

**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,

John Doe, a late stage prostate cancer
Patient who resides in Ohio
C/O CareToLive
6295 Emerald Parkway
Dublin, Ohio 43016

Plaintiff,

Case No. 2:07 CV 729

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.

FIRST AMENDED 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, Mike Leavitt in his official capacity, Richard Pazdur, in his capacity as an employee of the FDA and in his own individual capacity, and Howard Scher, in both his individual capacity and as a special government employee of the 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), 28 U.S.C. s 1343 and 1346, 42 U.S.C. § 1985 and 1986 as well as under the Administrative Procedures Act (APA), 5 U.S.C. 702 & 704, under the United States Common Law, and under the Fifth and Fourteenth Amendment Due Process and Equal Protection Clauses of the United States Constitution.

Claims against individual Defendants are alternatively brought pursuant to diversity of citizenship; Plaintiffs claim damages in excess of \$50,000.00 against individual defendants only for the specific actions that exceeded the scope of their employment.

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, member prostate cancer patients are living and dying in Ohio and families and doctors in Ohio want this treatment for their family, friends and patients.

THE PARTIES

3. The Plaintiffs are cancer patients individually, advocates, doctors seeking help for their patients, families seeking help for their loved ones, current, past and future prostate cancer patients, potential prostate cancer patients individually and through and as members of a not for profit corporation, CareToLive, whose 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 make informed decisions with their doctors and choose to live and enjoy a continued quality of life that access to an undeniably safe immunotherapy, Sipuleucel-T (hereinafter referred to under its marketing name of “Provenge”) may provide, and who otherwise seek to immediately enjoin the Defendants from denying, for even one more day, the distribution of Provenge to them. One doctor member of CareToLive has 12 patients awaiting Provenge. John Doe Plaintiff is one of several Ohio prostate cancer patients who may die before he can receive Provenge. His hastened death could occur as a result of the prostate cancer and the denial of due process by the FDA

and its co-conspirators and due to the continued intentional denial of due process despite the knowledge of Defendants wrongdoings, which will cause an action to arise for intentional wrongful death. Every man in this country has a one in six chance to get prostate cancer, Plaintiffs include them all.

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 ignored and continues to ignore the agency’s dysfunction.
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 the FDA Advisory Committee and applying improper pressure on Advisory Committee members and other FDA employees, and did participate in actively and purposely insuring the denial of due process during the Biologics License Application (hereinafter referred to as “BLA”) for Provenge filed by Dendreon Corporation, in an effort to achieve a predetermined outcome of his choosing.
7. Dr. Howard Scher is a special government employee of the FDA and acting in both his capacity as a temporary government employee and as an individual citizen 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 act intentionally with wanton and willful disregard in a manner that has callously deprived cancer patients access to 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 require drug manufacturers to receive affirmative FDA approval before marketing their 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.

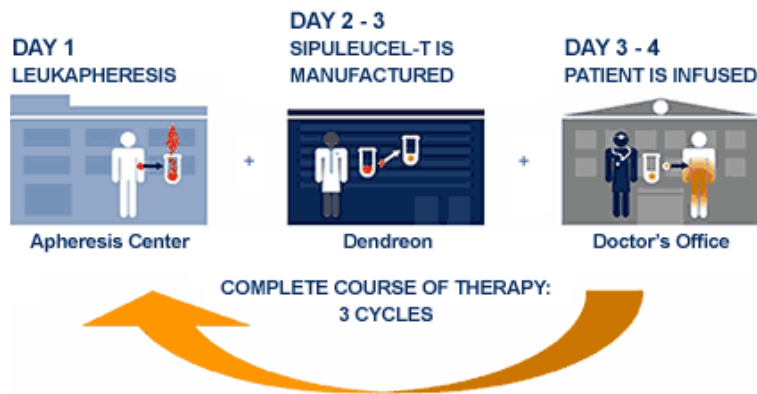
11. The Kefauver-Harris Amendments transformed drug regulation and the approval process in several respects. First, the Amendments required the FDA to review a new drug for both safety and effectiveness and specified that to demonstrate effectiveness manufacturers were required to submit data from “adequate and well-controlled investigations.” 21 U.S.C. § 355(d).
12. Because the FDA is charged with protecting the health and welfare of patients, it owes those patients that might benefit from a given treatment, particularly those that involve end stage diseases for which there are no viable or reasonable alternatives, that when that drug or treatment comes before them by way of a BLA, a due process that is not arbitrarily and capriciously applied to prostate cancer patients.

HISTORY OF PROVENGE

13. Provenge is manufactured by Dendreon Corporation.
14. 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.
15. Provenge is Dendreon’s lead ACI candidate and is designed to treat asymptomatic, metastatic, androgen-independent prostate cancer.

16. 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.
17. 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.
18. 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 and hormone-refractory are 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.

19. 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 patient's 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 to 60 minute process. The process is performed 3 times over the course of a six week period, upon which time the treatment is complete.



20. 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.

21. 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.
22. 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
23. A fourth Phase III clinical trial is underway in hormone-refractory prostate cancer which will be completed in 2010.
24. Dendreon has other immunotherapies it seeks to develop using a very similar technology as that used by Provenge, including Neuvence for breast cancer, which very recently had publication of its very promising Phase I data for the treatment of breast cancer published in the Clinical Journal of Oncology. Further development of Neuvence has been delayed for financial reasons, due in part to the improper decision of the FDA to deny Provenge.

THE FDA ADVISORY MEETING AND APPROVAL PROCESS
DUE PROCESS DENIED

25. The FDA believed there was enough data from the phase I, II and III trials of Provenge and based on that finding of sufficient data, the FDA indicated that they could immediately evaluate Provenge.

26. Based on the established finding of the FDA that there was *sufficient data for a decision*, the FDA encouraged Dendreon to file a BLA, an extremely expensive endeavor for a small biotechnology company.
27. 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).
28. 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.
29. The FDA empanelled an Advisory Committee of renowned 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 away from them and given over to the Center for Drug Evaluation and Research (CDER), specifically a newly created sub-division of CDER called the Office of Oncologic Drugs, except for the review of cellular and gene therapies which remained within CBER. The assignment of Provenge review to CBER/CTGT for review was consistent with current FDA guidance for active cellular immunotherapies like Provenge, and was also consistent with the regulatory history for Provenge within the FDA, reaching back into the 1990's.
30. Defendant Pazdur is the head of OOD, and the assignment of the Provenge BLA to CTGT angered him, which set off a chain of events that can only be explained by calling it "political infighting" or "human nature" at a dysfunctional governmental organization.

31. OOD, being lead by Defendant Dr. Richard Pazdur, believed his division should have power over all oncology immunotherapies, now and forever, (and not CBER/CTGT), and wanting to assert his/its power within the agency (internal power struggle) Defendant Pazdur began an overt and blatant power grab whose result was that Provenge and dying patients became the betrayed and discarded victims in the aftermath.
32. Defendant Pazdur has a history of this improper wielding of his power, much to the dismay and detriment of the cancer patients he is sworn to protect.
33. CTGT Director Dr. Celia Witten determined that the FDA required guidance from their standing CTGT Advisory Committee on whether to approve Provenge and empanelled a group of world renowned and recognized immunotherapy experts, supplemented with representatives of patients, who were joined by two oncologists that were placed on the Advisory Committee by Defendant Pazdur.
34. Defendant Pazdur purposely located two conflicted oncologists who he was sure for a variety of reasons would be anti-Provenge and he instructed them to try to derail the approval of Provenge. Defendant Pazdur was reasonably certain that with a little encouragement from him they would help him to encumber Provenge's approval, and thus deny Plaintiffs Due Process and Equal Protection of the law.
35. In Defendant Scher and Doctor Maha Hussain, Defendant Pazdur likely found two of the most conflicted oncologists in the country to sit in judgment of Provenge, and who would both assuredly continue his plot to lobby others at the FDA to vote for non approval.
36. At the behest of Defendant Pazdur, and for their own future political and monetary benefit, these two oncologists did everything they could think of to obstruct and impede the approval of Provenge. Following the advisory meeting, the two conflicted recruits of

Defendant Pazdur, asserted themselves vocally while the other thirteen (13) non conflicted experts conducted themselves professionally and appropriately. The non conflicted “yes” voters and the non conflicted “no” voters performed no post committee lobbying as was unlawfully done by the two oncologists.

37. One of these oncologists was Defendant Howard Scher, who actually believed that Provenge was safe and effective, yet decided for political and monetary reasons that his own interests were best served by doing Defendant Pazdur’s bidding instead of abiding by his Oath to do what was in the best interests of prostate cancer patients.
38. Defendant Scher is a Scientific Advisor and lead trial investigator for a competitor of Provenge called Novacea. Defendant Scher also has an interest in Proquest Investments, which stood to reap windfall profits if Provenge was not approved.
39. The CTGT Advisory Committee met to review Provenge on March 29, 2007.
40. FDA standards dictated by Congress hold that drugs must be safe and that there must be “substantial evidence of efficacy” in order to garner FDA marketing approval.
41. The CTGT Advisory Committee scrutinized a series of eight (8) questions which were put to the panel for their review.
42. Question #7 asked if Provenge was considered safe. The CTGT Advisory Committee members, notably including Defendant Scher, voted 17-0 that Provenge was safe. On Question #8, the FDA standard question on “efficacy” was incorrectly worded and subsequently amended by Dr. Witten and CBER Director Dr. Jesse Goodman to reflect the FDA standard of “substantial evidence of efficacy” as is the status quo under the FDA guidelines. Once the question was corrected, the CTGT Advisory Committee voted 13-4 that Provenge demonstrated “substantial evidence of efficacy”. This panel of experts

chosen by the FDA itself voted that Provenge met the FDA approval guidelines of safety and efficacy necessary for the FDA to approve the drug for marketing.

43. On May 9th, dubbed “Black Wednesday” by Dr. Mark Thornton in the Wall Street Journal (on May 14, 2007), succumbing to political pressure from Defendant Pazdur and his co-conspirators, FDA Commissioner Dr. von Eschenbach decided not to approve Provenge for immediate use and instead issued a Complete Response Letter requesting more data which might not be available until 2010.
44. FDA Commissioner Defendant Dr. von Eschenbach was in support of CBER’s recommendation to approve Provenge and did himself believe that Provenge should be approved for immediate marketing and distribution, but instead of approving it he gave in to Defendant Pazdur’s demands after Defendant Pazdur threatened a political demonstration that could jeopardize pending FDA funding and other legislation that Dr von Eschenbach as the Commissioner of the FDA, needed passed by Congress.
45. By encouraging and accepting the BLA for review and placing it on Fast Track status, the FDA had already determined that it had sufficient data, a fact which was confirmed by the Advisory Committee, yet the issuance of the Complete Response Letter denying the immediate distribution of Provenge was supposedly issued due to a “lack of data”. This was the very same data on Provenge that Dendreon shared with the FDA in January of 2007 when it was told by the FDA that the data was sufficient to file a BLA for accelerated review, resulting in Dendreon expending enormous amounts of money and manpower in order to do so.
46. This concocted “lack of data” statement was the falsely created agency’s excuse to deny Provenge, an immunotherapy voted safe and effective, from being made available to

dying prostate cancer patients. The denial had nothing to do with science or any other reasons than “politics” and “human nature”.

47. Prior to the coup by Defendant Pazdur the FDA was all set to issue a conditional approval letter to Provenge on May 15, 2007, and an approval letter had even actually been written which had to be hastily edited following the successful coup by Defendant Pazdur to instead reflect the conditional response and the delay in Provenge’s approval. The original approval letter is believed to still be among the internal records at the FDA.
48. The FDA contradicted its own guidance by denying approval for Provenge. Guidance published by the FDA itself in 2005 and 2006 stated that only survival is an adequate measure for approval of drugs for hormone-refractory prostate cancer and that no surrogate endpoints are considered sufficient for approval for drugs treating this disease. This guidance was confirmed at a CDER/OOD sponsored Advisory Committee meeting on July 24th, 2007 when a drug for prostate cancer was rejected because it had not yet demonstrated a survival advantage even though it demonstrated a statistically significant advantage on a surrogate endpoint. Despite this blatant contradiction, 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.
49. Provenge had met the threshold of survival, previously agreed upon by the FDA as the single best measure of effectiveness for cancer treatments such as immunotherapies.
50. In order to sabotage the Provenge approval process and ensure the denial of due process, Defendant Pazdur recruited the two “no” voters in his effort to “stack the deck”, and pressured others to allow these two doctors onto the Advisory Committee, even knowing

that they had excessive conflicts of interests which should have disqualified them from voting, no less from serving.

51. Contrary to US law and regulations, the Defendants not only allowed these two doctors to serve on the committee and deliberate with their Conflicts of Interest (COI's), but they were also given the right to vote on the fate of the Provenge BLA in direct contradiction to US Laws and Regulations.
52. According to Proquest Investments, Defendant Scher is a Proquest Executive and member of the Board of Directors. This Investment Firm reaps millions of dollars investing in prostate cancer companies based on advice from Doctors such as Defendant Scher, and Proquest's funds own stock in direct competitors to Provenge, including Novacea which recently received \$440 million dollars following the orchestrated non approval of Provenge. Dr. Scher is also a paid Scientific Advisor for Novacea.
53. It is undeniable that Provenge did not receive due process due to the wrongful actions of the Defendants yet the FDA continues to compound their error by failing to take reasonable and timely remedial action to right this wrong and reconsider the BLA for Provenge, this time with proper procedural safeguards in place. Such an uncaring stance invites the question of whether the future deaths of Plaintiff members are the result of intentional government misconduct, since all of these misdeeds have repeatedly been brought to the FDA's attention, yet no attempts have been made whatsoever to remedy the situation.
54. It is undeniable that the FDA is now aware of the undisclosed conflicts of the two most activist Committee members, and that Defendant Pazdur's plot assured Provenge and patients denial of due process.

55. Since that time an FDA employee has acknowledged that the two vocal COI doctors had an influence on the FDA decision to not approve Provenge, yet knowing all this they still refuse to correct the situation (e-mail from Patricia Healey).
56. Every day forward since the FDA became aware of the undisclosed COI's by the Doctors brought in to sabotage the Provenge BLA, and that no corrective action is taken, is yet another due process denial to terminal patients and their families, and every additional day of due process violation costs as many as 80 additional lives.
57. Obviously the conflicted doctors were two of the four "no" votes on the issue of substantial evidence of efficacy.
58. Soon after Defendant Scher's anti-Provenge actions, and in concert with other Defendants including Defendant Pazdur, Novacea, a direct competitor to Provenge, announced a major funding deal with drug maker Schering Plough, wherein Schering Plough agreed to jointly fund and develop a competing prostate cancer drug for which none other than the very same Howard Scher so happened to be the lead investigator for, and which one of Scher's employers, Proquest Investments, owned stock in.
59. This major funding deal for Defendant Scher's clinical trials would likely not have occurred if Provenge had been approved on May 15, 2007 as expected. This Novacea-Schering Plough \$440 million dollar deal was announced on May 29, 2007 and would likely not have occurred at all if not for the orchestrated and collective actions of the Defendants wherein they did contrive the non-approval of Provenge on May 9, 2007.
60. 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 obstruct Provenge's approval at the FDA. In other words there may have been 15 reasons for Defendant Scher to be negative

towards Provenge and to cause in him a desire to see that Provenge was not approved on May 15 (Attached as “Exhibit A”, is the list of currently collected conflicts of Defendant Scher at the time he conspired to obtain non-approval of Provenge).

61. Defendant Scher agreed to conspire with Defendant Pazdur, the single most important person to placate at the FDA for reasons known and unknown, which helped motivate Defendant Scher to make false claims and perform unlawful wanton and willful actions.
62. Defendant Richard Pazdur’s hunger for a “no” recommendation from the CTGT Advisory Committee, including his selection of two severely conflicted panelists who would vote “no” on efficacy, along with pressuring others to negatively impact the outcome, was a very serious and intentional denial of the due process rights of patients.
63. Prior to the vote Defendant Pazdur and his co-conspirators changed the statutory question regarding efficacy from “substantial evidence” to “absolute certainty” of efficacy, in an effort to obtain a “no” vote on Provenge, and in an attempt to subvert the scientific question and divert the scientific community from the mandated question of whether the committee is 95% certain of the effectiveness of Provenge to whether they are 100% certain that Provenge is effective, and to trick them into denying the Provenge BLA.
64. Absolute proof positive 100% certainty is unattainable and has not ever been, nor will it ever be, the threshold for marketing, even for relatively minor medical treatments, much less for oncology drugs intended as third-line therapy for men dying from prostate cancer.
65. This attempted manipulation by the Defendants was discovered and promptly corrected by the FDA’s Dr. Witten and Dr. Goodman, during the voting.

66. The Defendants rewrote and distorted the FDA regulations by altering the efficacy question in an attempt to deceive other Advisory Committee members to cast their votes negatively, in order to further their own nefarious agenda of non approval for Provenge.
67. Dr. Scher and Dr. Pazdur were very upset when the negative outcome they sought did not in fact occur despite their best efforts to sabotage Provenge. It is believed that Investment Funds and others whom Dr. Scher was advising either directly or indirectly, helped contribute to a short interest in the stock of approximately 40% of the outstanding shares, (to the detriment of some plaintiffs who were long the stock), and that Defendant Scher was pressured to take further actions to undermine the approval of Provenge. It is believed that requests (pressure) were made for Defendant Scher to change his position that Provenge is safe, even after the Advisory Committee was over and the votes all tallied, and completely outside the scope of his employment at the FDA, and he now attempted to obstruct Provenge's approval by challenging its safety profile for the first time, AFTER the advisory meeting.
68. Defendant Scher acceded to this pressure and did then falsely purport in writing that he felt the uncontrollable need to attack Provenge, both publicly and internally within the FDA, in a manner that was not in the least bit honest or sincere, and that this was after his employment as a special government employee as to the Provenge BLA was over.
69. Defendant Scher's sudden change of heart on the safety issue was completely and totally insincere, as he himself did not really believe that there were any real issues with regards to the safety of Provenge. Furthermore, at a symposium sponsored by Provenge competitor Novacea, Dr. Scher was quoted as saying, "It may be time we focus less on statistical significance alone and more on patient benefit," proving that when it came to

Novacea and his own financial interests that Defendant Scher applies a different set of standards. This statement was made on February 26, 2007, the exact same day Defendant Scher signed his Provenge BLA Conflict of Interest Waiver.

70. An anti-Provenge letter signed by Defendant Scher was “leaked” to the press; however Defendant Scher was overheard to admit that he did not in fact write the anti-Provenge letter, and that others had actually written it for him.
71. Defendant Pazdur, upset by a perceived usurpation of his carefully cultivated power, and wanting to regain control, recruited Defendant Scher and others to act inside and outside the agency to try to influence others to deny the approval of Provenge.
72. The results 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 and illegal assistance of Federal employees, with help from undisclosed members of the medical, as well as financial community. These letters were written with the specific purpose that they be “leaked” to the press by Defendants.
73. It is believed that Defendant Pazdur organized this plan of attack and recruited and illegally used FDA employees at meeting, post Advisory Committee, to assist him in his private quest to become a one man wrecking crew to the Provenge BLA, in part to fulfill his promise that he had stated that no new cancer treatment would ever be approved if it did not go through his CDER division at the FDA. Pazdur requested the letter writing campaign and designed the method for “leaking” them to the press. He also unlawfully pressured other FDA employees and advisors to aid and abet him.
74. Defendant Pazdur threatened political action if Provenge were approved and he threatened to organize a public demonstration at the FDA on the eve of an expected vote

by Congress concerning FDA funding and other legislation that would directly impact the FDA, that might politically and economically damage and/or shut down certain programs at the FDA which were important to the Commissioner of the FDA, Dr. von Eschenbach.

75. Dr. von Eschenbach, concerned about the funding bills that were to be voted on by Congress, was forced to succumb to the Pazdur threats and finally did announce publicly non-approval on May 9th, several days prior to the BLA PDUFA date of May 15, 2007.
76. The announcement of the Complete Response letter from the FDA that denied dying cancer patients 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 are awaiting this revolutionary benign and potentially life extending treatment.
77. The “leaked” letters debacle was a conspiracy between Defendant Pazdur and Defendant Scher, who were aided and abetted by FDA clerical employees in addition to Dr. Maha Hussain and Dr. Thomas Fleming, outside of the scope of their employment.
78. Some information in Defendant Scher’s letter was disingenuous and intentionally inaccurate, but Scher agreed to pass this false information on, including directly and indirectly to the investment community for his own political and financial gain in violation of Federal Law and contrary to FDA regulations.
79. Defendant Scher’s “leaked” letter also contradicted his own vote during the CTGT Advisory Committee meeting that Provenge is 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 by one of his staff at his direction.

80. It is believed that Defendant Pazdur did assist and unlawfully approve the use of FDA personnel to assist Defendant Scher in his effort to obstruct the planned approval of Provenge, and that he plotted with certain members of the ODAC division of the FDA to arrest the Provenge approval that Commissioner von Eschenbach was planning on signing on May 15, 2007.
81. Further “data” from a third phase 3 clinical trial is currently being collected with many patients being denied access to the trials, and many in the trials receiving only placebo.
82. The men chosen randomly to get the placebo are still dying.
83. The men who cannot get into the trials are still dying.
84. When enough men have died, more data will be available to the FDA. The better Provenge works, the longer men will live during the trials, and the greater the number of men outside the trials that will die waiting for their right to access Provenge.
85. Provenge would be prescribed by Doctors in accordance with State regulations on control of prescriptions. Ohio law does not allow prescriptions by state licensed doctors until it is approved by the FDA, and thus state action denies the ultimate use of Provenge.

PETITIONS AND ADVOCACY EFFORTS FOR PROVENGE
PRIOR TO INVOLVING THIS COURT

86. Plaintiff incorporates paragraphs one through eighty five above as if fully rewritten herein. 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.
87. The uproar and anger demonstrated by the public, doctors, experts, oncologists, urologists, scientists, patients and their families, and others over the FDA’s denial of

immediate access to a proven safe immunotherapy to doctors and their patients is unprecedented.

88. The medical community wants this treatment option now. Patients want it now. Any delay costs lives. There is no legitimate government interest in delaying its use after it was found safe and effective by the FDA experts. Plaintiffs, joined by advocates and other Provenge supporters have faxed, e-mailed, and sent thousands upon thousands of letters and other correspondence to including calls to the FDA, Congress, Senators, Justice Departments (DOJ), SEC, and others and have tried every imaginable advocacy action to right the injustice that began with the “Black Wednesday” denial of Provenge, yet 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 to them. Despite the efforts of CareToLive and other advocacy groups the Legislative and Executive branch of the Federal Government have been completely unresponsive to date and the FDA refuses to correct their due process mistakes leaving this court as the last alternative.

89. Plaintiffs, as well as other Provenge/Patient Rights groups, supporters, and patient advocates have recently run an advertisement attached hereto as “Exhibit B”, which ran in the Washington Post on July 15th 2007 and called for reconsideration of the FDA decision on Provenge,. It was again met with no response from the FDA, Department of Health and Human Services or any other governmental authority.

90. Plaintiffs and advocates staged rallies In Chicago and Washington DC and are participating in another rally on September 18th 2007 in Washington DC to get the attention of the Government.

91. Considering the dysfunction and prior lack of due process provided to Plaintiffs the first time around, it is fundamentally unfair and completely unrealistic to ask them to wait for any period of time so that the FDA may continue to deny them their due process rights a second time around. Patients and advocates cries have fallen on deaf ears.
92. Compliance with Title 21 in this case is futile.
93. The FDA failed to follow the rules of Title 21 when it docketed the Plaintiffs pending petition and thus has already denied proper due process during the petition phase.
94. On June 4th 2007, Plaintiffs and patient advocates for Provenge met with FDA commissioner Andrew von Eschenbach, requesting that he reconsider his decision to deny immediate approval for Provenge. FDA commissioner Dr. von Eschenbach specifically denied reconsideration of the Provenge matter when the Advocates, who share common members as CareToLive, requested it. Dr. von Eschenbach, by agreeing to meet with the Plaintiffs herein, and discussing the matter with them, did effectively by listening and then 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 summarily denied.
95. After von Eschenbach'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 who were not qualified to participate on the Advisory Panel in the first place, no less to vote therein.

96. Many of the Plaintiffs herein signed a petition, which was also sent to the FDA requesting reconsideration in June 2007. Again the FDA denied the petition.
97. Yet another petition, attached hereto as (“Exhibit C”) was recently filed by Plaintiffs asking the FDA to reconsider, and to date there has been no meaningful response.
98. Plaintiffs and other advocates have made thousands upon thousands of requests to the Government to right the FDA injustice on behalf of the patients.
99. The FDA itself has failed to take action responsive to the many thousands of requests they have received by Plaintiffs and others combined.
100. Other administrative remedies are meaningless and are essentially unavailable since there are no controls in place at the FDA and it fits the description of government run amuck.
101. Other administrative remedies are illusionary and do not really exist beyond what has already occurred in this unusual and unprecedented case, and as this case is extremely time sensitive as men are dying every day without other options, as they are being denied a safe and potentially effective therapy that Dendreon is more than ready to provide.
102. Agency dysfunction renders the petition process to be a completely useless waste of time and resources by those that are dying and do not have the luxury of time.
103. 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. In six months another 15,000 patients will have died waiting for justice and reform at the FDA.
104. Abigail Alliance, a patient advocacy group, also filed a petition on behalf of patients asking for earlier access to cancer drugs such as Provenge for the terminally ill on June 11, 2003, and they have yet to receive a response from the FDA. Numerous other citizen

petitions have been filed by groups like the Abigail Alliance with the FDA, asking for similar relief as that of the Plaintiffs, yet the FDA has been completely and repeatedly unresponsive. It is a waste of time that dying patients do not have to seek further redress from an out of control and dysfunctional FDA. The FDA has proven by their consistent and repeated non-responsiveness that their due process is illusionary.

105. The so called “due process” that is set up by the agency is in reality just a further deprivation of the Constitutional Due Process rights of the patients.
106. Repeatedly, the FDA has proven that any petition effort is a completely futile action.
107. Title 21 (citizen petitions) is unconstitutional both in general but particularly 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 serve only to further destroy the due process rights of patients. This is particularly true as applied to the facts of this case.
108. Provenge is a treatment for the terminally ill and the same rules that apply to other types of treatments should not be used or be judged the same as other unnecessary type of treatments. It is a safe and potentially effective treatment for those that are terminally ill and who have no other treatment options (making the denial unprecedented).
109. The futility exception also applies to negate the requirement of further pursuit of this matter directly with the FDA.

COUNT I

CONSTITUTIONAL CLAIMS
DENIAL OF CONSTITUTIONAL RIGHT TO DUE PROCESS
AND EQUAL PROTECTION OF THE LAW

- A. Paragraphs one through one hundred and nine are incorporated by reference into each count set forth herein.
- B. By their actions all the Defendants violated the Constitutional Rights of the Plaintiffs when they denied them their due process and equal protection of law as guaranteed them under the US Constitution and by denying them the proper due process of law did improperly infringe upon several of their constitutionally afforded protections.
- C. The Due Process Clause of the Fifth Amendment to the United States Constitution provides that “no person shall be ... deprived of life, liberty, or property, without due process of law.” U.S. CONST. AMEND. V. The Supreme Court has held that the Clause “guarantees more than fair process” and accords substantive protection to the rights it guarantees.
- D. When the FDA, an agency of the Federal Government, which is charged with protecting the health and welfare of patients, decides to take government action with regards to the health of patients and in particular take action with regards to a potential life saving immunotherapy when there is no viable treatment option, they must give due process to the patients when the patient’s life or death may hinge upon their right to that immunotherapy, and is affected by any action or non action of the FDA.
- E. Because of the fundamental and age old rights of Plaintiffs to privacy, dignity, autonomy, self defense, to protect their own life, to live, to not to be denied aid by a third party or have their aid and rescue improperly interfered with, and considering the

stated purpose of the FDA to protect them, they have a due process right to a fair process, meaning one that is not arbitrary and capricious when a decision regarding their health is being made for them (rather than by them and their doctor) by a government agency with regards to a potential life saving treatment for terminal patients, and no Government agency has the authority to deny them or terminate their due process rights. Due Process was denied and equal protection of the law was denied when individuals Andrew von Eschenbach, Richard Pazdur and Howard Scher conspired to ignore FDA regulations as well as the mandates of Congress.

- F. The fundamental rights of Plaintiffs herein for which due process and equal protection is required include:

The Right to Preserve our Life (The Right to Self Preservation)

The Right to Privacy

The Right to Personal Dignity and Autonomy.

The Right to Self Defense.

The Right not to have interference with the attempted aid by others.

A Right of control over one's body.

Rights implicit in the concept of ordered liberty.

Life, Liberty and the Pursuit of Happiness.

- G. Barring a terminally ill patient from the use of a potentially life-saving treatment impinges on their right of self-preservation. At the very least such action cannot be taken without giving the dying patients due process of law. Due Process of law cannot be found when a Government agency fails to follow its own regulations, and has no oversight controls in place, and then ignores the specific recommendations of Congress.

- H. The Defendant Andrew von Eschenbach and the co-conspirators Defendant Pazdur and Defendant Scher acted arbitrarily and capriciously and acted unlawfully so as to completely deny any semblance of due process to plaintiffs.
- I. The failure of Dr. von Eschenbach to make his decision based on science versus other arbitrary and capricious reasons was a total denial of due process and equal protection.
- J. These rights that were intentionally violated by Dr. von Eschenbach, Dr. Pazdur and Dr. Scher were known by them, as they are long recognized rights throughout the history of America. 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.
- K. The rights of the Plaintiffs in this case are “so rooted in the traditions and conscience of our people” so as to be ranked as fundamental, and as immunities implicit in the concept of ordered liberty.
- L. These rights include 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 infringes upon the rights of others. (“This doctrine of necessity applies with special force to the preservation of human life”). In that Provenge is extraordinary in

its potential ability to help these men with no other treatment options, while being safe at the same time (unlike chemotherapy), it begs to be approved

COUNT II

42 U.S.C. SECTION 1985 AND 1986 CLAIMS

- M. Plaintiff AIPC Patients are all men, they are mostly elderly men, and African Americans are disproportionately affected by AIPC.
- N. Defendants von Eschenbach, Pazdur and Scher conspired to cause injury and deny equal protection of law to this discriminated against group of people with the intent to harm this classification of persons for their own benefit.
- O. This class of elderly men with AIPC, are a group that has been long discriminated against because they are largely a group that has difficulty because of advanced age and a lack of effective patient advocacy in this area, to fight for their own rights. The group of AIPC men are being treated differently and not equally as many other groups of patients, such as AIDS patients. Proposed treatments are judged more stringently than other patient groups due to a lack of accountability at the FDA when it comes to prostate cancer patients. The lack of being a threat also derives because some large advocates that should be helping prostate cancer patients are instead working closely with Howard Scher and Proquest Investments and are financially invested against the success of any treatment, other than ones they are invested in, for reasons of monetary gain and grandeur and this conspiracy regards this elderly population is to Defendants an easily expendable group, subjecting them to the abuse of this detached agency.

- P. The denial of equal protection that occurred due to the conspiracy between Dr. von Eschenbach, Dr. Scher and Dr. Pazdur against aged AIPC patients is discriminatory to African Americans, the elderly and to the all male patient group.
- Q. At minimum, substantive due process protects the general right of an individual to be free from the abuse of governmental power. If the deprivation of interest in a group stems from an abuse of governmental power and of constitutional stature and it is undertaken for an improper motive and by means that are pretextual, arbitrary and capricious, and without any rational basis, then Plaintiffs have a right to relief.
- R. The Defendants engaged in a civil conspiracy between two or more people to injure another individual by unlawful action (Plaintiffs and all prostate cancer patients).
- S. A single plot existed, the alleged co-conspirators shared in the general conspiratorial objective, and an overt act was committed in furtherance of the conspiracy that caused injury to Plaintiffs.
- T. Defendants Pazdur and Scher had the common objective to obtain a denial or non approval of the BLA for Provenge even though they knew that the decision would hurt all prostate cancer sufferers.

COUNT III

VIOLATION OF CONSTITUTIONAL TORTS/INTERFERENCE WITH AID **INTENTIONAL CONSTITUTIONAL TORTS AS TO** **THE INDIVIDUAL DEFENDANTS**

- U. The individual Defendants Dr. Scher and Dr. Pazdur, exceeding the scope of their employment, as the Advisory Committee was over and the process seemingly completed, did conspire against patient interests and did intentionally interfere with the rescue efforts of third parties that could save a terminally ill patient's life. Although the

common law imposes no general duty to rescue or preserve a life, it does create liability for interfering with such efforts. Section 326 of the Restatement (First) of Torts, first published in 1934, explained that one who without a privilege to do so, intentionally prevents a third person from giving to another aid necessary to his bodily security, is liable for bodily harm caused to the other by the absence of aid which he has prevented the third person from giving. While infrequently invoked, this common law rule is of venerable vintage.

- V. This gross negligence which triggers a constitutional violation is synonymous at the very least with the idea of wantonness; conduct of a government official which conduct in this matter was outrageous conduct or conduct indicating arbitrary use of government power.
- W. The intentional interference of aid by a third party and deprivation of right to life was the result of an abuse of governmental power sufficient to raise an ordinary tort to the stature of a constitutional violation. Defendants Pazdur and Scher are liable for intentional torts against the Plaintiffs.
- X. The action of Defendant Scher and Defendant Pazdur as individuals was intentional and done with purpose to deny Provenge to patients who desperately need it, and was done to suit their own personal purposes and with such total disregard to the rights of patients that is so utterly outrageous that the acts could be stated to have even have been done with premeditated constitutional malice. At minimum their conduct was wanton and willful conduct that served to deny Plaintiffs their right to life and deny their right to be provided with a potentially life saving immunotherapy.

Y. Intentional or wantonly reckless torts rise to the level of constitutional torts and are exempt from the FTCA. With wanton and willful disregard to the rights of the Plaintiffs, the Defendants interfered with a third party's (Dendreon Corporation) right to provide aid to terminal cancer patients. This action was intentional or wanton and willful and will result in the early death of some members of the Plaintiff group.

COUNT IV

WRONGFUL DEATH UNDER OHIO WRONGFUL DEATH STATUTE AGAINST INDIVIDUAL DEFENDANTS

Z. John Doe Plaintiff is an Ohio late stage prostate cancer patient, and his family members, who may soon die due to the intentional torts of the individual Defendants and if FDA continues its denial of due process, despite their knowledge that due process was denied in the consideration of the Provenge BLA, and this ongoing FDA denial of due process, combined with the previous unlawful acts, and outside the scope of the employment actions of Defendant Pazdur and Scher, who served to insure the wrongful death of John Doe Plaintiff, whose death would not have occurred if not for the ongoing acts of the FDA and the prior acts of Defendant Pazdur and Scher. The continued due process denial in the face of the fact that the FDA now knows that Provenge was denied due process is simply shocking to the conscience. This matter is unprecedented in that there may never have been a case where a clear and ongoing Constitutional violation will lead to certain death and yet the violation is not attempted to be cured by the Defendants.

AA. This court can and should exercise pendant jurisdiction over the Ohio wrongful death action (intentional) as justice compels, which will be more fully identified upon the

death of the first Ohio prostate cancer patient who is a member of CareToLive and whose death could have been avoided and still could be avoided if the FDA did the right thing to correct this incredible injustice.

- BB. After the advisory meeting the further actions taken by Pazdur and Scher for their own self interest were done as private citizens and exceeded the scope of their employment and took them outside the protections afforded government employees.
- CC. The degree of culpability in both the § 1985-1986 claim and the wrongful death claim will be basically the same.
- DD. Plaintiffs seek no monetary damages from the Defendant government, but in so far as the individual Defendants actions occurred outside their scope of employment the Plaintiffs seek over \$50,000 and allege diversity of citizenship between the Plaintiffs and the individual Defendants Scher and Pazdur, residents of New Jersey and Maryland, respectfully.

COUNT V

OTHER INTENTIONAL TORT RELIEF AGAINST ONLY DEFENDANT SCHER

- EE. Restatement (Second) of Torts § 323 (1965). One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other's person or things, is subject to liability to the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking, if his failure to exercise such care increases the risk of such harm, or the harm is suffered because of the other's reliance upon the undertaking, as occurred here.

FF. Defendant Scher did not exercise care in his responsibility that he undertook to aid patients and provide them a fair process, and the patients, families, doctors, and advocates relied upon him to do so to their detriment.

FURTHER DECLARATORY ACTION (Injunctive relief will be requested by separate motion in accordance with local rules)

ADDITIONAL REQUEST FOR DECLARATORY RELIEF: FDA HAS NO REGULATORY AUTHORITY OVER IMMUNOTHERAPIES THAT ARE WIDELY CONSIDERED SAFE AND EFFECTIVE, WHICH IS THE STATUTORY DEFINITION

GG. Provenge should not be declared to be “new” because it has been around for more than 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 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, biotechnology experts, scientists, FDA experts and others in the medical community as safe and effective.

HH. This court also needs to make a determination since Congress and the FDA have not specifically done so, as to whether the FDA has authority over immunotherapies of this type without specific Congressional authority and whether the immunotherapy Provenge is a “New Drug” by statutory definition.

II. 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 safe immunotherapies of this kind, by statute, by regulation, or otherwise.

- JJ. 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.
- KK. 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 evidence of efficacy", the FDA's own threshold for approval.
- LL. The immunotherapy is designed for each particular patient and is tailored to stimulate one's own immune system to fight cancer.
- MM. 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.
- NN. There is no history or tradition with regards to immunotherapy regulation.
- OO. Provenge technically is no longer a "new" therapy (or even a drug,) and even our history for more quantifiable drug regulation is not 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.

- PP. 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 and such attempts to regulate safe and effective treatments meant for the terminally ill is unconstitutional.
- QQ. 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.
- RR. 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.

- SS. It is truly unconscionable that there are terminally ill men who could be helped yet are receiving a placebo in trials.
- TT. 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.
- UU. 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 upon FDA reconsideration if made without the influence of Defendant's Scher and Pazdur.
- VV. Provenge is not a narcotic and cannot be misused or over used.
- WW. 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 statute.

FURTHER REQUESTS FOR RELIEF

Previous Federal Courts have ruled that the FDA's denial of aid to terminally ill prostate cancer patients is completely irrational. Plaintiffs ask this court to do the same.

WHEREFORE this court should grant a temporary and permanent injunction, grant declaratory relief, award damages against individual Defendants acting outside their scope of employment and grant any other relief appropriate under the legal and equitable power of this court, plus court costs. Provenge should be declared an immunotherapy that has cleared and otherwise achieved all reasonable, rational and commonsensical hurdles and may be used and

recognized for use by dying prostate cancer patients and/or that it is irrational to allow a government agency to further control it and/or deny it to patients.

Respectfully submitted,

S/Kerry M. Donahue

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BELLINGER & DONAHUE
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CERTIFICATE OF SERVICE

This amended complaint was filed electronically and it is understood that the clerk will send e-mail transmissions of same to the Defendant representatives this 5th day of September 2007.

S/Kerry M. Donahue

Kerry M. Donahue

EXHIBIT A

1. NOVACEA: grants & research support; STUDY CHAIR of DN-101; Direct competitor to Provenge
2. GPB BIOTECH: financial conflict of interest per Scher in MedPage
3. PHARMION: financial conflict of interest per Scher in MedPage
4. SANOFI-AVENTIS: grants & research support
5. BRISTOL MYERSSQUIBB: consultant, grants & research
6. MILLENNIUM PHARMACEUTICALS: grant of research support
7. COUGAR BIOTECHNOLOGY: principal investigator; advisory board;
8. INNOVIVE PHARMACEUTICALS: principal investigator
9. INFINITY PHARMACEUTICALS: principal investigator
10. BIOGEN-IDEC: jointly held stock with spouse
11. PFIZER: jointly held stock with spouse

12. GENTA: scientific advisory board (as of March 6, 2007; since removed from web but cached)

13. CONFOMA THERAPEUTICS: scientific advisory board

14. DEPARTMENT of DEFENSE: Principal Investigator PCClinical Trials-P1 and P2

15. AMBRILIABIOPHARMA INC: Principal Investigator PCK3145, Phase I/II

16. MEDIVATION, INC: principal investigator MDV3100

17. PROQUEST INVESTMENTS, Board of Directors, Advisor. Invested in Novacea.

EXHIBIT B

DYSFUNCTION AT THE FDA

Prostate Cancer Victims Face Needless Suffering and Premature Death

FACTS

- In the United States alone, nearly 30,000 men die annually of prostate cancer.
- Today, chemotherapy (which may have severe side effects) is the only approved treatment for androgen independent prostate cancer (AIPC), which is the terminal stage of prostate cancer.
- The FDA selected an Advisory Committee of renowned experts to review Provenge®, an immunotherapeutic “cancer vaccine” developed for men dying from AIPC. On March 29, 2007 the Advisory Committee voted 17-0 that Provenge is safe. They also voted 13-4 that Provenge demonstrated substantial evidence of efficacy (the federally mandated standard). Put another way, the experts found Provenge works.
- In a rare rejection of its own Advisory Committee’s recommendation, the FDA, on May 8, 2007, denied approval of Provenge, requesting additional data.
- Provenge has been demonstrated to be safe in more than six clinical trials. The most common complaint is 2-4 days of flu-like symptoms following each of the three, 2-hour infusions. Again, the expert panel voted 17-0 that Provenge is safe.
- Provenge demonstrated a statistically significant ($p=0.01$) overall median survival benefit of 4.5 months in its D9901 Phase 3 trial. Three year survival benefit was also statistically significant ($p=.0046$), with 34% of Provenge recipients still alive at 36 months compared to only 11% of controls. A second trial, D9902A, showed a 3 year survival benefit (32% vs. 21%), and the two studies combined showed a three year survival benefit (33% vs. 15%).
- Provenge stimulates the immune system to fight cancer cells continuously, month after month, year after year. Some Provenge recipients have lived over 6 years following initial treatment, an impressive feat considering average life expectancy of AIPC patients is about 20 months.
- On July 1, 2007 a review article coauthored by National Cancer Institute experts and published in a prestigious journal of the American Association for Cancer Research found that certain cancer vaccines enhance patient outcome. The authors said, regarding the Provenge D9901 trial, “Overall survival ... was statistically significant ...” and, regarding it and the D9902A trial “[I]ntegrated analysis of both ... showed a statistically significant increase in overall survival ...” Regarding a combination therapy trial using Provenge, they said, “There was a statistically significant increase in survival ... when patients received [Provenge].” Schlom et al *Cancer Vaccines: Moving Beyond Current Paradigms*. Clinical Cancer Research 2007; 13:37763782
- It may take 2-3 years to acquire (through an additional clinical trial), analyze and submit the additional data for Provenge that the FDA has requested. In that time, 60,000 to 90,000 men, many of whose lives could be extended without severe side effects from Provenge, will die.
- The FDA could have approved Provenge and requested post-approval studies, thereby allowing these dying men the chance to benefit from Provenge while further studies are conducted.

QUESTIONS

1. Why did the FDA reject its own expert Advisory Committee’s overwhelming recommendation and turn its back on tens of thousands of dying men who could have a chance to benefit NOW from this safe, effective drug? There is no explanation.
2. Did highly unusual events and conflicts of interest with certain Advisory Committee members exist that could have tainted the fairness and objectivity of the FDA process? A thorough investigation would reveal the answer.
3. Was the FDA’s denial reasonable? **NO. Please ask your Senators and Representatives to demand a reconsideration.**

The FDA wants to wait as much as 2-3 years for more data. Men dying of prostate cancer don’t have that luxury.

**All citizens, especially prostate cancer victims and family members, should immediately contact Congressional representatives, urging them to ensure this travesty is reversed.
APPROVE PROVENGE NOW!**

For further info on efforts to make Provenge available NOW visit www.caretolive.com www.abigail-alliance.org www.provenge.blogspot.com

Arnie Mass, prostate cancer patients, their family members, activists, investors, and health care professionals paid for the placement of this ad.

EXHIBIT C

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

Rory Kearney
President,
CareToLive,
a not for profit corporation
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Thorofare, NJ 08086-0464

CareToLive,
a not for profit corporation
PO Box 464
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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.

In re — Request for the Commissioner of Food and Drugs
to reconsider the failure to approve Provenge
June 26,2007
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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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to reconsider the failure to approve Provenge
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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 patients.

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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