

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

CareToLive, a not for profit corporation  
et al.,

Plaintiffs

Case No. 2:07 CV 729

vs.

Judge Frost

Andrew von Eschenbach, et al.,

Magistrate Judge King

Defendants.

**REQUEST FOR ORAL  
ARGUMENT**

**MOTION FOR EMERGENCY PRELIMINARY  
INJUNCTIVE RELIEF**

Now comes CareToLive on behalf of it's membership (hereinafter "CareToLive"), which includes prostate cancer patients, cancer patients, patient families, doctors, advocacy groups and advocates, and anybody else with an interest in same, and hereby requests that this court grant emergency injunctive relief under Federal Civil Rule 65, and pursuant to Southern District of Ohio Local Rules 65.1 and 7.1(b)(1)(2)(3) against the Defendants in this matter for reasons set forth in the attached memorandum of law.

RESPECTFULLY SUBMITTED,

S/Kerry M. Donahue

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## MEMORANDUM

It is of significant note at the outset that the due process denial of CareToLive is an ongoing due process denial in so far as the Food & Drug Administration (hereinafter “FDA”) could easily rectify this *emergency* situation by taking immediate remedial action to reestablish the Plaintiff’s due process rights, which the FDA is more than well aware they have violated. Each and every day the FDA fails to abide by its own rules and regulations and continues to ignore the purpose and intent of the Congressional mandate set out for them, including protecting the health and well being of the citizens of these United States of America, including their right to equal protection under the law, and each and every day the FDA fails to take corrective action to restore the denial of these civil rights of the Plaintiffs, more than 80 men die without hope.

Under Civil Rule 65 the Plaintiffs must satisfy four prongs for injunctive relief to be ordered. Plaintiff can demonstrate all four factors that entitle them to injunctive relief.

A preliminary injunction is an injunction that is “issued to protect [a] plaintiff from irreparable injury and to preserve the court's power to render a meaningful decision after a trial on the merits.” 11A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2947 (2d ed.1995). In deciding whether such relief is appropriate, a court must consider four factors: “(1) the likelihood of plaintiff’s success on the merits; (2) whether the injunction will save the plaintiff from irreparable injury; (3) whether the injunction would harm others; and (4) whether the public interest would be served by the injunction.” *In re DeLorean Motor Co.*, 755 F.2d 1223, 1228 (6th Cir.1985); see also *Doe v. Barron*, 92 F.Supp.2d 694, 695 (S.D.Ohio 1999).

The four criteria are meant to guide the court's discretion and to serve as factors to be balanced, rather than rigid requirements to be met in every case. *Golden v. Kelsey-Hayes Co.*, 73 F.3d 648, 653 (6th Cir.1996). The district court is required by Rule 52 of the Federal Rules of Civil Procedure to make findings concerning all four of these factors unless fewer factors dispose of the issue. *United States v. Sch. Dist. of Ferndale, Mich.*, 577 F.2d 1339, 1352 (6th Cir.1978). *Davis v. Bastings* 2005 WL 2099744, \*2 (W.D.Ky.) (W.D.Ky.,2005)

### **I. Plaintiff must show irreparable harm**

Plaintiffs in this matter include cancer patients, families of patients, doctors on behalf of their patients, advocacy groups and advocates. Some in the Plaintiff group consist of terminal stage prostate cancer patients. More particularly some of the Plaintiff Group includes those with Androgen Independent Prostate Cancer or Hormone Refractory Prostate Cancer (both terms are interchangeable and mean exactly the same thing, hereinafter referred to as “AIPC” or “HRPC” patients).

Plaintiffs seek injunctive relief that would allow the AIPC patients immediate reasonable access to the immunotherapy Provenge with the advice and consultation from state licensed doctors, a treatment which has already been found by the FDA and much of the medical community to be a safe and effective treatment for AIPC. The FDA has failed to act, continues to refuse to act, and it is clearly aware that it should have acted, in the best interest of the patient population it is sworn to protect. Plaintiffs alternatively seek an order that the FDA provide them the due process of law regarding Dendreon’s Provenge, Biologics License Application (hereinafter “BLA”), which thus far the FDA has arbitrarily and capriciously denied them.

Prostate cancer afflicts 1 in 6 men and is the most common form of non skin cancer in the United States, as well as the second leading cause of cancer death causing 30,000 men to lose their lives each year. Unlike some other forms of cancer, the only available treatment for terminal AIPC is a chemotherapy drug, Taxotere. The effectiveness of Taxotere is so superficial, and the side effects so severe, that most men decline the treatment, as the risks far outweigh the benefits. Between one and two percent of the patients that take Taxotere die from the treatment itself. If the same standards for approval that Provenge has had to undergo, were applied to the chemotherapeutic approval process which includes Taxotere, neither Taxotere nor any other chemotherapeutic agent would ever have seen the light of day. Three hundred (300) to Six hundred (600) patients are killed each year by the Taxotere treatment alone, the only approved treatment for terminal stage prostate cancer in the past 42 years. This is truly amazing considering the cost of the treatment and the cost of hospitalization and that the average benefit is an increase in survival of only 2 ½ months.

Dr. Mark Moyad from the University of Michigan Medical Center, Department of Urology said it clearly:

I really believe they thought that within 5-10 years there was going to be newer and more effective treatments offered, and some doctors really believed that in 10-15 years the disease itself would be wiped out. Keep in mind that this was over 30 years ago and now we have 1 drug (yes, 1 drug) approved for the extension of life for hormone refractory prostate cancer (HRPC) patients, and patients are aware that it is an interesting and potentially effective medication (Taxotere®), but it is not an easy drug to take or stay on for a long period of time.

The bottom line is that it seems many of us, including myself, misjudged how difficult an enemy this HRPC really is when you consider all the compounds that have been thrown at it over the past 3 decades. Think about it for a second, hundreds or perhaps thousands of clinical trials and only one drug approved. Hundreds and really thousands upon thousands of lives and only one drug approved.

Well, one could argue that it was a funding issue and I am sure part of this is true because I still think cancer funding is so pathetically funded in this country that sometimes I am even surprised that one drug got approved. However, we also need to be honest and admit that one cannot argue that thousands of men have volunteered to be part of clinical trials in the past because it represented the right thing to do and it represented “hope” to us, and them. The hope that they could live longer to do more things they wanted to do, the hope of spending just a little more time with their families, and the hope that future generations would die of other diseases at older ages and not of prostate cancer. Finally, I believe they trusted and hoped that their doctor would do the right thing for them and future patients and this is how and why many of them were recruited to be in these trials.

Provenge was overwhelmingly recommended to be approved by the FDA advisory panel in March and simply put it was a democracy and the FDA almost always follows this democratic recommendation. Obviously the approval caught some by surprise and evoked an almost visceral and at times unusual scientific opposition to approval with most comments revolving around the fact that more data was needed. Yes, the science of medicine has been so well represented over the past several months with p-values, statistical significance and words like “time to progression” being thrown out as reasons as to why it should not be approved. In all the discussions I never really heard much about the word “hope,” “patients,” and the “past track record” in treating this disease. In other words, the science of medicine was well represented but who represented the “human” side of medicine in this controversy?

Let’s say that in 3-5 years the vaccine is completely ineffective what will have been lost except a tremendous gain of even more immunologic knowledge? Patients are not children that need to be completely protected by doctors at every stage of life or at every stage of treatment. HRPC patients understand at this point of their disease the general outcome and what is and is not available to them. It is time to respect the fact that patients want some new options or new directions because this at least represents progress. To deny patients the “option” to try this vaccine is to be almost completely ignorant of the past and current options that patients have today for HRPC.

Urologists and oncologists prescribe hundreds if not thousands of secondline hormonal therapies for advanced patients daily but NONE of these drugs have ever been FDA approved for extending life. Why? One reason is because of the lack of options at this stage of the disease and doctors want to at least attempt to extend the quality or quantity of life despite not having FDA approval with these medications, but this is exactly what makes doctors so wonderfully “human” and not just 100% science oriented.

Patients deserve better and instead of opening up the floodgates even more than they are opened to vitamin clinics in Mexico City, the Dominican Republic, and a

host of other countries, I sincerely hope that by the time you read this column the vaccine will now be available to all patients with HRPC. If Provenge is delayed or rejected for several years than not only will I be disappointed but I have to believe some of the opposition to this vaccine will have allowed the science of medicine to completely cloud the human side of medicine. Patients have rights, they deserve better, and they should be allowed a voice especially when so many have sacrificed up to this point with the hope that we would deliver on the promise of allowing treatments with less side effects for patients that have so few options.

It is hypocritical to aggressively advertise and offer mechanical devices or other less invasive therapies” at almost every medical institution in this country with no randomized trials but not to allow a potentially life extending therapy for many dying patients because not enough men have gone through enough randomized trials. Well, some may say that two wrongs do not make a right, but what is so wrong in my opinion was that a democracy clearly recommended approval but a handful do not want to believe that this opinion of the majority was correct. Perhaps if this same energy or passion in the opposition for Provenge was redirected to another area of prostate cancer it may play a small part in my ability to tell my son the next time he comes to the hospital with me that daddy thinks there will be no prostate cancer by the time he needs a PSA test, but this time it may turn out to be true. No offense to my father of course who I know in his heart really believed we were going to cure or control this thing already in his lifetime, but I guess what my dad never figured on was that the science of the disease might replace the art or human side of medicine.

Please do not mention the dollars, or the p-values, or the time to progression or whether or not this side effect was found at 5% versus 3%, or the degrees or number of publications because we have already endlessly debated those issues and that is what an FDA recommendation panel has already debated quite well. Instead, please now mention the thousands of patients that we have recruited in clinical trials because we sold them and recruited them on “hope” in my opinion, and for what, only to see one drug approved in my 42 years of life; and for God (yes, I meant to use this word) sake bring back the human side of medicine because it is desperately needed in this debate (otherwise you might as well allow a machine take care of HRPC patients)."

Reference:

The thousands of “hopeful” patients that I have met over the past 30 years”

Mark A. Moyad, MD, MPH

University of Michigan Medical Center, Department of Urology

June 2007

The FDA rejection is even more amazing when you consider that the Provenge safety profile is so good that nobody has died from it, and in fact many are living longer, being active longer, and feeling good longer. The FDA's own Advisory Committee voted 17 to 0 that Provenge is safe. The side effects of Provenge in less than one in four patients are some mild flu like symptoms lasting one or two days.

On average an AIPC or HRPC patient lives 20 months. AIPC patients are those men that have already either had their prostates removed or undergone chemotherapy or radiation therapy. A not uncommon side effect for men who undergo radiation therapy, which includes brachytherapy, may include urinary problems and impotence. If a man's PSA keeps rising the next step may be hormone therapy, whereby men receive hormones which may include estrogen, a hormone that produces female sex characteristics in an attempt to block their testosterone, a key component in spreading the cancer. Some men undergo testicle removal in an attempt to eliminate the androgens from spreading their cancer. AIPC patients are prostate cancer patients whose cancer has usually gone into remission only to return later with a vengeance having spread into other parts of their bodies including the bones, the lymph nodes, the bladder, the rectum, the liver, and the lungs. Needless to say, these stage IV, AIPC patients, are very sick men.

To qualify for Provenge, AIPC recipients must have already undergone either the removal of their prostates, and have failed hormone therapy. Once eligible for Provenge, the Provenge recipient undergoes a one time bout of 3 visits to their urologist's or oncologist's office where they give blood, and 3 more visits where their enhanced blood is infused back into their arm. Period. Provenge is an immunotherapy meaning its goal is to strengthen the immune system instead of current methods of killing all or parts of the

immune system off while attempting to eradicate the cancerous cells, thereby destroying the healthy cells indiscriminately in the process.

CareToLive's Ted Girgus, a prostate cancer sufferer whose prostate cancer has metastacized into his bone, discussed on Andrew Schorr's HealthRadio.net Patient Power, how he underwent brachytherapy and his doctor likened it to spilling a shaker of salt, whereby if one granule of salt is missed, which he was told happened to him, then the whole treatment was done in vain. Ted desperately wants access to Provenge, and his doctor wants him to have access to Provenge, but he is not allowed to as it is unavailable commercially due to the FDA denial of his due process rights by delaying its approval when it unfairly reached a predetermined decision based on erroneous reasons other than science and humanity.

In contrast, Eduardo Garcia, on the same radio show, also a prostate cancer sufferer whose prostate cancer has also metastacized into his bone, had given up on life when his daughter persuaded him to go into a Provenge trial. It is 6 years later and Eduardo is vital and cheerful and has gone back to work, and cannot crow enough about how Provenge saved his life. The full affects of Provenge can not truly be measured because many of the recipients are still alive and it is unknown how long they will live. Further evidence of the effectiveness of Provenge is still being measured and it is being evaluated whenever someone dies (in the trials this is called a death event). The better Provenge works, and the longer patients live, the longer it takes to provide the additional data, data which is unreasonably and irrationally being sought by the FDA.

Dendreon has closed its ongoing clinical trials as the prespecified numbers of patients have been admitted, and no other patients can gain access to the trial or

Provenge, due to FDA trial regulations. Of those that were fortunate enough to be admitted into the trial, approximately one in three received a placebo (in other words nothing).

The ability of the terminally ailing and enfeebled plaintiff to attain justice in a system which enables his abuser to wear him down further, physically, emotionally, mentally, and financially, including withstanding prolonged deliberate and expensive delays by the very people who denied him his due process rights in the first place, is the ultimate slap in the face which he must now endure. Is it any wonder that men up until this time wander off to die, rather than rise up and fight back? To allow this to continue unabated would be a travesty of justice.

The Court must reinstate the inherent rights of these men and allow them the treatments they need that were unfairly taken from them. The Court must enforce and protect the rights of these men so that it sends a loud and clear message that nobody has the right to deny another person their life, by manipulating the evaluation of a cancer therapy thereby cutting off their lifeline to fight for their right to use it. In this case "Justice Delayed is Justice Denied."

There are some powerful forces inside the FDA who have a purposefully enacted plan, which in some cases is one of denial and then later approval, which is meant to enrich certain people in and associated with the FDA by enabling them to trade on insider information knowing which treatments will be approved and which will be delayed. In the case of Provenge the rejection was done with such certainty that there was over a 40% "short" interest in Dendreon's stock even after an overwhelmingly positive FDA Advisory Committee vote, which flew in the face of reason. This positive vote should

have ensured the approval of Dendreon's Provenge, but instead the approval process was completely controlled through a conspiracy led by Richard Pazdur, which caused the potential approval of Provenge to be delayed by as many as 4 years, thereby enabling certain individuals to reap windfall profits at the expense of the lives of 30,000 men a year. This is likely not an isolated case and has probably been going on for years, to the detriment of the public at large and to the benefit of the insiders involved and those persons that they advise.

Provenge likely would have been voted 13 to 2 that there is substantial evidence of efficacy if you throw out the 2 Pazdur "ringers" who were part of the conspiracy, and placed on the Advisory Committee by Dr. Pazdur to try to control the outcome and delay a safe and effective immunotherapy that will not harm anyone, and is likely to help many dying men.

Mike Huckman on CNBC wrote this a week before the Advisory Committee meeting:

Prostate cancer is the second most common cancer among men. It's incidence is expected to increase as boomers age. And there's nothing available to patients once they've been on Sanofi-Aventis' chemotherapy drug Taxotere or the generic docetaxel. Next Thursday afternoon we will find out if those men could soon have a new alternative in Provenge."

Dendreon Going to the Big Dance  
By Mike Huckman Reporter  
22 Mar 2007 | 03:42 PM ET

Physically: Plaintiffs are burdened with limited physical and mental energy and endurance. A considerable amount of this limited energy and endurance is being used in the furtherance of his attempt to get Due Process under the law and the Constitution. Also in these states of severe exhaustion

plaintiff's judgment and awareness are compromised when he performs ordinary tasks such as getting out of bed to get the morning newspaper. But of course worst of all, he is dying right now. This decision must not be allowed to stand for one more hour, no less for many more years.

Mentally: With adequate rest, plaintiff's mental function may be maintained. His short term memory, even on a good day is not normal, and he frequently forgets things he meant to do or say, unless he has specific reminders. But the most damaging element of this delay is the depression that settles in while the patient waits and worries. Depression settles in and that in and of itself is not good for the immune system, further deteriorating his last straw of health.

Emotionally: Plaintiff, by self knowledge, due to his philosophical outlook and secondary effects of his illness, is prone to give up when under great stress. In the current situation, plaintiff is very careful to monitor his emotions and take appropriate action in the way of extra rest, sometimes with no choice because he has no energy, and consultation with those in his support system, when he feels his emotional function deteriorating. He must not give up hope.

Financially: Financially: Some of these Plaintiffs are totally disabled and do not have the financial means to help fight this devastating disease. They were hoping for approval which their insurance would cover.

If this court does not grant this injunctive relief being sought many of these men will needlessly die early deaths awaiting a trial in this matter. These men might have been able to flourish and at least may have been able to extend their quality of life if they had

received the best available treatment to date. The FDA should have at the very least granted conditional approval to Provenge.

Many other patients have longer and better quality lives because they have received Provenge previously through now closed clinical trials. Eduardo Garcia recently appeared with Ted Girgus and CareToLive Director Mike Kearney on Andrew Schorr's Patient Power Radio Program. The transcript of that radio show is attached hereto as "Exhibit A". Eduardo received Provenge and has been doing great.

Eduardo received Provenge and has expressed that it changed his life! He flew to Washington, D.C. with his grandsons, George Giacomo and Eddie Garcia Jr., to testify before the FDA Advisory Panel this past March in hopes of the approval of Provenge.

Eduardo interviewed with CBS Evening News and CBS discussed Eduardo and Prostate cancer on its web site:

<http://www.cbsnews.com/stories/2007/03/29/eveningnews/main2625626.shtml>, attached hereto as "Exhibit B". The video is at:

[http://www.cbsnews.com/sections/i\\_video/main500251.shtml?id=2627020n](http://www.cbsnews.com/sections/i_video/main500251.shtml?id=2627020n)

"It worked for me, and it could work for many people in the future," Garcia says.

The transcript is not attached but is at:

[http://uwnews.washington.edu/ni/apps/dailyclips/scraped/CBS\\_2007-03-30.html](http://uwnews.washington.edu/ni/apps/dailyclips/scraped/CBS_2007-03-30.html)

Harry Petersik late stage prostate cancer patient:

"I never felt sick, not once," says Harry Petersik, who had prostate surgery 12 years ago because a high prostate-specific antigen test led to the discovery of a tumor. Petersik, a 64-year-old electrician who lives near Edmonton in Alberta,

Canada, thought he was out of the woods. But over the years his PSA levels kept climbing, indicating the cancer was back. Other treatments failed.

By the start of 2005, the cancer had spread through his lymph system. And he had tumors in his back and shoulders.

[http://health.usnews.com/usnews/health/articles/060403/3vaccine\\_3.htm](http://health.usnews.com/usnews/health/articles/060403/3vaccine_3.htm)

The problem in this case--in all cancer cases--is that tumors were evading his immune system, because that system didn't recognize them as foreign invaders. So Petersik turned to a Seattle-based company called Dendreon that teaches old cells new tricks with a therapeutic vaccine called Provenge.

Doctors take cells designed to spot intruders out of the patient's body, juice them with prostate cancer molecules, and put them back in the patient. These cells then point the immune system toward the real enemy. In January, as part of a clinical trial, Petersik lay still for three hours while the vaccine flowed into his body through an IV drip. "I got infused three times," says Petersik.

"There had been a large tumor in my lower back. It practically disappeared. And the pain it caused went away, too."

[http://health.usnews.com/usnews/health/articles/060403/3vaccine\\_4.htm](http://health.usnews.com/usnews/health/articles/060403/3vaccine_4.htm)

Harry Petersik further stated:

I feel that Dendreon has given me a different opportunity-a chance to postpone the inevitable. The way I look at it, I'm getting the best treatment there is in the world right now." Harry was first diagnosed with prostate cancer at age 52. His father died of prostate cancer; he, too, experienced a relatively early onset. Knowing the genetic implications of

this disease, Harry is concerned that his son, who is in his thirties, will face a similar diagnosis some day. He believes that his participation in a Dendreon clinical trial will help future generations in the quest to find more effective, better-tolerated treatments for cancer. Right now, Harry is looking forward to a week-long summer backpacking trip in the Canadian Rockies.

Jim Lanpher, Prostate Cancer patient interviewed by ABC after the June 4th Rally.

Here is an ABC video after the Washington June 4th Rally.

It is an interview with Jim Lanpher - "dying of prostate cancer"

<http://video.yahoo.com/video/play?vid=617207>

He was hoping for Provenge Dr. Roy Berger joins the Provenge discussion "Jim Lanpher is 60 years old and dying from prostate cancer. He just heard the FDA did not approve Provenge. His initial reaction was "Oh, no! Oh, please no!"

Steve Fleischmann prostate cancer patient.

He found out he had prostate cancer in 2003 at the age of 47. Now the cancer is back. He wants Provenge. He has young children he wants to hang out with for a few years. He is also on the ABC video.

<http://video.yahoo.com/video/play?vid=617207>

Steve Fleischmann said, "There are so many men around this country that are livid! They're angry that this drug has not been approved!"

To put Steve's quote in perspective, he raised a lot of money for prostate cancer research. In his testimony before the Advisory Committee he states how men

were calling him from all over the country. All of them were just told they have prostate cancer. So when he says there are a lot of angry men, he knows it!

Ted Girgus Prostate Cancer Patient:

Ted is married and has 5 beautiful grown children, 4 sons and 1 daughter. Ted has a strong faith based belief in God and is a medically retired, (due to his prostate cancer) VP of Admissions & Marketing from a private college in Santa Barbara, California.

He also served 8 years in the Air Force from 1961-69. Ted was diagnosed with prostate cancer on February 13th, 1997. After researching the disease, he chose brachytherapy at NW Hospital in Seattle. The procedure was performed by Dr. Haaken Ragde, a pioneer of the procedure at that time. Unfortunately, his cancer was outside the gland and continued to spread. Ted's last MRI showed extensive metastasis in his vertebrae and pelvic region, his lymph nodes were affected as well. He has been on hormones for the past year, but his PSA is starting to climb back up. Ted could benefit from Provenge. As Ted said on Patient Power (Exhibit A): "If the FDA wants statistics, I will give them some statistics." He then discussed numbers like those given by the American Cancer Society which estimates that during 2007 about 218,890 new cases of prostate cancer will be diagnosed in the United States. About 30,000 of those men will die each year. That's 82 men every day. Steve Fleischman and Eduardo Garcia testified at the Advisory Committee (See advisory panel transcript. attached hereto and incorporated by reference as "Exhibit C", pages 220 thru 231).

Other Plaintiff members who are patients submit the following affidavits to the court, attached hereto as "Exhibit D".

A party's injury is considered irreparable if it is not fully compensationable by money damages. Performance Unlimited Inc. v. Questar Publishers Inc., 52 F.3d 1373, 1382 (6th Cir.1995); Basiccomputer Corp. v. Scott, 973 F.2d 507, 511 (6th Cir.1992). Captain John J. Kelley Post 1355 v. City of Sturgis 2006 WL 2398746, \*1 (W.D.Mich.) (W.D.Mich.,2006).

**II. Plaintiff must demonstrate whether the injunction would cause harm to others.**

Any conceivable harm that could be caused others is clearly outweighed by the benefit to the patient group by receiving Provenge now, or by requiring the FDA to immediately rectify these ongoing due process violations. The threatened injury clearly outweighs any harm that the proposed injunction would cause. Death clearly outweighs any such harm as mild flu like symptoms for less then one in four patients. No harm to others will occur if the request for injunctive relief is granted.

**III. An injunction would serve the public interest.**

**PUBLIC IMPORTANCE/COMPLEXITY LOCAL RULE 7.1(b)(2)**

Because about one-quarter of the goods purchased by Americans are regulated by the U.S. Food and Drug Administration (FDA), its dysfunction has a huge impact not only on the Nations health, but it also impacts the Nations wealth.

Two million men currently have prostate cancer in the United States. One in six men is slated to get prostate cancer in his lifetime. Considering the effects on the friends, families and employers involved in the lives of these men, the stakes are significant in

that most Americans will be impacted in some way, either directly to themselves or to their loved ones, by this dreaded disease. The stakes are high as the FDA decision on Provenge has hurt the entire biotechnology sector and the advancement of cancer therapies across the spectrum. There will be approximately 30,000 deaths from prostate cancer in the U.S. this year alone. Many more deaths will be caused by the negative affect to other drugs trying to be developed throughout the Biotechnology industry, including Dendreon's pipeline drugs such as Neuvence for Breast Cancer, which uses the same science as Provenge, and has recently shown phase I success (published in Journal of Clinical Oncology).

This case is historical in nature in that there has never been a greater public outcry over the non-approval of a drug. The closest case was the Imclone, Sam Waksil, Martha Stewart fiasco wherein Erbitux, one of the drugs Frank Burroughs of the Abigail Alliance fought to gain access to for his daughter Abigail but was denied, was rejected by the FDA only to be called back and later approved by them, but not before Abigail's untimely death at the age of 21 years. At that time the forthcoming non approval of Erbitux was leaked by none other than Dr. Richard Pazdur to The Cancer Letter, the very same publication that the Fleming, Scher, Hussain anti- Provenge letters were 'leaked' to. In many circles it is believed that Pazdur was behind the denial of Erbitux, a drug he later "allowed" to be approved, and which it turned out has and is helping scores of patients. A publication called The Cancer letter has a source within the FDA who unlawfully "leaks" information and that source was previously found to be Defendant Pazdur himself, and this time it may be the same culprit or it could be an employee acting upon instruction of Defendant Pazdur. See <http://www.washingtonpost.com/ac2/wp->

dyn/A43533-2002Aug4 and

<http://www.bcaction.org/Pages/SearchablePages/2004Newsletters/Newsletter083A.html>

With the announcement that there would be a delay of Provenge's approval, came a tremendous uproar. The advocates, including current members of CareToLive, took to the streets and a rally was quickly organized in Chicago outside the ASCO conference. Soon after, another rally was organized and held in Washington DC on June 4, 2007 organized by Jan Manarite of Raise a Voice, the PCRI group, UsToo and Thomas Farrington's Prostate Health Education Network (PHEN). A ProvengeNow.org website was erected by Mr. Farrington (a page of ProvengeNow is attached hereto as "Exhibit E" (ProvengeNow.org) in response to the shocking FDA refusal to allow Doctors to prescribe Provenge for their patients. The rallies were organized to fight the injustice of the Provenge delay. Jan Manarite and Thomas Farrington spoke at the rally in Washington DC, outside the Russell Senate Building, in protest of the FDA's decision to delay Provenge. Dr. Mark Moyad was the keynote speaker at this rally. Dr. Moyad made his now famous "We think a mistake has been made" speech. The video is at: <http://video.google.com/videoplay?docid=3946327005662640676&q=Dr.+Moyad+at+DC+Rally>.

This action inspired CareToLive creation, and CareToLive, still reeling from the decision, embarked on a grass roots effort and helped raise tens of thousands of dollars which they used to take out a half page ad in The Washington Post protesting the Dysfunction at the FDA (attached to Plaintiffs Amended Complaint as Exhibit B). CareToLive with the help of many current members and supporters, and with help from Investors and the Investor Village (IV) message board, began a letter writing campaign to

the government, FDA, Congress and the media to focus attention on the Provenge denial and the denial of the due process right of cancer patients.

Numerous press articles and commentaries were written and published in newspapers and magazines and outrage was expressed by internet publications and on blogs around the world of cyberspace. A sampling of some of the many editorial pieces and articles are attached hereto as "Exhibit F". Included therein is an article entitled, "The FDA's Deadly Track Record." It stresses the importance and all encompassing effect the dysfunction at the FDA had on the cancer community. Also included is an article by Dr. Mark Thornton, a former medical officer of the FDA Office of Oncology Products, who dubbed May 9, 2007, the day the non approval of Provenge was announced, as "Black Wednesday" at the FDA. Dr. Scott Gottlieb, a physician and resident fellow at the American Enterprise Institute and a former senior official at the Food and Drug Administration and the Centers for Medicare and Medicaid Services stated:

I remain worried that the bar on approving new cancer drugs might be climbing higher.....But, I don't think it is possible to learn everything there is to know about their benefits.

The FDA has a very poor track record of being able to predict the full scope of a new cancer drug's benefits and their record is littered with cancer drugs that they thought would be marginally useful, at best, but nonetheless went on to prove widespread benefits. One example is Eloxatin, which they held off the market here in the US for years. So the idea that a drug needs to prove to the FDA beyond all doubt that it can extend life shouldn't be the standard, especially if it's an otherwise safe drug for a disease that has few or no treatments.

Moreover, the FDA should not be asking for more and more data until the agency finally reaches a comfort level. They need to make decisions based on the small amounts of data that are typically available when you are studying a rare or terminal disease. These data are more often going to be a mixed bag since, almost by necessity, you are dealing with sub-optimal studies. And sometimes for patients, it's not a question of benefit, but of the side effect profile.

"Patients faced with terminal illnesses deserve to have options available to them, and we know that much of a new cancer drugs' benefit is established in the post market, after they are put into practical use by doctors. If the FDA's cancer division comes to believe that the full benefits of new cancer drugs need to be completely established before they receive approval, then a lot of very active new cancer drugs are going to be held off the market for years.

The record shows that it's only after drugs are approved that we can fully answer these questions. We need to embrace that and accelerate that learning.

Following the Provenge Complete Response Letter, the National Cancer Institute released its study indicating that the new immunotherapies for late stage cancer patients need to be evaluated differently than is currently being done by the FDA. Here is an NCI announcement shortly after the Provenge non-approval:

Clinical data are providing evidence that patients are living longer following vaccination, de-spite the fact that trials do not show the vaccines can induce the immune system into shrinking tumors. The data suggests that the scientific community and regulatory committees ought to rethink the design of clinical vaccine trials and our current approach to measuring the effectiveness of a cancer vaccine.”

Dr. Jeffrey Schlom

July 1, 2007

Ph.D., chief of the Laboratory of Tumor Immunology and Biology at the National Cancer Institute.

<http://www.newswise.com/articles/view/531250/>

The FDA changes the rules as suits it. One time they say tumor Time to Progression (TTP) is the optimal way to evaluate therapies for cancer, and another time they say: no, survival is the best way to measure them.

To this day articles appear weekly regarding the failings of the FDA to do its duty. Attached hereto as “Exhibit G” is a very thorough discussion of perceived FDA shortcomings regarding this debacle by Life Extension Magazine, which demonstrates the importance to the public of this issue, in accordance with local rules, which justify

this court in scheduling a hearing and devoting the courts time and resources to this matter of considerable public importance.

On 18 September, a coalition of patients and advocates will continue the campaign with "A Right To Live Day" rally on the doorstep of the FDA in Rockville, Maryland. Their purpose is to protest the recent decisions by the FDA to deny cancer patients new, potentially lifesaving therapies, including Provenge for patients with advanced prostate cancer (A Right To Live: arighttolive.com) and to call for justice and reform at the FDA. Among the featured speakers are Ray Matyshyn and Bruce Towers, both Provenge clinical trial participants.

The public has a great interest in seeing a rational, reasonable and realistic approach to new cancer treatments by the FDA, rather than a dysfunctional antiquated approach ensconced in political infighting, sabotage, lying, leaking, and unlawful decisions being made based on arbitrary and capricious justifications.

#### **IV. Plaintiff has presented a substantial case.**

As the irreparable harm present in this case is so great, and time to death so precarious, the Plaintiff need only show a substantial case, not a substantial likelihood of success on the merits.

The “substantial likelihood of success on the merits” element is not reviewed in a vacuum without consideration of the other elements, namely the irreparable harm sought to be prevented. Determining the substantial likelihood of success on the merits “requires a delicate balancing of the probabilities of ultimate success at final hearing with the

consequence of immediate irreparable injury which could possibly flow from the denial of preliminary relief.” *Siegel v. Lepore*, 234 F.3d 1163, 1178 (11th Cir. 2000) (en banc).

The greater the irreparable harm sought to be prevented, the lesser the showing of likelihood of success on the merits is needed. The Eleventh Circuit has held that “where the balance of the equities weighs heavily in favor of granting the [injunction], the movant need only show a substantial case on the merits.” *Gonzalez v. Reno*, No. 00-11424-D, 2000 WL 381901 at \*1 (11th Cir. Apr. 9, 2000) (emphasis added). Both the Ninth and Tenth Circuits have also reduced the “likelihood of success on the merits” element in light of a strong showing on the other elements. *Walmer v. U.S. Dept. of Defense*, 52 F.3d 851, 854 (10th Cir. 1995) (“We have adopted a modified likelihood of success requirement in the Tenth Circuit.”); *Abbassi v. Immigration and Naturalization Service*, 143 F.3d 513, 514 (9 Cir. 1998). In addition, the United States Supreme Court has recognized in stay proceedings that the likelihood of success on the merits is even (neither strongly for nor against either party), “a strong showing on the equities can still carry the day for the [movant].” *McNary v. Haitian Centers Council, Inc.*, 505 U.S. 1234, 1234 (1992).

“A showing of irreparable harm is the sine qua non of injunctive relief.” *Northeastern Fla. Chapter of the Ass'n of Gen. Contractors of Am. v. City of Jacksonville*, 896 F.2d 1283, 1285 (11th Cir. 1990). As Judge Wilson stated in his dissenting opinion in the Schiavo case, “[T]he immediate irreparable injury [in Terri's case] is not only possible. It is imminent. I am aware of no injury more irreparable than death.” *Schiavo*, Docket No. CV-05-00530-T at 19. This is no different then the case with AIPC prostate cancer patients whose death is imminent and will be irreparable. Here,

because the magnitude of the imminent irreparable injury and death, is so great and irreversible, the Plaintiff is merely required to prove a substantial case, not a substantial likelihood of success on the merits.

Even if this Court declines to apply the reduced standard mandated by the Eleventh Circuit, Plaintiff's Complaint states a claim that is sufficient to show likelihood of success on the merits. Even if success is measured by a declaratory order of this court that the FDA give immediate due process to the Provenge BLA, without undue interference from Defendants Dr. Scher and Dr. Pazdur and with proper and reasonable safeguards to assure a fair hearing or open decision making process, the Plaintiffs are satisfied that such relief may be equal to success on the merits and it is in fact one of the alternative measures of relief sought by the Plaintiff's Complaint.

The facts of this case clearly demonstrate that due process was denied. The FDA's own advisory committee of hand picked experts voted 17-0 that Provenge is safe (Exhibit B). There are some at one spectrum of the argument, including a thesis written with the help from a professor at Harvard who would state that when it comes to treatments for serious life threatening conditions that safety alone should be enough for approval (Exhibit H, note: just an excerpt is attached as the entire paper is over one hundred pages). While that theory is not generally accepted it's indicative of the fact that whatever far side of the argument one takes what is clear is that in this case the safety and benefit analysis or weighing and balancing of safety and efficacy as conducted was seriously flawed. The safety profile plus the unmet need for help for late stage cancer patients far outweighs any concerns that there is only a 39 out of 40 chance it is effective. When there is virtually no risk and there is substantial evidence of efficacy why would

the FDA not make Provenge immediately available to the Doctors to prescribe to their dying patients? Why indeed.

Provenge is to be labeled for use in life threatening conditions; AIPC patients, and for which there exists no reasonable alternative treatments, and when the only other choice is death, and that the treatment analysis as currently being ascertained by an out of control FDA that is irrational and unreasonable. The FDA is hard pressed to find any supporters in the medical community for their current flawed risk/benefit analysis, as the vast majority of doctors, experts and even past FDA section chiefs will state that the application process was not appropriate. Now consider that the FDA Advisory Committee also voted that there was substantial evidence of efficacy, the congressionally mandated standard by a vote of 13-4. That's a vote by 13 unbiased experts that say that Provenge can help the patients.

These 13 experts that are already stipulated to be experts by the FDA are now Plaintiffs experts and are in addition to the other expert testimony currently available to Plaintiffs: Their identities and some of their sworn testimony is as follows:

### **Plaintiffs "Courageous 13" Experts**

#### **Is There Substantial Evidence of Efficacy?**

Richard B. Alexander, M.D.  
Professor of Surgery  
Chief of Urology Service, Baltimore Veterans Affairs Medical Center  
Surgery: Urology  
Greenebaum Cancer Center: Surgical Oncology  
Greenebaum Cancer Center: Genitourinary Oncology  
Special Interests: Kidney Cancer; Urologic Oncology; Prostate Cancer; Prostatitis; Immunology; Cancer  
Medical Degree: Johns Hopkins University  
Residency: Johns Hopkins Hospital, Urology  
Fellowship: National Cancer Institute, Immunotherapy  
Certification: Urology

VA Maryland Health Care System

DR. ALEXANDER: Yes. I mean the issue is -- yes, there is substantial evidence. I mean, the 150-some patients, they're substantial evidence.

Jeffrey S. Chamberlain, Ph.D.

University of Washington School of Medicine

Professor of Neurology, Medicine, and Biochemistry

Director, Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Center

EDUCATION

Ph.D. in Biochemistry, University of Washington, Seattle, 1985

Post doctoral fellow, Molecular Genetics, Baylor College of Medicine, Houston, 1985-2000

RESEARCH INTERESTS

- Molecular genetics of, and gene therapy for, the muscular dystrophies.

DR. CHAMBERLAIN: I vote yes, there is substantial evidence.

Larry W. Kwak, M.D., Ph.D.

Chairman Department of Lymphoma/Myeloma

University of Texas

M.D. Anderson Cancer Center

1982, Northwestern University Medical School

1984, Northwestern University Graduate School

Research Interests: Tumor immunology; cancer vaccines; adoptive T-cell therapy; lymphoma and myeloma

DR. KWAK: Yes, substantial evidence.

Michèle P. Calos, Ph.D.

Associate Professor of Genetics

Department of Genetics

Stanford University School of Medicine

B.A. Zoology, Oxford University, Oxford, England

Ph.D. Biochemistry and Molecular Biology, Harvard University, Cambridge, Massachusetts.

Advisor, Wally Gilbert.

Postdoctoral research, Biologie Moleculaire, Universit de Genve, Geneva, Switzerland.

Advisor, Jeffrey H. Miller.

Research Interests: DNA, particularly chromosomes and how the coding information of DNA is organized as the genetic material. Also interested in modeling chromosomes and in finding ways to precisely engineer them.

DR. CALOS: Yes, I think there's substantial evidence. I don't think that it's been conclusively established, but there's substantial evidence, and certainly

it's very exciting, and certainly something that one would want to see continued, and hopefully patients would have access to. But scientifically it falls short of being established.

Steven M. Dubinett, M.D.

Director, UCLA-Wadsworth Pulmonary Immunology Laboratory

Lung Cancer Research Center Program

Division of Pulmonary and Critical Care Medicine

David Geffen School of Medicine at UCLA

Education: M.D., New Jersey Medical School

Clinical Research and Training:

Fellowship, Pulmonary and Critical Care, Massachusetts General Hospital

Research Fellowship, Pathology, Harvard University

Residency, Internal Medicine, UCLA SFVP

Areas of Interest:

- \* Cyclooxygenase-dependent regulation of malignant phenotypes in non-small cell lung cancer

- \* Development of targeted therapies for lung cancer

- \* Lung cancer chemoprevention and early detection

- \* Lung cancer immunology and tumor-mediated immune suppression

DR. DUBINETT: Yes, I think that there is substantial evidence for this. You know, and I also say in sort of coming to some middle ground is that, you know, I think that there is precedent if we look to what happened with gefitinib in lung cancer is that things went forward with gefitinib, it was found to not be demonstrated in a Phase III trial, but another EGFR inhibitor was. So I think both the patients and the community benefited from that approach. So I think that there is more than one way to actually approach this, but I would come down on saying that there's substantial evidence.

Matthew J. Allen, Vet. M.B., Ph.D.

Associate Professor

Department of Orthopedic Surgery

SUNY Upstate Medical University

Research Program and Department Affiliations:

- \*Physiology Program

- \*Orthopedic Surgery

- \*Neuroscience and Physiology

- \*Biomedical Sciences Program

Research Interests:

Tumor-bone cell signaling and the cellular/molecular basis of implant loosening.

DR. ALLEN: I believe there's substantial evidence. I think what's compelling to me is, although there are doubts about these primary outcome measures, for me the point is that this is a new therapy. We may not -- as scientists, it is important for us to understand what we don't know, and one thing we don't know is what this thing is doing really. It

may be changing the biology of the disease in a way that chemo drugs just aren't. So for me the fact that you've got evidence of, in my opinion, substantial evidence of survival advantage means that it should be opened up, given the dire landscape of other drugs out there, it should be opened up and followed very, very carefully, but nevertheless I believe it should be approved.

Robert J. Samuels

Founder of the Florida Prostate Cancer Network

Founding chairman of the National Prostate Cancer Coalition

Retired in 1992 as Vice President of the Global Financial Institutions Group

Attended the American Institute of Banking, New York Institute of Credit

A graduate of Rutgers University and Stonier Graduate School of Banking.

MR. SAMUELS: Yes.

NOTE: Since Mr. Samuels gave a single word response to the question, here is what he said to WebMD

Medical News after the panel vote:

"If we can buy them a couple of minutes or a couple of months or a couple of years, then it's our obligation to do that," said Robert J. Samuels, a member of the panel who said he was diagnosed with prostate cancer 13 years ago. "We understand it's a risk. But it's a risk most of us are willing to take."

Source: FDA Panel OKs New Prostate Cancer Drug Agency Will Consider Recommendation to Approve Provenge for Advanced Prostate Cancer

By Todd Zwillich

WebMD Medical News

Reviewed by Louise Chang, MD

Sharon F. Terry, M.S.

Executive Director, PXE International; President and CEO, Genetic Alliance

Genetic Alliance, a coalition of over 600 disease specific advocacy organizations working to increase capacity in advocacy organizations and to leverage the voices of the millions of individuals and families affected by genetic conditions.

Founding Executive Director of PXE International

EDUCATION/TRAINING:

State University of NY at Stony Brook BA 1980 Geochemistry

Assumption College, Worcester, MA MA 1983 Theology

Assumption College, Worcester, MA PhD Candidate 1986- 1988

Counseling Psychology

MEMBERSHIPS, PROFESSIONAL ORGANIZATIONS:

Member, American College of Medical Genetics

Member, American Society of Human Genetics

Member, Association for Research in Vision and Ophthalmology  
Member, Coalition of Patient Advocates for Skin Diseases  
Member, Society of Investigative Dermatology  
Member, American Association for the Advancement of Science  
Member, National Organization of Rare Disorders  
Charter Member, The American Society of Matrix Biology

MS. TERRY: So I'm a layperson and don't have the scientific knowledge to answer this question scientifically, but I'm here as the consumer representative, and so I'm going to answer it from the consumer point of view. And one of the things I'm going to harken back to for myself is remembering going with my brother, who had a glioblastoma multiforme, to his physician who said, "There's substantial evidence that this stereotactic radiosurgery will keep you alive for 10 years," and he died nine months later. I think new fields need this kind of foray, and new fields are hard to foray into if we wait till everything is perfect. And so therefore I'm going to vote that there is substantial evidence.

Doris A. Taylor, Ph.D.  
Medtronic Bakken Professor  
Center for Cardiovascular Repair  
University of Minnesota

Education:

B.S., Biology, Mississippi University for Women, Columbus, MS, 1977

Ph.D., Pharmacology, Southwestern Medical School, Dallas, TX, 1988

Research Interests:

As the Medtronic-Bakken Chair in Cardiac Repair, Dr. Taylor will blend research from the University's Biomedical Engineering Institute and Stem Cell Institute to develop novel cardiovascular technologies--ones that would treat and cure various heart ailments using molecules and cells instead of mechanical devices.

DR. TAYLOR: I agree with everything I've heard. I think the real question, in my mind is, is there a risk benefit ratio here that's appropriate go forward. We've all voted that we believe that this is safe, and I think we really don't yet know whether or not there's compelling data that it's efficacious, but I think there is substantial evidence, so I have to vote yes, and let patients make that decision.

Francesco Marincola, M.D.  
Director, Immunogenetics Laboratory  
Department of Transfusion Medicine  
Clinical Center, National Institutes of Health  
Graduated from the University of Milan, Italy, in 1978  
One year of mandatory Military Service as an Italian Air Force Medical Officer  
Completed surgical & research training in transplant and cancer immunology Stanford University, CA

Research Interest: Tumor immunology by developing strategies for studying tumor/host interactions in the context of human genetic polymorphism and cancer heterogeneity

DR. MARINCOLA: Well, I think that, based on the facts and on the information that we have so far, I think there is substantial evidence, and I think that not only about this particular treatment, but in general in the field, and I do believe that this is just the beginning of an era where there is going to be so much more that can be done to improve these kind of therapies. If you look at the evolution of these therapies, it's just the beginning, and I do think that there is evidence, and there is a lot of evidence besides this particular study that immunological intervention can be very useful, and I think this is not counter-intuitive as a result, and so I think it's something that is promising, and I would offer it to the people.

William W. Tomford, M.D.  
Professor of Orthopedic Surgery  
Harvard Medical School  
Massachusetts General Hospital  
Clinical Interests: Bone and Tissue Bank  
MD Degree: Vanderbilt University School of Medicine, Nashville, TN  
Board Certification: Orthopaedic Surgery, 1979

DR. TOMFORD: Well, I was prepared to say no to the submitted data establish the efficacy, but I believe there is substantial evidence that the treatment works in some form. And so what I'm concerned about is, if it goes forward from here, and substantial resources are put into this treatment, I'm not convinced that it will be something that's really worthwhile. Immunotherapy I support, but I'm not -- there are too many questions about this. However, for the substantial evidence question, yes, I believe there is substantial evidence for the treatment.

Farshid Guilak, Ph.D.  
Laszlo Ormandy Professor of Orthopedic Surgery  
Orthopedic Research Laboratories  
Duke University Medical Center  
Education:  
-Rensselaer Polytechnic Institute, Troy NY            B.S.    Biomedical Engineering  
-Rensselaer Polytechnic Institute, Troy NY            M.S.    Biomedical Engineering  
-Columbia University, New York NY                    M.Phil.      Mechanical  
Engineering  
-Columbia University, New York NY                    Ph.D.    Mechanical Engineering  
Awards:  
Faculty of 1000, BiomedCentral, 2004  
College of Fellows, American Institute for Medical and Biological Engineering, 2005

Marshall Urist Award for Excellent in Tissue Regeneration Research, Orthopaedic Research Society, 2006

DR. GUILAK: I think it's not unusual in science to have these borderline p-values, or studies that aren't completely definitive. I wish we could all have voted maybe on this, but I don't think we can. And so I think it does boil down to, as Dr. Taylor said, a risk-reward issue, and a way to promote this type of research in the field, and so I have to say yes, substantial evidence.

James J. Mulé, Ph.D.

Associate Center Director

Applied Science and Technology Development

Michael McGillicuddy Endowed Chair

Melanoma Research and Treatment

H. Lee Moffitt Cancer Center and Research Institute

Holds the U.S. Senator Connie Mack Distinguished Chair in Melanoma Research and Treatment

Was a Professor in the Departments of Surgery and Internal Medicine at the University of Michigan

An internationally known senior cancer immunologist and gene therapist

A consultant to the National Cancer Institute, the National Institutes of Health, and is on several governmental and publication advisory Boards

DR. MULÉ: When I look at the field in general, immunotherapy field, and given the question as it's restated substantial evidence, I vote yes, with the proviso, however, that the definitive Study 3 is completed, and there's a commitment for doing so. And wrapped into that is the concern raised by Mr. Samuels with respect to recruitment of minority population.

MS. DAPOLITO: Okay, for the public record, the question was, is there substantial evidence the product is efficacious. The vote was 13 yes, 4 no, zero abstain.

(Applause)

So as recognized by the experts this benefit analysis must be weighed against the safety analysis, which analysis indicated Provenge was safe by the unanimous vote. We are not talking about a treatment for hemorrhoids. We are talking AIPC patients which by definition are patients that have already been unsuccessful on hormone treatments and

have had a relapse of the cancer. With AIPC patients they are going to die of prostate cancer unless something else kills them first.

AIPC patients in consultation with their Doctors have a right to have access to this therapy considering there are no other viable treatment options.

The above evidence is compelling on its own but let's add the additional element of this case which is that *at least 2* of the 4 (13-4) no votes as to substantial evidence of efficacy (which had to be phrased as "established" to themselves to justify it and since they knew the question was to be corrupted before it was asked) had conflicts of interests that made their bias against Provenge only understandable in light of their own best interests. That it was in their own best interests to sabotage Provenge cannot be denied as it was in addition to the fact that they were also doing Defendant Pazdur's bidding and it would be important for these two doctors career to seek to gain favor with Dr. Pazdur for a multitude of reasons.

Is the FDA explanation that "they need more data sincere? No. The FDA, "fast tracked" Provenge for accelerated approval, a special category which they qualified for. Congress had mandated the accelerated approval process after they realized that safe and effective cancer drugs were being delayed and stalled by the FDA. Congress also mandated that the FDA empanel an Advisory Committee of experts to help the FDA evaluate certain cancer treatments fairly, intelligently and reasonably. To gain approval Provenge still had to qualify to be accepted into the fast track program. The FDA decided Provenge had *sufficient data* and thus met the fast track requirements.

The FDA followed the Congressional mandate in form but not in substance when it empanelled an Advisory Committee of experts to review Provenge but completely

disregarded their advice. In Provenge's case this empanelment was nothing more than a sham. Apparently some of those in the FDA with the power to circumvent the Congressional mandate of giving Provenge due process in its licensing hearing, had already decided they were not going to approve Provenge, no matter what any panel of renowned experts advised. In other words, some of the people on one side of the internal political and power struggle within the FDA that had say in the Provenge's approval decision had their minds made up prior to the panel, and were not going to let the facts and the science and the experts stand in the way of a predetermined decision to work for a delay in approval for Provenge. The FDA's actions were an intentional and flagrant disregard of the Congressional mandate and the rights of the patients whose health and well being they are sworn to protect. The Advisory Committee was effectively only for show. This dishonest and dishonorable agenda by certain individuals at the FDA did not go exactly as planned by the conspirators. First Dr. Pazdur caused there to be an incorrectly worded question on efficacy changing the FDA requirement of substantial efficacy to 100% efficacy, but it was discovered by the very honorable and courageous FDA employee, Celia Witten, who correctly asked Dr. Goodman to change it back which she did. In the final tally the Advisory Committee voted overwhelmingly in favor of the approval of Provenge. This approval caused co-conspirators Dr. Pazdur and Dr. Scher, to go into panic mode as it is believed they were prodded by the devastated financial investment community they were involved with; after Dr. Scher and other insiders assured them that Provenge was not going to obtain approval. Many of those upset in the investor financial community, based on the inside information they had were either "short the stock" as Dendreon had a nearly unheard of 40% "short" interest; or were invested in

direct competitors of Dendreon's Provenge. Feeling the pressure, the conspirator's recruited Dr. Hussain and Dr. Fleming to lobby against and wage a campaign against Provenge to depress its stock value and to lobby both the public and the decision makers at the FDA. These actions by Dr. Pazdur and Hussain, assisted by others, were done outside their scope of employment and were a critical attack on Provenge. This effort, spearheaded by Dr. Richard Pazdur, the head of the CDER division of the FDA, removed the last vestiges of due process from Provenge's application process. These letters, written with the help of others, by Dr. Scher, Dr. Hussain and Dr. Flemming, were written to the FDA but were designed to be leaked by the FDA to the press. Persons at the FDA under the control of Dr. Pazdur "leaked" the letters to the Cancer Letter in direct violation of FDA rules and regulations. Worse still is the fact that the letters were fabricated and disingenuous and served as part of the excuse for denial as indicated by FDA employee Patricia Harley. That the decision was science based could not be further from the truth. The Plaintiff's due process was tainted from the go when Dr. Pazdur pressured the CBER division of the FDA to allow two CDER affiliated "ringers" to be placed on the Advisory Committee, with a goal of defeating the Provenge BLA approval at all costs. First they attempted to sway the other experts on the panel into denouncing Provenge. Despite Dr. Pazdur's plan to use political pressure and anything else he could think of to garner a rejection it didn't work and the Advisory Committee voted 17-0 that Provenge is safe and 13-4 that there is substantial evidence of effectiveness (efficacy), the Congressional mandated standard of measure. The four no votes included one doctor who Plaintiffs believe may have been confused about the phrasing of the question, one biostatistician who thought the 1 in 40 chance that the results could have been by chance

was a problem statistically, and of course the two “ringer” oncologists brought in by Richard Pazdur despite the fact that they had disclosed and undisclosed conflicts of interest, which should have disqualified them from serving and voting on the committee. These undisclosed conflicts of interest which were uncovered by Plaintiffs post hoc and identified to the FDA, along with the FDA agenda to derail the Provenge approval, reflect a complete and shameful lack of impartiality and honesty, thereby denying patients an honest shot at approval and did expose a totally anti-Provenge game plan, which cannot be denied.

The bias and manipulation is evidenced at the Advisory Committee itself. The FDA conspiracy members almost succeeded in getting away with changing the question from the Congressionally mandated “substantial evidence of efficacy” to “100% efficacy” in an effort to obtain a no vote from the panelists. Dr. Celia Witten alerted Dr. Gooden to the error and the question was corrected and the four “no” votes promptly changed “yes”. The Transcript of the FDA Advisory Committee hearing (Exhibit B) or see <http://www.fda.gov/ohrms/dockets/ac/07/transcripts/2007-4291T1.pdf> contains the following:

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And the second voting question is, does the submitted data  
ESTABLISH the efficacy of sipuleucel-T in the intended population.

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DR. CHAMBERLAIN: Well, so I guess at this point I'm not entirely sure  
how to answer this question. It's not a yes or no question in my opinion  
the way it's phrased.

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DR. WITTEN: Yes. The regulatory definition is "provide substantial evidence." So that's our standard. Is there substantial evidence that it works. Is there substantial evidence of efficacy, if that helps.

So is there SUBSTANTIAL EVIDENCE.

DR. MULÉ: Okay. So just to clarify what you're asking, is there SUBSTANTIAL EVIDENCE that the product is efficacious.

(NOTICE: ESTABLISH is changed to SUBSTANTIAL EVIDENCE which is the proper standard. When you re-visit the four who voted no, notice how three of them play with this. They insist on staying with Establish. That this trickery was going to occur was likely told to them by Dr. Richard Pazdur ahead of time. By the time Scher's turn came up, it appears Dr. Mule had enough and insisted on Substantial Evidence (the proper congressionally mandated standard).

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DR. MULÉ: Dr. Chappell?

DR. CHAPPELL: No. Regretfully and very sympathetically, I don't believe that the data ESTABLISH efficacy. I dearly hope that the next trial does, but -- and I realize the need for hope, but I don't want to give that hope on a false premise.

DR. MULÉ: Dr. Hussain?

DR. HUSSAIN: So to me

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"substantial" and "establish" are the same, and no to either. So no to both.

(emphasis added)

Added Note: It appears Dr. Hussain the well educated Doctor had trouble with defining or recognizing the difference in the terms. “Substantial” and “Establish” are two different words. “Establish”, is to bring something about. The other, “Substantial”, shows a considerable amount of something. So, either we bring about efficacy or we show a considerable amount of evidence that there is efficacy. Establish suggest 100% percent certainty. Substantially is something less then establish and surely the learned doctor did not briefly have difficulty with word definition particularly words that are congressionally mandated and bandied about by her prior to this date.

sub·stan·tial /s b stæn l/ adjective

1. of ample or considerable amount, quantity, size, etc.: a substantial sum of money.
2. of a corporeal or material nature; tangible; real.
3. of solid character or quality; firm, stout, or strong: a substantial physique.
- ...4. pertaining to the substance, matter, or material of a thing.
5. of or pertaining to the essence of a thing; essential, material, or important.
6. Philosophy. pertaining to or of the nature of substance rather than an accident or attribute.

noun

7. something substantial.

es·tab·lish / stæbl /

1. to found, institute, build, or bring into being on a firm or stable basis: to

establish a university; to establish a medical practice.

2. to install or settle in a position, place, business, etc.: to establish one's child in business.

3. to show to be valid or true; prove: to establish the facts of the matter.

4. to cause to be accepted or recognized: to establish a custom; She established herself as a leading surgeon.

5. to bring about permanently: to establish order.

6. to enact, appoint, or ordain for permanence, as a law; fix unalterably.

.....

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DR. MULÉ: Dr. Scher?

DR. SCHER: I think we are really poised at the beginning of what will be hopefully an outstanding era of immunotherapy. I think there is sufficient evidence demonstrated which justifies the definitive study, and obviously there are investors in that who concurred, but I think it does not meet the -- as the question was phrased, to establish the efficacy. I think this is still an open question. (emphasis added)

DR. MULÉ: So I take it you're saying yes with these provisos?

DR. SCHER: We have two questions. I would say yes to one, no to the second. The first question as posed, as established, I say no.

DR. MULÉ: No, it's substantial evidence.

DR. SCHER: I will say no.

DR. MULÉ: No. Dr. Tomford?

The subversion by Dr. Maha Hussain and Dr. Howard Scher took the form of their anti Provenge stance and attempt to sway the other voters at the advisory meeting. The post meeting actions were taken as part of the political infighting as one side desired one outcome and one side another. On political faction already decided even before the Advisory Committee was ever convened and the other desired approval after the meeting. In fact the approval faction had the conditional approval letter completed only to hastily revise it when Defendant Pazdur threatened that his political faction would stage a demonstration. This hastily revised letter of conditional approval became the Complete Response letter delaying the approval of the BLA for Provenge. That the improper and unlawful actions of these individuals acting in concert with Pazdur's plan to delay Provenge to market actually affected the outcome, was confirmed by FDA employee Patricia Harley in the e-mail attached hereto as "Exhibit I" when she identified it as a factor in the denial of Provenge. Despite the dysfunction at the FDA there are many hard working and honest employees that are as fed up as Plaintiffs are with the continued actions of Defendant Pazdur.

These letters by Dr. Hussain and Dr. Scher contained intentional misrepresentations and were written with the assistance of those in the FDA and in the financial community with the intent to falsely affect the other political faction within the FDA and to falsely validate why the approval process for Provenge was going to be derailed. Their actions to derail Provenge continued even after their advisory employment by the FDA was over.

The bias of these conflicted doctors is clear. The whole intermingling of different self serving financial and political interest by those involved in this matter is

disconcerting to the Plaintiffs as well as the American public in general. Briefly the Prostate Cancer Foundation was founded by Michael Milken with the assistance of then National Cancer Institute (hereinafter NCI) head and current FDA commissioner Andrew von Eschenbach. Mr. Milken is an investor in Proquest Investments. This is the same Proquest Investments which Defendant Scher serves as a Scientific Advisor and for which he is a board member. This is also the same Proquest Investments that makes the bulk of its money investing in Cancer development companies. What better way to make money in the cancer field then to have an advisor who works inside the FDA colluding on approvals, denials and delays. This is the same Proquest Investments that started up a fund with a focus on investment in Prostate Cancer companies

<http://www.proquestvc.com/scienceadvisory.asp>. and six out of seven of their medical advisors work in the prostate cancer field.

[http://sis.windhover.com/buy/abstract.php?id=1998900165&utm\\_source=company](http://sis.windhover.com/buy/abstract.php?id=1998900165&utm_source=company)

<http://proquestvc.com/scienceadvisory.asp>

Proquest Investments owns stock in Novacea, a competitor to Provenge. They own stock in Novecea, but not in Dendreon. Defendant Scher conveniently left this information off his conflict of interest waiver request field with the FDA, thereby destroying the integrity of the process and thereby gurnateeing due process denial of CareToLive. Prior to placing Dr. Scher on the Advisory Committee it is believed that Dr. Pazdur may have already known about these clear conflicts of interest that would demonstrate that Dr. Scher was his man.

- Defendant Scher submitted a Novacea 8K to the SEC on March 26th, 2007. Scher voted against Provenge on March 29th, 2007.

- On May 9th (issued on the 8th released on the 9th) the FDA issued the Complete Response Letter (CR Letter) 5 days before the PDUFA date that indicated that Provenge approval was being delayed until additional data from not yet completed trials was submitted on the issue of efficacy.
- On May 29th Novacea announced a 440 million buy out deal with Schering Plough to the benefit of Defendant Scher, Novacea and Proquest Investments.

<http://www.portfolio.com/resources/company-profiles/275479>

<http://investing.businessweek.com/businessweek/research/stocks/private/people.asp?privcapId=22549>Sloan-Kettering which gets around \$15 mill a year from Milken's PCF to whom Defendant Scher advises through at least Proquest Investments if not directly to Michael Milken himself.

<http://www.portfolio.com/resources/company-profiles/95839>

Scher is a top executive and on the BOD of Sloan-Kettering

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- ProQuest set it self up as a Prostate Cancer Investment Firm:  
 The Opportunity in Cancer: Goldberg's Variation  
 By Mary Stuart, Start-Up, 11/1998 (Art# 1998900165)  
 Prostate cancer will be the focus of ProQuest Investments LP, a new venture fund founded by Jeremy Goldberg. With investors the Ann and Robert H. Lurie Foundation of Chicago, Alza Corp., and high net worth individuals, including Michael Milken, ProQuest has raised \$40.5 million in its first closing.

[http://sis.windhover.com/buy/abstract.php?id=1998900165&utm\\_source=company](http://sis.windhover.com/buy/abstract.php?id=1998900165&utm_source=company)

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- Milken credits Dr. von Eshenbach for helping start the Prostate Cancer Foundation

September 22, 2004

Prostate Cancer Foundation Conference - Optimal Strategies For Managing Prostate Cancer

Michael Milken's Speech:

One of the individuals who helped found the Prostate Cancer Foundation with me 11 years ago, Dr. Andy Von Eschenbach, is today the Director of the National Cancer Institute. In the last year, he has put out a proclamation suggesting and pledging that by the year 2015, cancer will no longer be the cause of death in America or suffering. So we have a busy 11 years in front of us and this multidisciplinary approach is required, participation by patients, local doctors, local urologists, with major research centers. It is only that approach that will allow us to be successful and hopefully beat that goal.

<http://www.medscape.com/viewarticle/490811>

Dr. Scher, is on Novacea's scientific advisory board as lead investigator of the Asentar Phase III clinical trial in the same stage of prostate cancer as Provenge. He is also lead investigator on a clinical trial investigating the chemotherapy drug Taxotere in early-stage prostate cancer – a trial some in the prostate cancer community believe would be

adversely affected by Provenge approval. Further, Dr. Scher himself, who adamantly opposed Provenge approval, said this, “It may be time we focus less on statistical significance alone and more on patient benefit”. This quote was reported on February 26th, 2007. The report stated he said this at a conference sponsored by Novacea.

February 26th is the same day Dr. Scher signed his COI waiver (which turned out to be a partial conflict waiver). This is important because it demonstrates how when Defendant Scher is evaluating a drug for which he has a financial stake, patient benefit is important. When Dr. Scher evaluates his competitor Provenge, it’s a much different standard. Dr. Scher likes to change the way he evaluates therapies according to whether his financial and political interest dictates approval or denial.

One of the co-conspirators was Dr. Maha Hussain (Dr. Pazdur hand fed her information to help her attack Provenge during breaks at the Advisory Committee) who also changes her standards with the direction of the wind and/or her best interest. When Dr. Hussain was voting on a drug called Tarvceva she stated even slight benefits are significant in “a tough Disease”. Of course when it came to Provenge her opinion changed. Maha Hussain reported in her conflict disclosure that she was the principal investigator on a research contract awarded by a competing company for a product that is not related to Provenge. She also disclosed that her husband owns stock in three companies that compete with Provenge.

The statistician that did the work for Dendreon stated that the FDA criteria for approval is 1/1600 chance for error. This same standard is apparently used by FDA statisticians whether the drug or therapy is for late stage cancer or for some small cosmetic or minor health problem (skewed benefit risk analysis). Statistics are more of

an art then a science in this regards but even so the Advisory Committee statistician, based on his “review”, indicated that there was a 1/40 chance that the efficacy evidence could have been produced by chance (see substantial versus establish above). There is not a late stage prostate cancer patient in this country who would not take a chance on an immunotherapy that has a 39 out of 40 chance of helping them live longer and more quality lives. This is demonstrative of the kind of unreasonable, irrational, non sensical manner in which the FDA makes decisions and proves once again that the FDA is a dysfunctional organization which lack common sense and which has its own agenda which does not include protecting the civil rights of American patients as is to be its number one goal.

Many patients who gained access to Provenge through the clinical trials are living with an improved quality of life. Since so many are still living long after their treatment with Provenge, complete analysis of the benefits cannot be measured on an ongoing basis. Furthermore, Provenge in combination with other treatments has extended life even longer longer than for those that got it without combination in the other trials.

CareToLive member Dr. Patrick Bennett in his affidavit attached hereto as “Exhibit I” explains that there is an important need for this safe treatment for AIPC patients. Dr. David Penson testified at the Advisory Panel hearing. He traveled to it on his own dime and his own time. He tells them right away what his conflicts of interests are and then he reports what he sees, upfront and personal. He has a Masters in Public Health and a research expert on the quality of life. He offers expert opinion on pages 208 thru 214 of the Advisory Panel hearing:

DR. PENSON: Ladies and  
19 gentlemen, members of the panel, good  
20 afternoon. I am Dr. David Penson. I am an  
21 Associate Professor of Urology and  
22 Preventative Medicine at the Keck School of  
Medicine, University of Southern California,  
2 in Los Angeles, California. As per FDA  
3 policy, I'd like to make a few disclosures.  
4 I am a site investigator for Dendreon's  
5 9902B study. That means my institution  
6 receives research support, but it also means  
7 I have firsthand experience with this agent.  
8 I do have a consulting agreement with  
9 Dendreon. However, neither I nor any member  
10 of my family has any financial position,  
11 stock or otherwise, with the company. Those  
12 statements aside, I come to you today as an  
13 independent clinician scientist. I am not  
14 receiving any support from Dendreon. They  
15 have not paid for my lodging, they are not  
16 providing me with an honorarium, and  
17 importantly, I have not discussed my  
18 testimony with anyone from the company, any

19 employees. As they say, I've come to you on  
20 my own dime.

21 I do not come to you today as a  
22 clinician who treats prostate cancer  
patients. I am, but you already have those  
2 people on your committee. Rather, I come to  
3 you today as a health services researcher  
4 with a Master's in Public Health and a  
5 research expertise in quality-of-life in  
6 prostate cancer. I am well-published in  
7 this area and I am the principal  
8 investigator of an NCI-funded study  
9 examining long-term quality-of-life outcomes  
10 in prostate cancer.

11 With that stated, I want to start  
12 by saying that I firmly believe that  
13 Provenge is effective and will extend life  
14 in androgen-independent prostate cancer,  
15 based on the clinical trial data showed  
16 today. However, that is not my decision to  
17 make, it is yours and ultimately the FDA's.  
18 What my goal is today is to provide you with  
19 additional information to help in your

20 deliberations. I want to make two points to  
21 you today. The first is that I believe that  
22 there is a quality-of-life advantage to  
Provenge over existing therapies, and the  
23 second is, I want to remind you that your  
24 decision today has public health  
25 ramifications beyond what you may think.  
26 Let me address each of those points  
27 individually.  
28 First, to quality-of-life. As  
29 was already stated, there is a single FDA  
30 approved agent which has been shown to  
31 extend life in androgen-independent prostate  
32 cancer. There is no doubt that docetaxel is  
33 effective and is a valuable tool in treating  
34 these patients, but it has been said time  
35 and time again today, the median survival  
36 advantage is roughly two to three months.  
37 As the last speaker alluded to, this is a  
38 difficult drug for patients. The  
39 administration is prolonged, and there are  
40 many side effects that come with it. These  
41 toxicities are significant and often will

21 require inpatient hospitalization, and this  
22 clearly affects quality-of-life. With this  
in mind we have to ask the question is the  
23 modest survival benefit that we get with  
24 docetaxel negated by the potential negative  
25 quality-of-life effect of prolonged  
26 administration and potential toxicity? I am  
27 afraid that the answer to this question is  
28 yes.

29 Now unfortunately, quality-of  
30 life was not studied in the Provenge trials.  
31 However, as you've seen this morning, the  
32 toxicity profile is clearly quite benign.  
33 This drug allows patients to live their  
34 lives while they are on the drug. It does  
35 not seem to affect quality-of-life in my  
36 opinion. So let me repeat again. It is my  
37 expert opinion that Provenge offers a  
38 considerable quality-of-life advantage over  
39 the existing treatment docetaxel with an  
40 equivalent or possibly better survival  
41 advantage, and I implore the panel to  
42 consider this in your deliberations.

22 My second point concerns the  
public health ramifications. I don't need  
2 to tell you that prostate cancer is a  
3 considerable public health burden in this  
4 country. Hundreds of thousands of men are  
5 diagnosed with this disease every year and  
6 tens of thousands of men die of it. As you  
7 know, any delay in approval, assuming this  
8 drug is effective, will likely shorten the  
9 lives of tens of thousands of men with  
10 androgen-independent prostate cancer. The  
11 advocates will drive that point home  
12 shortly.

13 But I want to make a point to  
14 you. There is an additional ramification  
15 here. Delayed approval of this drug will  
16 send the wrong message to the research  
17 community. If you turn this drug down, it  
18 will likely set back the innovative field of  
19 active cellular immunotherapy in cancer  
20 many, many years. So this will not only  
21 affect prostate cancer patients, but it may  
22 have an effect on the larger population of

oncology patients in general. So I do hope  
2 that the panel will consider both of these  
3 points in your deliberations. I am very  
4 confident that you will make the right  
5 choice. Thank you very much for your  
6 attention.

7 DR. MULÉ: Thank you, Dr. Penson.

8 (Applause)

Dr. Penson also later stated:

Dr. Penson later noted: “many of the IMPACT subjects in his trial know when they are in the treatment group because they feel so much better”.

Doctor Scott Gottlieb is a practicing physician who recently left the FDA where he served as deputy commissioner.

<http://www.foxnews.com/story/0,2933,274441,00.html>. Just after the surprising non-approval of Provenge Dr. Scott Gottlieb was interviewed and stated the following

Scott Gottlieb, welcome. Good to have you here.

SCOTT GOTTLIEB, PHYSICIAN, FORMER FDA DEPUTY

COMMISSIONER: Thank you.

GIGOT: About 1,500 Americans die from cancer every day, more or less, yet the FDA recently didn't approve drugs for prostate cancer and rare bone cancer in children. Were those good decisions?

GOTTLIEB: Well these were two drugs, which were new kinds of therapies.

They are immunotherapies. They work by boosting the body's ability to fight the

cancer. It is a new paradigm in cancer treatment.

In each case, there wasn't really a question about the safety of these products.

That was pretty well-established. The questions the agency had were around just how effective were they. In each case there was evidence that they were effective, but that evidence didn't rise to the bar that the agency is setting which is a new statistical standard. A higher standard, if you will, than what it has looked at in the past.

In at least one case with one drug, Provenge, the drug for prostate cancer, an outside advisory committee to the FDA of medical experts voted 13-four the drug should be approved. And the agency didn't go with that decision.

GIGOT: You are talking about a standard - I think a statistical standard that the FDA says you have to have 95 percent certainty the drug is effective. That might be fine if you have flu or something commonplace or cure for a cold but if you have terminal cancer or very serious cancer, wouldn't you want to settle for a 50 percent chance of effectiveness or even maybe a 10 percent chance? Give you the chance to extend your life?

GOTTLIEB: I think a lot of people would be willing to tolerate more uncertainty, especially with cancers that are otherwise terminal. It is not just the statistical certainty by which a product needs to demonstrate effectiveness to meet the FDA's requirements, but also the kind of trial that needs to be conducted.

Increasingly, the FDA's requiring placebo control trials that are randomized, which means patients that enter the clinical trials either get a sugar pill or the active drug and don't know what they are getting.

GIGOT: Is that fair for cancer patients? Somebody who is really sick?

GOTTLIEB: I think in a lot of cases it is probably not fair and it does test ethical boundaries, but particularly with the immunotherapies, it could be the wrong paradigm for testing drugs. The immunotherapies might well work better in people who have earlier stage cancers, who still have immune systems capable of being boosted, but the placebo controlled trials - when you run a placebo controlled trial it is often the case that people with early stage cancers don't want to enter the trials. So you are forced to have to recruit people who have very late stage cancer. Those might be the very people who don't respond to these drugs. So it could very well be that we have the wrong model for testing these kinds of drugs.

GIGOT: How much of this is a fall out from the Vioxx controversy where that drug, a pain killer, was pulled from the market after it was found too increase the risk of heart attack in some patients. Big political flare-up over that. People said the FDA moved too fast to approve it. Is this a counter reaction a counter reaction, a blow back against that political uproar?

GOTTLIEB: Well, I don't think you have seen that in the cancer space. This has been a movement that's been under way for a number of years now to try to increase the statistical, the mathematical certainly of effectiveness of drugs approved in the cancer space. Usually safety questions aren't the issue whether it comes to approvability of a new cancer drug.....

GIGOT: Where do you come down?

GOTTLIEB: I think we should be able to tolerate a little more uncertainty when it

comes to these kinds of drugs. And I think you are dealing with a therapeutic space where the clinicians are good at reading literature and explaining things to their patient. And they should shall given an opportunity to try new drugs.

It is also the case, Paul, that cancer patients don't just choose medications based on effectiveness but sometimes on the side effect profile.

In fact, there was a case where the drug Zarnestra, where the FDA didn't approve that drug for a very terminal form of blood cancer because it was worried the drug might not have been as effective as the leading therapy, but was far more tolerable. And they literally worried patients would be encouraged to use this drug rather than the standard of care, which might have been more effective because the drug was more tolerable. I would say that's a decision patients ought to be able to make.

GIGOT: I agree with you. Patients should be in on that decision.

Thank you, Scott Gottlieb.

<http://www.foxnews.com/story/0,2933,274441,00.html>

Based on the FDA advisory committee's vote and as evidence as contained in the attached transcript of that Advisory Committee meeting, Exhibit B, and also based on the agency's "Statistical Briefing Document," and other evidence contained herein, attached hereto and/or evidence as will be presented at a hearing, the absurdity of the FDA decision to indefinitely delay the introduction of Provenge because of a patently false and unjust claim that it requires more than the already acknowledged substantial evidence of the product's efficacy is clearly evidence of the arbitrary and capricious nature of the FDA's decision to delay.

The most compelling and least understandable part of this saga is that the FDA knows it got caught with its hand in the cookie jar (figuratively speaking) yet they take no action to correct the civil rights and due process violation in what is clearly an emergency situation. Thousands of letter have been written regarding this travesty. Attached hereto as “Exhibit J” is a very small sampling of pleas made to the FDA since Black Wednesday.

**Local Rule 7.1(b)(2) & (3). REQUEST FOR URGENT ORAL HEARING.**

Local Rule 7.1(b)(1). As set forth above oral argument is essential to the fair resolution of this case because of its public importance, or because of the complexity of the factual or legal issues presented.

Local Rule 7.1(b)(2) This court may, for good cause shown, provide for an early hearing with or without memoranda by the parties.

The above stated facts and law set forth the basis for an emergency hearing being set wherein in this court can hear the evidence in support of the motion for injunctive relief.

WHEREFORE, Plaintiffs request that this court issue an order enjoining the FDA from denying the marketing and distribution of Provenge as there is clear and convincing evidence that it is safe and effective and/or declare that the FDA must correct the ongoing due process denial of CareToLive by immediately providing them their due process rights as afforded them by being citizens of these United States of America heretofore denied.

RESPECTFULLY SUBMITTED,

S/Kerry M. Donahue

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**CERTIFICATE OF SERVICE**

This motion was e-filed with the court and it is understood that the clerk will serve all parties of record by e-mail transmission this 10th day of September 2007.

S/Kerry M. Donahue

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Kerry M. Donahue