Provenge alone and one using Provenge in combination with an FDA-approved anti-angiogenesis drug trade named Avastin.
27. The primary Phase III trial (D9901) demonstrated nominal statistical significance on a surrogate endpoint of time to disease progression (TTDP) at a p-value of $p=0.053$ after clerical errors were corrected. More importantly, the D9901 trial demonstrated a statistically and clinically significant advantage in survival ($p=0.01$) for patients. This survival benefit was subjected to significant secondary analyses to determine whether it was perhaps due to imbalances and chance. The company, medical experts and the FDA's own review team concluded the survival benefit was real.
 28. Data from the second Phase III trial (D9902), when pooled with D9901, continued to demonstrate clinically and statistically significant survival benefits for patients who received Provenge
 29. A fourth Phase III clinical trial is underway in hormone-refractory prostate cancer which will be completed in 2010.
 30. The FDA believed there was enough data from the phase I, II and III trials and based on that finding of sufficient data, the FDA indicated that they could immediately evaluate Provenge.
 31. Based on the established finding of the FDA that there was sufficient data for a decision, the FDA encouraged Dendreon to file a biologics license application (BLA).

32. The BLA was filed in December 2006 and the FDA granted fast track approval designation in January 2007. The date by which the FDA then had to make a decision was May 15, 2007 (the PDUFA date).
33. By law (Prescription Drug User Fee Act, or PDUFA) and according to funding regulations as well as in accordance with legal precedent, the FDA had to reach a decision on Provenge not later than the PDUFA date.
34. The FDA empanelled an advisory committee of medical experts and set the matter for committee review by the FDA's Center for Biologics Evaluation and Research (CBER), specifically CBER's Cellular Therapy and Gene Therapy (CTGT) division. CBER/CTGT previously had all the oncology drug reviews taken from them, except for review of cellular and gene therapies, and given to the Center for Drug Evaluation and Research (CDER), specifically a newly created sub-division of CR called the Office of Oncologic Drugs (OOD). This assignment of Provenge review to CBER/CTGT was consistent with a regulatory history for Provenge reaching back to the 1990's and was consistent with current FDA guidance for active cellular immunotherapies like Provenge.
35. Defendant Pazdur is the head of OOD, and the assignment of Provenge to CTGT made him angry and set off the course of events that can be explained only by calling it "political infighting" or "human nature" at a dysfunctional governmental organization.
36. OOD, being led by an apparently ambitious and power seeking individual, Defendant Dr. Richard Pazdur, who thought his division should have power over all oncology immunotherapies, now and forever, (and not CBER/CTGT) wanted to

assert its power within the agency (internal power struggle) and this was the start of the power grab by Defendant Pazdur, that left Provenge, and dying patients, as the disregarded victims.

37. CTGT Director Dr. Celia Witten determined the FDA required guidance from their standing CTGT Advisory Committee on whether to approve Provenge. Witten empanelled a group of world renowned and recognized immunotherapy experts, supplemented with representatives of patients, and two oncologists placed on the advisory panel by Defendant Pazdur. One of the oncologists was Defendant Howard Scher. The CTGT Advisory Committee meeting was held on March 29, 2007, to review Provenge.
38. FDA standards hold that drugs must be safe and must demonstrate “substantial evidence of efficacy” to be eligible for marketing approval. At the CTGT Advisory Committee meeting, a series of eight (8) questions were put to the panel for review. Question #7 asked if Provenge was considered safe. The CTGT Advisory Committee members, notably including Defendant Scher, voted 17-0 that Provenge was safe. Question #8 was amended by Witten and CBER Director Dr. Jesse Goodman to reflect the standard “substantial evidence of efficacy” criteria used by the FDA. Once the question was amended, the CTGT Advisory Committee members voted 13-4 that Provenge demonstrated “substantial evidence of efficacy”. This panel of experts, chosen by the FDA itself, therefore said that Provenge met the approval guidelines of safety and efficacy necessary for the FDA to approve the drug for marketing.
39. On May 9th (dubbed by the press as “Black Wednesday”), succumbing to political pressure from Defendant Pazdur and his co-conspirators, FDA commissioner Dr. von

- Eschenbach did decide not to approve Provenge for immediate use and instead requested more data that might not be available until 2010.
40. The head of the FDA, Defendant Dr. von Eschenbach was in support of CBER's recommendation to approve Provenge and did himself believe Provenge should be immediately approved for marketing and distribution, instead gave in to Defendant Pazdur's demands, after Defendant Pazdur executed a successful coup d'etat.
 41. By encouraging and accepting the BLA and placing it on Fast Track status the FDA had already decided it had sufficient data, which fact was confirmed at the advisory meeting by the FDA's own experts, yet the "Black Wednesday at the FDA", May 9th denial of immediate access and use of Provenge was supposedly issued because of a "lack of data" (the same data that the agency in January of 2007 said was sufficient for accelerated review).
 42. This "lack of data" statement was the created and false agency excuse to deny a safe and effective immunotherapy for dying cancer patients. The denial had nothing to do with science or for any other reason other than "politics" and "human nature".
 43. Prior to the coup d'etat by Defendant Pazdur, the FDA was set to issue an approval to Provenge and had even already written the letter of approval, which letter had to be hastily edited, following the coup by Defendant Pazdur, which letter is believed to still be part of the internal records at the FDA.
 44. The FDA refused to use good old fashioned common sense when it insisted on more evidence of efficacy for Provenge, when other drugs for far less serious conditions get approved without having nearly the outstanding safety and efficacy profile that was demonstrated by Provenge.

45. The FDA contradicted its own guidance by denying approval for Provenge.

Guidance published by the FDA in 2005 and 2006 set out that only survival was an adequate measure for approval of drugs for hormone-refractory prostate cancer. No surrogate endpoints are considered sufficient for approval for drugs treating this disease. This guidance was confirmed at a CDER/OOD sponsored Advisory Panel meeting on July 24th, 2007 when a drug for prostate cancer was rejected because it had not yet demonstrated a survival advantage, despite demonstrating a statistically significant advantage on a surrogate endpoint. Despite this, the FDA argued during the Provenge CTGT Advisory Committee meeting and in subsequent communications that the D9901 trial failed because it did not meet a surrogate endpoint.

46. The Dysfunction at the FDA includes a complete inability of the agency to be able to conduct a proper benefit vs. risk analysis when it comes to treatments for the terminally ill, which analysis could likely be better performed and determined by a ten year old child, who actually might have some degree of common sense.

47. Inappropriately and in an effort to improperly control the advisory panel decision regarding Provenge, Defendant Pazdur selected two of the advisory panel members.

48. The two members of the advisory committee hand picked by Defendant Pazdur, including Defendant Scher, voted “no” on the issue of substantial efficacy of Provenge. These two doctors also tried to lobby others at the meeting to vote against Provenge but their efforts failed.

49. In order to try and force these two doctors onto the advisory panel the FDA had to allow them on the committee, even knowing they had severe conflicts of interests.

Both members requested and received Conflict of interest (COI) waivers from the FDA.

50. In order to circumvent patients due process rights, in a completely arbitrary and capricious manner, and in order to evade FDA regulations, two of these doctors, that Defendant Pazdur absolutely knew would not be impartial and would even be assuredly negative towards Provenge, were pushed by Defendant Pazdur onto the committee despite their disclosed conflicts of interest.
51. Contrary to US law and regulations the Defendants even allowed the Conflict of Interest (COI) experts, to vote at the advisory meeting.
52. It is unknown for certain, at this time, whether and when some or all at the FDA knew that two of the panel members had additional undisclosed conflicts of interest as well as the disclosed conflicts, or that one of these COI experts was also advising and leaking information to hedge funds, stockbrokers and others on Wall Street (Defendant Howard Scher).
53. The FDA has since repeatedly been advised of and otherwise now knows of the undisclosed conflicts of interest and yet has done nothing in response to this discovery.
54. Despite the attacks and attempts of the two COI doctors to persuade the committee to see it as Defendant Pazdur and his COI conspirators wanted it seen, during the advisory meeting, the panel, following a 5 hour meeting, still voted 17-0 that Provenge is safe and 13-4 that there is substantial evidence of efficacy.

55. Two of the four no votes came from the two special FDA employees that completed Conflict of Interests Waivers (the COI experts). By FDA regulation these conflicted consultants should not have been able to even participate, much less to vote.
56. They should have been excluded, even irrespective of their UNDISCLOSED conflicts of interest, based on the already disclosed conflicts.
57. Obviously, the conflicted doctors were two of the four “no” votes on the issue of substantial evidence of efficacy.
58. One of these “no substantial evidence of efficacy” votes came from Defendant Dr. Howard Scher, who had both disclosed and undisclosed conflicts of interest which affected his decision with regards to Provenge, including payments to him by a direct competitor of Provenge.
59. Soon after Scher’s anti-Provenge actions, and in concert with other Defendants including Pazdur, a direct competitor to Provenge, (NOVACEA), announced a major funding deal with drug maker Schering Plough, wherein Schering Plough agreed to jointly fund and develop the competing prostate cancer drug for which none other than the very same Defendant Howard Scher, happened to be the lead investigator.
60. This major funding deal for Scher’s clinical trials would likely not have occurred if Provenge had been approved on May 15, 2007, as expected. The Novacea-Schering Plough deal was announced on May 29, 2007. The partnership of Defendant Schers Novacea, and Schering Plough, would likely not have occurred if not for the orchestrated and collective actions of Defendants wherein they did orchestrate the non-approval of Provenge, on May 9, 2007.
61. The Novacea- Schering Plough deal was worth over \$500 million dollars.

62. This is but one of what may have been as many as fifteen (15) conflicts of interests that Howard Scher had, when he worked so diligently to derail Provenge, at the FDA. In other words there were at least 15 reasons for Defendant Scher to be negative towards Provenge and cause in him a desire to see that Provenge was not approved on May 15, 2007, for reasons other than the best interest of prostate cancer patients and for reasons which had nothing to do with science or any other legitimate purpose.
63. Defendant Scher's actions, taken within the FDA to benefit himself and his own political and financial interests, was without regards to the fact that he was acting as an employee and advisor of the FDA (not to mention a doctor), and when the advisory meeting did not go as anticipated, the now conspiring Pazdur and Scher then further conspired and took action outside their roles as federal employees and did use federal resources to pursue their own political agendas even outside the FDA's internal process.
64. Defendant Richard Pazdur desired a "no" recommendation from the CTGT Advisory Panel Committee and his selection and allowance of several COI panelists that would vote and pressure others as he desired, was in a direct effort to effect the outcome and was a serious denial of the due process rights of patients.
65. Prior to the vote, Defendant Pazdur and his co-conspirators tried to change the statutory question regarding substantial evidence of efficacy from "substantial" evidence, to absolute certainty of evidence in an effort to obtain a "no" vote on Provenge (this basically was an attempt to change the scientific question from a question of whether the committee was 95% certain of the effectiveness of Provenge to whether they were 100% certain that Provenge is effective).

66. Absolute proof positive 100% certainty is unattainable and has not ever been the threshold for marketing even for relatively minor medical treatments, much less for oncology drugs intended to be used as third-line therapy on dying prostate cancer sufferers.
67. This attempted manipulation by Defendants was discovered at the last moment and corrected by others at the FDA.
68. In effect Defendants tried to rewrite the FDA regulations and/or manipulate them to suit their own desired agenda.
69. Dr. Scher and Dr. Pazdur were surprised when the predetermined outcome they sought did not in fact occur, despite their efforts to sabotage Provenge. It is believed that angry hedge funds and others to whom Dr. Scher was advising (which contributed to a shorting interest in the stock of approximately 40% of the outstanding shares, to the detriment of plaintiff investors who were long the stock), then pressured Defendants to take further actions.
70. It is believed that there were even requests (pressure) exerted upon Defendant Scher to influence him to change his advisory meeting position that Provenge was safe and take further post advisory meeting actions to derail Provenge approval, by challenging the safety profile, post AC meeting.
71. Defendant Scher acceded to this pressure and did then falsely purport that, because “he couldn’t sleep now”, that he felt the uncontrollable need to attack publicly, and internally within the FDA, Provenge, in a manner that was not the least bit honest or sincere.

72. Defendants Schers sudden change of heart on the safety issue was completely and totally insincere, as he did not really believe that there was any real issues with regards to the safety of Provenge.
73. Defendant Scher was pressured from sources within the FDA, and outside the FDA.
74. Defendant Scher even later admitted that he did not in fact even write the anti-Provenge letter, which was leaked to the press, and that others had actually written it for him.
75. Defendant Pazdur, upset by a perceived usurpation of his carefully cultivated power and wanting desperately to regain it as soon as possible, recruited others including Defendant Scher, to act inside and outside the agency to try to influence others in the FDA, as well as the public at large.
76. The result of that effort were three letters purportedly written by three doctors (including Defendant Scher's letter), which were all written in the same general pattern and were all prepared with the improper assistance of Federal employees with help from unknown members of the medical and financial community, which letters were written with the specific purpose that they be "leaked" to the to the press by Defendants.
77. Thee FDA was still all set to approve Provenge, despite the negative PR campaign mounted and maintained by Defendants and despite the other efforts to derail Provenge approval, so further action was needed by Defendant Pazdur to assure that the approval did not go forward as planned by the FDA.
78. Due to threatened political action and demonstration by Defendant Pazdur, aided by the outside actions of Defendant Scher and the others doctors, that might politically

damage the FDA, the head of the FDA, Dr. von Eschenbach, concerned over approaching funding bills that were to be voted on by Congress, succumbed to the Pazzdur threats and did announce non-approval on May 9th, several days prior to the BLA, PDUFA date of May 15, 2007.

79. The announcement and letter of the FDA that denied dying cancer patient's approval of the immunotherapy Provenge came on "Black Wednesday", a day that will go down in the annals of history, as one of the darkest of already dark days, for the prostate cancer patients that were waiting on this treatment.
80. "Black Wednesday" will also go down in history as the day the medical community came to suspect and even understand the dangers related to the current dysfunction at the FDA.
81. Two other doctors recruited by Defendants also co-conspired and helped leak the anti Provenge letters to the Press.
82. The "leaked letters" debacle was a conspiracy between Defendant Pazzdur and Defendant Scher who were aided and abetted by FDA employees as well as by Dr. Maha Hussain and Dr. Thomas Flemming, who are also sometime special government employees.
83. Some of the information in Defendant Scher's letter was disingenuous and even intentionally incorrect, but still Scher was in agreement to sign off on these letters and to pass the false information on directly or indirectly to the hedge funds, and investment companies including one in which he has a financial interest in and serves as a consultant, for his own political and financial gain in violation of federal regulations and contrary to FDA regulation. Defendant Scher also contradicted his

- own vote during the CTGT Advisory Committee meeting that Provenge was safe.
- Dr. Hussain did the same in a letter she purportedly penned to the FDA, which was also leaked to the press by Defendant Pazdur, or one of his staff.
84. It is believed that Defendant Pazdur did assist and did approve the use of FDA personnel to assist Defendant Scher in his public effort to derail the planned approval of Provenge as decided by the ODAC division of the FDA and which approval was to be signed off on by the head of the FDA Dr. von Eschenbach on May 15th 2007.
85. Defendant Scher violated federal laws and interfered with the rights of patients when he did not disclose all his conflicts of interest.
86. Defendant Scher purposefully failed to disclose all of his conflicts for fear he would not be allowed on the committee reviewing Provenge and therefore could not assist with efforts to keep Provenge from gaining approval.
87. Further “data” in phase three clinical trials is currently being collected with many patients being denied access to Provenge in the trials, and others who are in the trials are receiving a placebo (getting fake Provenge).
88. The men chosen randomly to get the placebo are still dying.
89. The men who cannot get into the trials are still dying.
90. When enough men have died, more data will be available for the FDA.

CLAIMS

91. The allegations in paragraph one through ninety above are incorporated as if fully rewritten herein.
92. The Defendants, acting at a minimum in an arbitrarily and capricious manner, did intentionally and/or with wanton and willful recklessness, disregard the rights of

- patients and did deny patients their right to live, in denial of the protections afforded them by the United States Constitution.
93. The FDA has no right to deny a terminal patient a safe immunotherapy for political, monetary, or any other reason, particularly when that patient's alternative is death.
 94. Previous Federal Courts have ruled that the FDA denying aid to terminally ill patients is completely irrational.
 95. Such FDA action serves no reasonable purpose and/or is not rationally related to a legitimate interest or goal of government.
 96. The Defendants failed to follow their own regulations.
 97. The Defendants have repeatedly failed to act with any consistency.
 98. The FDA has no authority to deny the use of Provenge by patients in the United States of America or anyone else that has the resources outside of the United States of America, to come here to obtain a proven safe immunotherapy treatment.
 99. A declaratory statement is needed to insure Dendreon Corporation that it can market and distribute Provenge to the terminally ill patients who need it, without fear of prosecution for saving the lives of these patients and also free from interference by Defendants or anyone else in government, in the best interests of patients.
 100. A declaratory statement is needed to insure that patients can receive insurance reimbursement for the cost of Provenge, just as if it was approved by the FDA.
 101. The Defendants have improperly interfered with the right of prostate cancer patients to live.
 102. The Defendants had no right to commit the tort of interfering with another persons attempt to provide aid to dying men.

103. It is unclear if the FDA even has authority (irrational or otherwise) to regulate immunotherapies as neither Congress, nor any other government authority has specifically given them the authority over immunotherapies of this kind, by statute, by regulation, or otherwise.
104. It is undisputed by the FDA that there is no addictive quality to Provenge, no potential for abuse, and it is safe. The FDA's own expert Advisory Committee, including Defendant Scher, voted 17-0 that the three Phase III trials, three Phase II trials, one Phase I trial, and blinded data from the fourth ongoing Phase III trial were sufficient to demonstrate Provenge is safe.
105. The FDA's own expert Advisory Committee voted 13-4 that the three Phase III trials, three Phase II trials, one Phase I trial, and blinded data from the fourth Phase III trial were sufficient to demonstrate "substantial efficacy", the FDA's own threshold for approval.
106. The immunotherapy is designed for each particular patient and is designed to stimulate one's own immune system to fight cancer.
107. Historically, there has never been an immunotherapy approved for use by the terminally ill by the FDA, and they may be without regulatory authority to deny dying patients such treatments.
108. There is no history or tradition with regards to immunotherapy regulation.
109. Provenge technically is no longer a "new" therapy (or even a drug,) and even our history for more quantifiable drug regulation is not so clear. Our Nation's history, legal traditions, and practices, in this regard, is that the government has not blocked access to new drugs throughout the greater part of our Nation's history. Only in recent

years has the government injected itself into consideration of the effectiveness of new drugs. The Food, Drug, and Cosmetic Act (“FDCA”), Pub.L. No. 75-717, §§ 1-902, **394 *473 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 et seq. (2000)), prohibits drug manufacturers from introducing any “new drug” into interstate commerce until manufacturers have applied for, and received, FDA approval. 21 U.S.C. § 355(a). ”A “new drug” is any substance covered by the FDCA not “generally recognized, among experts ... as safe and effective for use under the conditions prescribed ... in the labeling.” 21 U.S.C. § 321(p)(1). Before a new drug is eligible for full approval and marketing, the Secretary of the U.S. Department of Health and Human Services must find “substantial evidence that the drug will have the effect it purports or is represented to have.” 21 U.S.C. § 355(d). Exempted from this general ban are new drugs “intended solely for investigational use by experts” Id. § 355(i)(1). Amazingly, Provenge is already generally recognized by experts, even the FDA’s own experts, to be safe and effective.

110. There is no rational basis or legitimate government purpose in denying terminal patients a clearly safe immunotherapy even if the FDA is only 95% certain that it works.

111. Provenge also was determined by a near majority (almost all of the non-COI experts) to be effective. It is also believed that one of those previous “no” votes by one of only two non conflicted in the minority, may change their vote, if the panel was reconvened, as that advisory committee member was apparently confused by the change in the question as first presented (as attempted by the Pazdur conspirators).

112. One needs to look no further than the FDA's very own experts who have already recognized Provenge as being safe and effective to a degree of 95% certainty, to determine that Provenge is widely accepted by health professionals, and as such is absolutely and undeniably unique, in that it has attained the status of a widely accepted immunotherapy in the medical community even without approval by the FDA.
113. Because of wrongdoings, improper conduct, illegalities and inappropriate actions by Defendants, the Department of Health and Human Services has not, properly free from improper influence and bias; been provided a chance to properly approve Provenge. Because of the Defendants illegal and improper actions and inactions the immediate use of Provenge has been denied to the patients that need it.
114. The Department of Health and Human Services has not properly supervised the rogue actions of the Defendants.
115. The current trials are double blinded and many of the current participants are being given a placebo which denies them the benefits of Provenge now. The trials are double blinded by order of the FDA.
116. It is truly unconscionable that there are terminally ill men who could be helped but yet are receiving a placebo in trials.
117. The right of control over one's body has deep roots in the common law. The venerable commentator on the common law William Blackstone wrote that the right to "personal security" includes "a person's legal and uninterrupted enjoyment of his life, his limbs, his body, [and] his health," as well as "the preservation of a man's health from such practices as may prejudice or annoy it." WILLIAM

BLACKSTONE, 1 COMMENTARIES *125, *130. This right included the right to self-defense and the right to self-preservation. “For whatever is done by a man, to save either life or member, is looked upon as done upon the highest necessity and compulsion. As recognized throughout Anglo-American history and law, when a person is faced with death, necessity often warrants extraordinary measures not otherwise justified. Indeed the principle holds even when that action impinges upon the rights of others. (“This doctrine of necessity applies with special force to the preservation of human life”).

118. Such a bar puts the Defendants in the position of interfering with efforts of others that could save a terminally ill patient's life. Although the common law imposes no general duty to rescue or to preserve a life, it does create liability for interfering with such efforts. Section 326 of the Restatement (First) of Torts, first published in 1934.
119. The Defendants, assisted by others known and unknown have, without privilege to do so, intentionally prevented those dying from prostate cancer a chance to live as they have not given them available aid necessary to the patients bodily security and have interfered with others attempts to do so and thus are liable for the bodily harm caused to them by the absence of the aid of Provenge, which is a proven and known aid and which wants to be given to aid those persons by a third person (Dendreon).
120. While infrequently invoked, this common law rule is of venerable vintage.
121. Defendants did exceed the scope of their employment and took action for their own monetary and political gain to the detriment of patients and with a complete lack

- of concern for dying cancer patients and by taking other actions to ensure that prostate cancer sufferers would be denied access to Provenge.
122. For his own personal benefit and gain, Defendants did ignore the rights of patients and serve to commit the tort of interference with aid to dying patients.
123. Due to illegal manipulation by Defendant Pazdur, in conspiracy with others, the CTGT Advisory Committee could and should be ordered immediately reconvened with the same advisors less any advisors with any conflicts of interest.
124. The same expert panel if ordered reconvened by this court, without anyone with conflicts of interest participating, would very likely be 17-0 on safety and either 15-2 or better, on the issue of substantial efficacy. We are talking about a treatment that is to be used only on those dying of prostate cancer. The utter insanity and irrationality demonstrated by the FDA in this matter is inconceivable and would not be believed even in a fiction book yet it has occurred.
125. Provenge is not a treatment that should be judged the same as other types of treatments. It is a treatment for those that are terminally ill, who have no other treatment options.
126. Even if this court fashioned a general remedy that orders an immediate reconsideration of Provenge by the FDA and that the decision is not allowed to be arbitrary and capricious or based on politics, power, money, or undue influence of others then Provenge would be approved on FDA reconsideration.
127. The FDA and the Department of Health and Human services acted arbitrarily and capriciously in regards to the decision of the FDA to deny dying patients access to an immunotherapy that might save their lives and a declaratory judgment is proper.

128. Alternatively a declaratory judgment that unequivocally declares that Provenge is not a “new drug” and that it did not or at least no longer requires FDA approval to be marketed and distributed in the United States of America.
129. Provenge is not a narcotic and cannot be misused or over used.
130. There are thousands of experts in the field, including the 17 members of the FDA’s own advisory committee that can testify as to the safety and efficacy of Provenge and that it is an immunotherapy widely accepted by the medical community and thus not “new” as the word “new” is defined by federal regulation.
131. Provenge should be declared an immunotherapy that has cleared and otherwise achieved all reasonable, rational and commonsensical hurdles and may used and recognized for use by dying prostate cancer patients and thus it is irrational to allow a government agency to further control it and/or deny it to patients.
132. The FDA collectively (without fear of Defendant Pazdur) believes Provenge is safe and effective but its immediate use was denied by the FDA due to ulterior motives and due to improper and unlawful pressure and other acts of Defendant Pazdur and his co-conspirators.
133. Provenge should also be declared not to be “new” because it has been around for nearly a decade, and has completed Phase III, Phase II, Phase I and is well on its way through a fourth Phase III trial that was blinded by the FDA and as it is widely accepted as safe and effective by the medical community. It is not a new drug, rather it is an immunotherapy recognized by doctors including but not limited to Plaintiffs, oncologists, urologists, immunotherapists, biotech experts, and others in the medical community as safe and effective.

134. Doctors want Provenge for their patients NOW, patients want Provenge NOW, families of patients want Provenge for their family NOW. Plaintiffs want to help get it to the patients NOW.

135. If patients had the right to make their own informed choice after Provenge was explained to them from their Doctor, most all would choose Provenge over absolute imminent death and/or debilitating chemotherapy followed by death.

**PETITIONS AND ADVOCACY EFFORTS FOR PROVENGE ADVOCACY
PRIOR TO INVOLVING THIS COURT**

136. Plaintiff incorporates paragraphs one through one hundred thirty five above as if fully rewritten herein.

137. This case is absolutely without precedent in that there has never been such an incredible, irrational and unjustifiable denial of the rights of dying patients by such a dysfunctional agency.

138. The uproar and anger demonstrated by the public, doctors, experts, oncologists, urologists and others over the FDA denial of immediate access to a proven safe immunotherapy to doctors and their patients is unprecedented.

139. The medical community wants this treatment option now. Patients want it now. Any delay costs lives. There is not legitimate government interest in delaying its use.

140. Plaintiffs, joined by advocates and other Provenge supporters have faxed, e-mailed, sent correspondence to and called the FDA, congress, senators, justice departments (DOJ), SEC, and others and have tried every imaginable advocacy action to right the injustice that was the Black Wednesday denial of Provenge, but they have

been met with a complete lack of reason, justification, answers and a refusal of the FDA or any other governmental agency to be responsive. The Legislative and Executive branch of the federal government has been completely unresponsive and downright inept.

141. This court is the last hope of those dying NOW because the legislative and executive branches of government refuse to help the dying patients and are unable to function with any level of Democracy.

142. Plaintiffs, as well as numerous other Provenge supporters have faxed, e-mailed, signed and sent letters and petitions to the FDA and have called and written letters to the FDA, but have been met with incompetence and inaction.

143. Plaintiffs, as well as other Provenge/Patient Rights groups, supporters, and patient advocates have even recently run the advertisement attached hereto as “Exhibit A”, which call for reconsideration ran in the Washington Post on July 15th 2007, asking the federal government to reconsider its position on Provenge. It was again met with no response from the FDA, Department of Health and Human Services or any other government authority.

144. Plaintiffs have no real timely remedy other then this court.

145. On June 4th 2007, Plaintiffs and patient advocates for Provenge even met with FDA commissioner Andrew von Eschenbach requesting that he reconsider his decision to deny immediate approval for Provenge. Dr. von Eschenbach responded with “talk to CDER”, an internal political division of the FDA. (Note: The statement was indicative and was in reference to the interference by Defendant Pazdur since CBER, and not CDER, was assigned to review Provenge. If indeed CDER, and

specifically Defendant Pazdur's OOD was involved in the rejection of Provenge, then the FDA did not follow its own rules by not allowing CBER/CTGT to make the approval decisions). FDA commissioner Dr. von Eschenbach also specifically denied reconsideration of the Provenge matter when the Plaintiffs requested it. Dr. von Eschenbach, by agreeing to meet with the Plaintiffs herein, and discussing the matter with them, did effectively by listening and responding that there would be no reconsideration, placed the FDA stamp of approval on and did otherwise obviate, waive and make unnecessary further redundant requests by Plaintiffs for reconsideration of the matter. Dr. von Eschenbach essentially accepted a verbal petition to the FDA for reconsideration, which he then denied.

146. Dr. Von Eschelman will state that it was political pressure applied by Defendant Pazdur and/or CDER/OOD, Defendant Pazdur's pressure on FDA employees, combined with his own concerns over funding and other bills before Congress, which contributed to the agency decision to deny Provenge.

147. After von Eschelman's discussion with the advocates, CDER and CBER were contacted and they put the blame for the decision on the COI's (conflict of interest doctors on the advisory committee), yet nobody within the FDA will agree to amend the voting records to properly reflect the votes, after disqualifying the votes of the COI doctors that were not qualified to participate in the advisory meeting and/or to vote therein.

148. Many of the Plaintiffs herein signed a petition, which was also sent to the FDA requesting reconsideration. Again the FDA refused the petition.

149. Yet another petition, attached hereto as (“Exhibit B”) was recently filed by Plaintiffs asking the FDA to reconsider, and to date there has been no response.
150. Plaintiffs and other advocates have made tens of thousands of requests to the government to right the FDA injustice, on behalf of the patients.
151. The FDA itself has failed to take action responsive to the many thousands of requests they have received by Plaintiffs and others combined.
152. Other administrative remedies are meaningless and are essentially unavailable because there is no control of the FDA as it is government run amuck.
153. Other administrative remedies are illusionary and do not really exist beyond what has already occurred in this unusual and unprecedented case.
154. Agency dysfunction renders the petition process to be a complete useless waste of time and resource by those that are dying and do not have the luxury of time.
155. Additional administrative remedies are not available because of the condition of the patients who need Provenge. They are dying every day. Tomorrow another patient’s remedy will be exhausted by his own death.
156. Abigail Alliance, a patient advocacy group, also filed a petition on behalf of patients asking for earlier access to drugs such as Provenge for the terminally ill on June 11 2003, and they have yet to receive a response from the FDA.
157. Numerous other citizen petitions have been filed by groups like the Abigail Alliance, with the FDA, asking for similar relief and the FDA has been completely and repeatedly unresponsive. It is a waste of time, that dying patients do not have, to seek further redress by an out of control and dysfunctional FDA. The FDA has

- proven by their consistent and repeated non-responsiveness that the due process is
illusionary
158. The so called “due process” set up by the agency in order to try to make them
complaint (litigation) proof, is a farce and nothing more than a deprivation of the
Constitutional Due Process rights of the patients.
159. Repeatedly, over and over the FDA has proven that any petition effort is a
completely futile action.
160. Title 21 (citizen petitions) is unconstitutional both in general and as applied to
cases of this sort, where immediate action by the courts is required or people will die.
All and or portions of Title 21 were not reasonably written and narrowly tailored for a
legitimate governmental purpose and serves only to further destroy the due process
rights of patients. This is particularly true as applied to the facts of this particular
case.
161. If patients die waiting on what has historically been a complete lack of
responses from the FDA then they were deprived of any remedy at all.
162. It’s an absolute that the patients do not have the luxury of time.
163. The FDA is currently dysfunctional and the Department of Health and Human
Services is unable to control it.
164. Provenge is a treatment for the terminally ill and the same rules that apply to
other types treatments should not be used or be judged the same as other unnecessary
type of treatments. It is a treatment for those that are terminally ill who have no other
treatment options.

**REQUEST FOR EMERGENCY TEMPORARY AND PERMANENT
INJUNCTIVE RELIEF**

165. The Plaintiffs incorporate the above paragraphs one through one hundred sixty-four above as if completely written herein.
166. Irreparable and immediate harm will be caused and many terminally ill androgen independent cancer patients will die because they have been improperly denied access to the immunotherapy Provenge, which drug is **UNDENIABLY SAFE** (shockingly, the FDA must stipulate to this safety profile as did their panel in a 17-0 vote).
167. Because of the inappropriate actions taken within and outside the FDA, by Defendants, an immediate emergency injunctive order should issue that enjoins the FDA from blocking in any way the immediate marketing and distribution to Provenge to the patients, as they have no other reasonable treatment options.
168. The failure of this court to act on an emergency basis and correct the manifest injustice caused by the actions of the FDA and others who acted in concert and conspiracy with the FDA, including, could result in the deterioration of life and the deaths of as many as 60,000 terminally ill patients.
169. This extraordinary emergency injunctive action is proper because this is an extra ordinary case that is without any precedent within the history of this country.
170. The actions of the Defendants have placed a black mark on the integrity of our government and caused the medical community at large to lose what little faith that remained that the FDA can function as a legitimate and rational government entity.

171. Based upon the demands of personal dignity and autonomy, when human life depends upon medical decision making and the FDA not only acts arbitrarily and capriciously with regards to our fundamental right to chose to live, then this court can and should take immediate emergency action and enjoin the FDA from blocking the marketing and distribution of Provenge.
172. This court must take extraordinary action based on an extra ordinary set of circumstances that has occurred within our government
173. The FDA actions are without administrative precedent and are costing lives every day.
174. FDA actions in this regard are arbitrary, capricious and inconsistent as demonstrated on July 24, 2007, when an OOD Advisory Committee, controlled by Defendant Pazdur, rejected a different prostate cancer drug because there was no survival advantage shown, even though a surrogate endpoint was positive. Provenge was purportedly rejected because a surrogate endpoint was negative, despite showing a clinically and statistically significant survival advantage.
175. The intentional wanton, willful and malicious obstruction by the FDA, for monetary and political reasons which is estimated will cost the lives of 60,000 men is due to actions from those within the FDA who acted both within and outside the scope of their employment and were assisted by outside co-conspirators.
176. Provenge is an immunotherapy that is for use only on androgen independent prostate cancer sufferers that otherwise have a terminal diagnosis.
177. Provenge has passed muster from the FDA in several ways and an immediate injunction order should issue as injunctive relief is easily provable at an injunction

hearing based on the FDA's own internal evidence which indicates: Provenge was approved to conduct Phase One testing, then approved for Phases II testing and then approved for Phase III testing., then approved for another Phase III trial (which was double blinded by the FDA. That data was then recognized by the FDA as sufficient for fast track approval, approved by an FDA advisory panel but then denied only due to improper actions of Defendants. There is ongoing trials that are being conducted but an undeniably safe immunotherapy that has been requested for and by dying patients goes unused. This is an easily provable emergency.

178. Despite requests to the FDA and post non-approval disclosure of the undisclosed Scher conflicts to the FDA, the FDA still refuses to amend the voting records to remove Scher's "no" vote on the substantial efficacy question.
179. Even at the advisory meeting itself Defendant Pazdur tried to direct Dr. Hussain on how to orchestrate the hearing to initiate more anti Provenge discussion, which written notes are in the possession of Dr. Hussain.
180. The National Cancer Institute recently criticized the dysfunction at the FDA when they suggested that the manner in which the FDA evaluates treatments for the terminally ill are unreasonable and should change and have suggested that the new era of scientific discoveries cannot be judged by age old scientific notions.
181. A dozen experts including a former FDA Chief as well as Doctors from The National Cancer Institute can be available to testify at an emergency injunctive hearing and will state that the decision to deny approval to Provenge was arbitrary and capricious and not in the best interests of dying cancer patients. These experts (the injunctive relief request can be proven by Plaintiffs with hardly any more effort

then bringing in the CBER/CTGT's own employees and experts as they agree (Provenge should have been approved) can also testify that the FDA is an antiquated and dysfunctional agency not well equipped to be evaluating biologics, and that new standards must be used to evaluate treatments and that the agency has demonstrated an inability to use good old fashioned common sense, since Provenge is safe and has been proven substantially effective and that the safety versus benefit profile has to be considered in light of the condition of the dying patients and their lack of other options.

182. A third party, Dendreon, has offered aid to dying patients with no alternative and the Defendants have conspired to block that aid in violation of common law.

183. Provenge patients have no alternative treatment options and thus the Defendants must be enjoined from interfering with aid to them by third persons who want to provide that aid.

184. Provenge can save lives but politics, greed and "human nature" have instead combined so as to cause men to continue to die when they can be saved.

185. The refusal to approve Provenge means men will die sooner and with less quality of life than they would if they were given immediate access to Provenge.

186. Based on the FDA's own employees and experts and the Plaintiffs' additional lay and expert witnesses, there is a substantial likelihood that Plaintiffs will prevail on the merits of this action as the movant, including doctors and their patients, families of patients as well as past and future prostate cancer patients will suffer irreparable injury if an injunction is not granted. The issuance of a preliminary injunction would

not cause substantial harm to any other interested party and the public will be served by the issuance of the injunction.

187. This is an emergency as someone dies everyday of Prostate cancer.
188. Because the FDA's denial of Provenge has resulted in Dendreon Corporation having to suspend work on related immunotherapy treatments for ovarian cancer, breast cancer and other cancers, the effect of the blocking of the treatments is even more widespread and damaging to patients with different kinds of cancer than is generally known.
189. Defendants, including Dr. Scher and Dr. Pazdur were negligent in their treatment of prostate cancer patients.
190. Defendants Scher and Pazur are Doctors and thus owe patients a duty in their capacity as both Doctors and as government employees charged with watching out for the best interests of patients.
191. Defendants breached the duty owed all cancer patients.
192. Plaintiffs were damaged by the breach of duty by Plaintiffs.

WHEREFORE, Plaintiffs seek an emergency temporary and permanent injunctive order from the court, as well as declaratory judgment that the FDA did arbitrarily and capriciously deny dying and terminally ill patients access to a safe immunotherapy without due process of law, and in violation of their right to personal dignity and autonomy, being that prostate cancer patients have an absolute constitutional and common law right to fight for their lives by having access to an undeniably safe immunotherapy and further assert that the Defendants have violated the laws of the United States as well as Federal Regulations and

is acting dysfunctional and seek immediate emergency injunctive relief that does some or all or the following conjunctively or alternatively:

- A) Enjoin the FDA from denying the marketing and sale of Provenge to androgen-independent prostate cancer patients.
- B) In accordance with established United States Common Law, Plaintiffs seek to enjoin the Defendants from denying immediate access to Provenge and ask that all Defendants collectively and individually be restrained and ordered to cease and desist their interference with Dendreon's lawful attempts to provide aid to dying patients by marketing and distributing Provenge.
- C) A declaration that the FDA's failure to approve Provenge was due to the failure of the FDA to follow its own regulations combined with the improper actions taken by Dr. Howard Scher, and Dr Richard Pazdur that improperly corrupted the process and influenced the decision not to approve Provenge on May 15th 2007.
- D) A directive of the FDA to immediately approve Provenge and/or to reconvene the same CBER panel without the influence and voting of the COI panelists who were previously improperly permitted to participate and were influenced and controlled by improper duress by Defendant Pazdur.
- E) Issue an order to the FDA to amend its advisory panel voting records to invalidate the votes of the doctors who had conflicts of interest both disclosed and undisclosed.
- F) Order that Defendant Richard Pazdur and Howard Scher be enjoined and restrained from playing any part in a reconsideration of immediate approval of Provenge, privately or publicly and be further restrained from influencing others at the agency who want to do their job without fear of reprisal from them.
- G) Declare that due process was denied and the process was corrupted by Dr. Richard Pazdur and/or Howard Scher, which improper actions served to deny Plaintiffs right to due process of law and that the May 9th decision of the FDA was arbitrary and capricious.

- H) Enjoin the continuing denial of access to Provenge by the FDA for terminally ill members and prostate cancer patients in the United States of America as an individual must be free to decide for himself with the counsel of his doctor whether to assume any known or unknown risks of taking a medication that might provide their only real chance at prolonging their life.
- I) Declare that the FDA is without authority to deny immediate access to Provenge as it is no longer a “new drug” as statutorily defined, or that because of the unique nature of this case, that Provenge no longer needs approval to be marketed and distributed because it has attained the appropriate stature in the medical community to be marketed and distributed without further approval.
- J) Declare that the FDA cannot interfere with its marketing, sale and use, absent additional findings or tests results that indicate any further safety concerns.
- K) Declare that due process was denied the patients.
- L) That Defendants as doctors and as federal employees were negligent towards cancer patients.
- M) That the Defendants improperly denied available aid to dying patients and are liable for any injuries caused to them
- N) Any other relief this court deems appropriate under law or equity as well as costs of this action.

Respectfully submitted,

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EXHIBIT A

EXHIBIT B