

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

CareToLive, et al.,

Plaintiffs,

Case No. 2:07 CV 729

vs.

Judge Frost

Andrew von Eschenbach,
et al.,

Magistrate Judge King

Defendants.

**PLAINTIFF'S MEMORANDUM CONTRA DEFENDANT'S
MOTION TO DISMISS AMENDED COMPLAINT**

Now comes Plaintiffs and hereby offer the following memorandum contra the motion to dismiss filed by the FDA Defendants regarding “in capacity” claims and request the court take notice that although the Defendants frame the arguments as “in capacity” claims; the actions of all the Defendants in this case, exceeded the authority of their office and thus were actions outside their capacity, rendering each and every argument in the Defendant’s motion to dismiss inapplicable to this matter at this stage of the proceedings.

MEMORANDUM

Standard of Review

Defendants have requested that the Plaintiffs Amended Complaint be dismissed pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6). In order for a court to dismiss a complaint for failure to state a claim, it must appear beyond doubt that plaintiff can prove no set of facts supporting his claim that would entitle him to relief. *Conley v. Gibson*, 355

U.S. 41, 45-46 (1957). Plaintiff is not required to specifically set out the facts upon which he bases his claim. *Id.* at 47. Rather, “a short and plain statement of the claim” pursuant to FED. R. CIV. P. 8(a)(2) gives defendant fair notice of plaintiff's claim and the grounds upon which it rests. *Id.*

The reviewing court must construe the complaint in the light most favorable to plaintiff and must presume all factual allegations in the complaint as true. *Morgan v. Church's Fried Chicken*, 829 F.2d 10, 12 (6th Cir.1987). The purpose of Rule 12(b)(6) is to give defendant the opportunity to test whether plaintiff is entitled to legal relief as a matter of law even if everything alleged in the complaint is true. *Mayer v. Mylod*, 988 F.2d 635, 638 (6th Cir.1993). “The Federal Rules reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits.” *Conley*, 355 U.S. at 48. A dismissal under Rule 12(b)(6) is generally disfavored by courts, as it is a dismissal on the merits. 2A JAMES W. MOORE, MOORE'S FEDERAL PRACTICE ¶ 12.07 (2d ed.1995).

A court can only decide a Rule 12(b)(6) motion on the basis of the pleadings. *Song v. City of Elyria, Ohio*, 985 F.2d 840, 842 (6th Cir.1993). Dismissal is appropriate if the complaint fails to set forth an allegation of a required element of a claim. *See Craighead v. E.F. Hutton & Co.*, 899 F.2d 485, 489-90 (6th Cir.1990).

The various Rule 12 motions to dismiss on the pleadings (and the standards applicable to such motions) are often confused with each other. In the oft-quoted decision of the Third Circuit in *Mortensen v. First Federal Savings and Loan Ass'n*, 549 F.2d 884,

890 (3d Cir.1977), the court explained the distinction between dismissals under Rule 12(b)(1) and Rule 12(b)(6):

The basic difference among the various 12(b) motions is, of course, that 12(b)(6) alone necessitates a ruling on the merits of the claim, the others deal with procedural defects. Because 12(b)(6) results in a determination on the merits at an early stage of plaintiff's case, the plaintiff is afforded the safeguard of having all its allegations taken as true and all inferences favorable to plaintiff will be drawn. The decision disposing the case is then purely on the legal sufficiency of plaintiff's case: even were plaintiff to prove all its allegations he or she would be unable to prevail. In the interests of judicial economy it is not improper to dispose of the claim at that stage. If the court considers matters outside the pleadings before it in a 12(b)(6) motion, the above procedure will automatically be converted into a Rule 56 summary judgment procedure. Here there are further safeguards for the plaintiff: in addition to having all of plaintiff's allegations taken as true, with all their favorable inferences, the trial court cannot grant a summary judgment unless there is no genuine issue of material fact.

The procedure under a motion to dismiss for lack of subject matter jurisdiction is quite different. At the outset we must emphasize a crucial distinction, often overlooked between 12(b)(1) motions that attack the complaint on its face and 12(b)(1) motions that attack the existence of subject matter jurisdiction in fact, quite apart from any pleadings. The facial attack does offer similar safeguards to the plaintiff: the court must consider the allegations of the complaint as true. The factual attack, however, differs greatly for here the trial court may proceed as it never could under 12(b)(6) or Fed.R.Civ.Pro. 56...

549 F.2d at 890-891 (emphasis added). *See also, Thornhill Publishing Co. v. General Telephone & Electronics Corp.*, 594 F.2d 730, 732-734 (9th Cir.1979); *Williamson v. Tucker*, 645 F.2d 404, 412-414 (5th Cir.), *cert. denied*, 454 U.S. 897, 102 S.Ct. 396, 70 L.Ed.2d 212 (1981); *Osborn v. United States*, 918 F.2d 724, 728-730 (8th Cir.1990); *Holt v. United States*, 46 F.3d 1000, 1002-1003 (10th Cir.1995).

A 12(b)(1) motion based on subject matter jurisdiction requests a dismissal without prejudice (in this case such a dismissal would likely merely mean the re filing of virtually the same complaint and corresponding motions on January 23rd, 2008). The Sixth Circuit adheres to the 12(b)(1)/12(b)(6) distinction noted by the courts in the above-cited cases. *Rogers v. Stratton Industries, Inc.*, 798 F.2d 913 (6th Cir.1986.) *See also*,

*1135 *Ohio National Life Insurance Co. v. United States*, 922 F.2d 320, 324-325 (6th Cir.1990).

Such simplified notice pleading is made possible by the liberal opportunity for discovery and the other pre-trial procedures established by the Rules to disclose more precisely the basis of both claim and defense to define more narrowly the disputed facts and issues” Conley, 355 U.S. at 47-48.

It is not necessary for the plaintiff to plead all elements of his prima facie case in the complaint, *Swierkiewicz v. Sonoma N.A.*, 534 U.S. 506, 511-14, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002), or “plead law or match facts to every element of a legal theory.” *Krieger v. Fadely*, 211 F.3d 134, 136 (D.C.Cir.2000) (internal quotation marks and citation omitted).

Motions to dismiss for lack of subject matter jurisdiction fall into two general categories: facial attacks and factual attacks. *United States v. Ritchie*, 15 F.3d 592, 598 (6 Cir.1994). A facial attack is a challenge to the sufficiency of the pleading itself. On a factual attack, the court must take the material allegations of the petition as true and construe them in the light most favorable to the nonmoving party. *Scheuer v. Rhodes*, 416 U.S. 232, 235-37 (1974).

In the instant case, Defendants' Rule 12(b)(1) motions are not a mere “facial” challenge to the Plaintiff's complaint. Rather, the district court has been called upon to weigh the evidence concerning jurisdiction presented by the parties and decide the jurisdictional facts. Where a trial court's ruling on jurisdiction is based in part on the resolution of factual disputes, a reviewing court must accept the district court's factual findings unless they are clearly erroneous. *Ohio National Life Ins. Co. v. United States*, *supra*, 922 F.2d at 326; *Osborn v. United States*, *supra*, 918 F.2d at 732 (if the trial court

relied upon its own determination of disputed factual issues, the appellate court must then review those findings under the “clearly erroneous” standard); *Holt v. United States*, *supra*, 46 F.3d at 1003. Because of the factual attack the court should allow some discovery and a hearing of this matter.

It may be helpful to this court to consider before it even burdens itself with a review of the briefing of this matter in full, that regardless of any other findings it is undeniable at a bare minimum that this court must proceed under the APA and also proceed on the Freedom of Information (FOIA) violations of the Defendants. Either alone would be an appropriate basis for the court to continue on to the injunctive issues, which should be set for a hearing. Notably both the APA and the FOIA have built in waivers of government immunity, so even if the court made the factual determination that the actions of all the Defendants in this matter were somehow within the scope of their employment it needs to make no further inquiry at this time. Standing, is an issue that can be reevaluated at each stage of the proceedings and the constitutional issues should not be decided until this court is convinced that such a determination is essential to a full decision in this case, which it is not, at this stage of the proceedings.

Summary of Facts

The facts in this matter are extremely important but due to the length and complexity of this document they will be easier for the court to read separately so they are attached hereto as

APPENDIX ONE.

A. Legal Standards: Ripeness, Finality, and Exhaustion

As to the standards of ripeness, finality and exhaustion, this case is similar to the case of *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 469 F.3d 129, *132-138, 373 U.S.App.D.C. 386, **389 - 395 (C.A.D.C.,2006) (the lower court determination and recitation of said issues, that were confirmed by the en banc DC Court of Appeals, is attached hereto as “Exhibit A”).

Defendants first assert issues of ripeness, finality, and exhaustion of administrative remedies. These are facial challenges to the courts jurisdiction and thus request a dismissal without prejudice, as those challenges are procedural and not substantive. The Defendants assert that the public, including cancer patients, their families and their doctors, have fewer rights, then the drug manufacturers. The Defendants essentially suggest that this court not decide the matter now, rather the court should decide it after 180 days have passed since July 27, 2007, which date would be January 23, 2008. There is no evidence that delaying resolution of this matter will enable further development of the factual issues involved, or that such development would assist the court in reaching a determination of the very narrow issues needed to be decided by the court at this stage; public accountability and whether the actions of the FDA were arbitrary or capricious.

Defendants arguments are inconsistent in that they claim the record is not fully assembled because it’s an ongoing process (though the applicant drug manufacturer, Dendreon, had 10 days to file an appeal from the date of the Complete Response Letter issued May 8, 2007) yet they also claim that the Plaintiffs must file a petition following the administrative decision and then wait 180 days to file litigation such as this. There is

no consistency in the argument that there is no final action so there is no right to file a citizen petition (and then wait 180 or more days after) until after some possible contingent future event, then a petition and suit could be filed. Further, 21 USC § 355. Sec. 505 (n)(8) states:

Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented *including the rationale* for the decision." (see <http://www.fda.gov/opacom/laws/fdcact/fdcact5a.htm>)

No rationale has been given by the FDA to anyone and no decision or rationale has been given directly to the public what so ever. Despite filing a citizen petition Plaintiffs have never been notified by the FDA that their petition was not being accepted for reasons that the FDA has not made a final decision yet. That would seemingly have been a simple response (just as a response that they are going to reconsider may have allowed this case to be stayed by agreement for a brief period while they do in fact reconsider). The lack of communication skills on the part of the FDA have only served to insure public outrage and this litigation. It's demonstrative of the dysfunctional and secretive manner in which the FDA is currently operating. They thus are actually asserting that the public has a right to file a citizen petition only if a *future contingent event occurs*. In this case the contingent future event would be the presentation of "more evidence (data) of effectiveness" which could occur sometime between late 2008 and 2010. Such a "new" later decision would only occur if a new application was submitted by the applicant, something not in the control of Plaintiffs or the FDA. The reason Defendants tip toe around that argument is they realize that it would provide not so much

as a modicum of accountability or due process to the public and in particular AIPC patients who are the most affected by the actions of the Defendants and thus such process would not be looked upon favorably by this court, as it would leave the public that is supposed to be served by the FDA, without any remedy. It's again a question of accountability to the public. The FDA would be making public hay of the fact that the drug companies have much more rights than the public, which public the FDA is sworn to protect. The drug manufacturers and drug companies have a right to appeal a CR letter but the public purportedly does not even have a right to contest by way of a Citizen Petition, the capricious actions of the agency.

The overlapping doctrines of ripeness, finality, and exhaustion each play a role in ensuring that courts do not unnecessarily and untimely interfere with the administrative processes. *Ticor Title Ins. Co. v. Fed. Trade Comm'n*, 814 F.2d 731, 735 (D.C.Cir.1987). (Edwards, J., separate opinion). The three doctrines have met with some confusion in their application. Courts have occasionally treated finality as an aspect of exhaustion. *Marine Mammal Conservancy, Inc. v. Dept. of Agric.*, 134 F.3d 409, 411 (D.C.Cir.1998) (explaining that unexhausted remedies suspend finality of administrative decisions). Sometimes courts have applied finality merely as a factor of ripeness. *Ciba-Geigy Corp. v. Env'tl. Prot. Agency*, 801 F.2d 430, 435 (D.C.Cir.1986); *Wash. Legal Found. v. Kessler*, 880 F.Supp. 26, 34 (D.D.C.1995). Other times courts analyze ripeness, finality and exhaustion as independent concepts. *Darby v. Cisneros*, 509 U.S. 137, 144, 113 S.Ct. 2539, 125 L.Ed.2d 113 (1993); *Fox Television Stations, Inc. v. Fed. Communications Comm'n*, 280 F.3d 1027, 1037 (D.C.Cir.2002); *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726 (D.C.Cir.2003). Because the defendants

have raised all three doctrines in their motion, and because the jurisprudence on this subject is unclear, ripeness, finality, and exhaustion are examined as distinct requirements.

The question whether administrative remedies must be exhausted is conceptually distinct, from the question whether an administrative action must be final before it is judicially reviewable. While the policies underlying the two concepts often overlap, the finality requirement is concerned with *whether the initial decision maker has arrived at a definite position on the issue* that inflicts an actual, concrete injury; the exhaustion requirement generally refers to administrative and judicial procedures by which an injured party may *seek review of an adverse decision and obtain a remedy if the decision is found to be unlawful or otherwise inappropriate*. *Williamson*, 473 U.S. at 192-93, 105 S.Ct. 3108. *Cramer v. Vitale* 359 F.Supp.2d 621, *627 (E.D.Mich.,2005). Unlike what is provide for in Title 21 chapter 10 and as unequally applied by the FDA towards “citizen concerns”, the review should be *meaningful*.

1. Ripeness

The ripeness doctrine lays on the foundation of Article III of the Constitution, which limits the jurisdiction of federal courts to cases or controversies. U.S. CONST. ART. III, § 2, cl. 1; *Ticor*, 814 F.2d at 735 (Edwards, J., separate opinion). The case-or-controversy requirement reflects the “common understanding of what it takes to make a justiciable case.” *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998). More generally, the ripeness doctrine is among the various prudential doctrines developed by the courts to test the fitness of controversies

for judicial resolution. *Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 47-48 (D.C.Cir.1999). In the agency review context, ripeness “is concerned primarily with the institutional relationships between courts and agencies, and the competence of the courts to resolve disputes without further administrative refinement of the issues.” *Ticor*, 814 F.2d at 735 (Edwards, J., separate opinion).

The ripeness doctrine asks “whether the case has been brought at a point so early that it is not yet clear whether a real dispute to be resolved exists between the parties.” 15 FED. PRAC. 3d § 101 .70[2]. Reflecting both constitutional and prudential considerations, the doctrine “is designed to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies and also to protect the agencies from judicial interference *until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.*” *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733, 118 S.Ct. 1665, 140 L.Ed.2d 921 (1998) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967)).

Toward that end, a court must examine whether a dispute is fit for judicial review and whether withholding court consideration would cause hardship to the parties. *Ohio Forestry*, 523 U.S. at 733; *Wyoming Outdoor Council*, 165 F.3d at 48. To measure fitness, the court looks to “whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final.” *Atl. States Legal Found. v. Env'tl. Prot. Agency*, 325 F.3d 281, 284 (D.C.Cir.2003). As for hardship, the court looks to see whether the party can show that it will suffer *injury in the interim*. *Id.* Importantly, “[c]ourts confronted with close questions

of ripeness are appropriately guided by the presumption of reviewability.” *Ciba-Geigy*, 801 F.2d at 434 (citing *Cont'l Air Lines, Inc. v. Civil Aeronautics Board*, 522 F.2d 107, 125 (D.C.Cir.1974)).

Ripeness turns upon two primary considerations: (1) “the fitness of the issues for judicial decision” and (2) “the hardship to the parties of withholding court consideration.” *Abbott Laboratories*, 387 U.S. at 149; accord *Toilet Goods Ass’n v. Gardner*, 387 U.S. 158, 162 (1967); *Dixie Fuel Co. v. Comm’r of Soc. Sec.*, 171 F.3d 1052, 1058 (6th Cir. 1999), *overruled on other grounds by Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 157 (2003).

The hardship to the parties and in particular the patients that are dying from AIPC is not seriously contested by the Defendants (The Prostate Cancer Foundation forecasts that, without new interventions, the number of deaths related to prostate cancer in the United States will grow to approximately 68,000 annually by 2025) and there are currently estimated to be approximately 90,000 patients in the US suffering from AIPC, each with an average life expectancy for time of diagnoses of 19 months; so the only real issue with regards to ripeness is whether the conduct of the FDA in issuing the Complete Response letter (CR) announcing that it was denying the approval of Dendreon’s Provenge BLA, unless Dendreon can obtain and present more clinical data that is sufficient in the eyes of the FDA, which it currently cannot, was a decision fit to be determined by a court to be either arbitrary or capricious. Despite Defendants unquantifiably false contention that there is some kind of on going process, until Dendreon obtains more data (more die) and that data is submitted by way of a new application, there is absolutely no “process” happening at he FDA with regards to the

Provenge BLA. It is equally untrue that the FDA is currently working with Dendreon on the issue of more data of efficacy (FDA won't consider quality of life evidence, post decision combination studies by Dr. Petrylak, or the fact that the discover of dendritic cells was just honored by the Laseker foundation for his discovery, or the testimonials of the doctors whose patients are thriving after having received Provenge or the testimony of those that received Provenge 6 years ago and are enjoying their quality lives now), since nothing short of "scientific data" is acceptable to the FDA. Shortly after the shocking decision of the FDA to issue the Complete Response Letter (CR) instead of approving or conditionally approving Provenge, CEO Mitchell Gold from Dendreon stated at their new conference that they were surprised that they had no communication from the FDA between March 29th and May 8th. When asked on May 9th whether CEO Gold thought that the decisions was made due to politics inside the FDA, he took the high road and said "I don't know if was politics I'd just say it was "human nature". Despite the FDA assertion that they are actively working with the applicant, Dendreon says there is no ongoing communication between them and the FDA and that until they can obtain additional data (deaths), to submit to the FDA, that they may acquire some time between Late 2008 and 2010, there is seemingly nothing to discuss (no ongoing process).

For the first time its history a life saving therapy voted to be safe by all 17 experts is being ignored by the FDA, who not only has gone against its self impaneled advisory committee experts, it has acted completely differently behind closed doors then it did in public. The failure to publicly explain or account for its seemingly nefarious conduct is all in evidence and the administrative record cannot be further developed in regards to the lack of accountability. The FDA has further not publicly explained why it granted

waivers to two doctors who just happened to be the two doctors who within and outside the FDA went to unlawful extremes to derail Provenge approval even after the AC was over, as evidenced by the administrative record plus the “leaked letters” penned by those same doctors. The FDA has also not explained their apparent forgiveness for the failure of the COI doctors to disclose all their conflicts prior to participating in the AC without correcting the record. The FDA continues to compound the public concern, by now, in this litigation, saying that it has investigated the undisclosed conflicts as well and has determined that it apparently has no problem with those. The public is left shaking their heads and saying, “WHAT”. The conflicts are easily demonstrable and were not disclosed in the conflict of waiver forms filed with the FDA and are extreme to the point of being ridiculous in the scope and depth of the conflicts and as set forth in “Appendix One”. Again this agency decision has been made without explanation to the public, who as a result of the FDA’s behind closed door actions and refusal to be accountable to the public, now see them as a corrupt and dysfunctional government entity. The FDA hides behind their own rules but do not follow their own rules.

Though the defendant's motion is styled as a motion to dismiss for lack of subject matter jurisdiction, the bulk of the defendant's arguments address whether the action at issue constitutes a “final agency action”—an inquiry that is more aptly characterized as an element of a cause of action under the APA than as a jurisdictional issue. *See Bangura v. Hansen*, 434 F.3d 487, 500 (6th Cir.2006) (“To state a claim for relief under the APA, a plaintiff must allege that his or her injury stems from a final agency action for which there is no other adequate remedy in court.”); *see generally Arbaugh v. Y & H Corp.*, 546 U.S. 500 (2006) (describing criteria for determining whether a statutory requirement is

jurisdictional). The Defendants cannot escape the fact that if there is no final agency action then there is no right to the administrative remedy which is the filing of a Title 21 section 10 citizen petition. If that is the case there is thus *no remedy* to either the Plaintiffs or the public at large for injury resulting from an arbitrary and capricious action of the agency (CR letter) even though the effects of that decision is death without hope for AIPC patients.

When determining whether this action is one fit for judicial resolution the court is required to make “a determination of whether the factual record is sufficiently developed to produce a fair adjudication of the merits of the parties' respective claims.” *Magaw*, 132 F.3d at 284. This matter is clearly more than an abstract disagreement and the record is fully developed (the matter was fully briefed by Dendreon and the FDA, experts were convened, a hearing held and decision of non-approval made and issued). If all the evidence is considered; the experts opinions, the data submitted, the briefing documents and the evidence refused to be considered by the agency by rule, then there is a safe and effective treatment for AIPC patients, that have no other reasonable alternative treatment available, the injury is self evident in the fact that the patients will instead die without the hope that access to Provenge would provide them. This matter is now fit for judicial review.

2. Finality Of Agency Action

Finality, a factor in the two-pronged ripeness balancing test, can also stand on its own as a distinct legal doctrine. *Darby*, 509 U.S. at 144; *Ticor*, 814 F.2d at 745-46. The finality requirement is expressed in section 704, of the Administrative Procedure Act (“APA”). 5 U.S.C. §§ 551, *et seq.* Section 702 of the APA creates a cause of action

against agencies by granting a general right of judicial review of agency actions, section 704 narrows the scope of reviewability to “final agency action” only. 5 U.S.C. § 704. The finality requirement has several purposes including the protection of agency rulemaking from judicial interference, which hinges on separation of power concerns, as well as conserving judicial resources by *allowing the agency to correct any error* there may be in its action. *Reliable*, 324 F.3d at 732. The agency is currently *not* taking any action to correct its errors and is failing to do so despite hundreds if not thousands of requests to do so.

For agency action to be final and subject to review under the APA, the action (1) must mark the *consummation of the agency's decision making process*, rather than merely being tentative or interlocutory in nature, and the action (2) must be one by which *rights or obligations have been determined* or from which legal consequences will flow. *Bennett v. Spear*, 520 U.S. 154, 177-178, 117 S.Ct. 1154, 137 L.Ed.2d 281 (1997). “Agency action is considered final to the extent that it imposes an obligation, *denies a right*, or *fixes some legal relationship*.” *Reliable*, 324 F.3d at 731 (citing *Role Models Am., Inc. v. White*, 317 F.3d 327, 331-32 (D.C.Cir.2003)).

Patients want Provenge now. Doctors want to prescribe Provenge to their patients now. Families want Provenge for their loved ones now. Doctors, despite their belief in the safety and efficacy of Provenge, are licensed by the State to prescribe only FDA approved medicines, so they cannot prescribe Provenge now because of the FDA’s arbitrary and capricious decision to issue a Complete Response (CR) letter rather than approve or conditionally approve Provenge. Before this matter gets to a trial on the merits thousands of those patients that want Provenge now will have died. Some of those

patients would have enjoyed longer and more quality lives if they received Provenge now. While the FDA did not cause them to get cancer the FDA is denying them a safe and effective therapy when their alternative is death. Dendreon wants to provide Provenge to the dying patients, doctors want to prescribe Provenge to their dying patients but they cannot because of an arbitrary and capricious decision of the FDA, which decision interferes with these third parties (Dendreon and the Doctors) desire to rescue the dying patients. How much more could someone be injured then to be denied a hope giving and health providing therapy because of capricious conduct of the FDA.

Provenge data was supplied to the FDA on a rolling basis until the final BLA was submitted, wherein the FDA reviewed the data and granted fast track status to the BLA and then after further review of the data submitted they determined that there was *sufficient data* for a determination on Provenge to be made by May 15, 2007, which was the PDUFA date, which date was based on the date of the acceptance and granting of fast track approval status (application submitted in November 2006 and fast track granted after a review of that date by the FDA in January 2007). Presumably the FDA was having a difficult time in determining whether to approve Provenge, so in March of 2006 it scheduled an Advisory Committee meeting so that they could get expert advice on the application. Based on the determination that there was sufficient data to make a decision regarding approval or non approval the FDA and Dendreon, at considerable expense to both, prepared briefing documents for the expert panel selected by the FDA and after review by the experts on that panel of those documents and a full hearing and discussion that was a vote 17-0 on safety and the vote of 13-4 on efficacy both in favor of approval or Provenge. The process was complete and nothing else seemingly occurred (other than

the COI Doctors public attack against Provenge) until one and a half months later when the FDA issued the Complete Response Letter which denied approval to Provenge. *Now, the agency asserts:* that despite the acceptance of the BLA on a rolling basis (reviewed as submitted) over the course of a year with a completion and final submission of data occurring in November 2006; the January announcement by the FDA that their review indicated that the Provenge BLA satisfied all the requirements for fast track status, and based on the sufficiency of the data that an expert panel would assist their decision making process; the actual occurrence of that expert hearing and the decision of the FDA announced after that hearing, *that even now there has been “no final decision made”*.

The finality requirement, must be applied in a “flexible and pragmatic way.” *Ciba-Geigy*, 801 F.2d at 435 (internal quotation omitted). Rather than relying on some formal regulatory definition of final agency action, the court “look[s] primarily to whether the agency's position is ‘definitive’ and whether it has a ‘direct and immediate ... effect on the day-to-day business’ of the parties challenging the action.” *Ciba-Geigy*, 801 F.2d at 436 (quoting *Fed. Trade Comm'n v. Standard Oil*, 449 U.S. 232, 239, 101 S.Ct. 488, 66 L.Ed.2d 416 (1980)); *see also Wash. Legal Found.*, 880 F.Supp. at 34. The FDA decision has the effect of immediately denying access to Provenge by the patients.

It makes no difference what label the archaic FDA rules place on an action. It is the action itself that should be determinative. In this case the agency issued to Dendreon (but has given the public NO EXPLANATION) a Complete Response Letter (CR). While the Defendants keep trying to allude to this document they have been unwilling to provide it for review to Plaintiffs. Plaintiffs have even agreed to sign a reasonable confidentiality order with regards to this document to no avail. Attached hereto as

“Exhibit C” is a request to Defendants counsel that that a confidentiality order be sent to Plaintiffs for their review so as to alleviate alleged concerns that Defendants have made to the court regarding review of the CR. To date it has not been responded to by Defendants. It is believed the CR letters give the applicant 10 days to appeal (Again Defendants suggest that the drug manufacturer has right to appeal for 0 days but that the public has not right to do anything or even be answered to. For the FDA to approve now it requires a new application be submitted by the applicant (Dendreon) with additional data that they do not have and arguably the applicant may or may not ever have. It’s akin to a court saying that they deny the relief sought in a complaint but saying hey if you get me more evidence and come back later I will reconsider and not closing the case but rather keeping it “open” and thus denying the complainant a chance to appeal. If the FDA’s contention is accepted then the case could stay open forever, never being able to be challenged by those most affected by the decision. Court following the same logic would keep cases open so they would never be reviewable by any higher court.

The FDA has never before ignored an advisory committee’s recommendation in favor of a treatment for a life threatening condition. This is the first time ever. The doctors and their patients (Medicaid had even assigned Provenge a number after the AC hearing) expected to be able to soon gain access for the patients but instead for no reason known or apparent to the public the FDA issued the CR letter. Because the expected approval was not forthcoming and instead the FDA issued the CR letter giving the applicant drug company a right to appeal it was a final decision by all reasonable interpretation and effected the rights of all the patients and doctors who were waiting on it.

When exactly the applicant (Dendreon) *might* have additional clinical data is unknown because additional data is only known, scientifically, when somebody dies. The FDA has essentially told the maker of Provenge to come back when more people have died. This scientific measurement is called a death event. The FDA does not consider quality of life improvements as scientific evidence so they will not consider the improved quality of life of all those fortunate to have received Provenge. They will only consider the date that they get by another persons death.

While the FDA asserts that its non approval “Complete Response” action is not a final decision and/or that it is not a final decision until the Citizen's Petition is answered, but “[t]he label an agency attaches to its action is not determinative.” *Wash. Legal Found.*, 880 F.Supp. at 34 (citing *Cont'l Air Lines*, 522 F.2d at 124). The D.C. Circuit in *Ciba-Geigy* held that an informal letter from an agency constituted a final agency action, because it amounted to an unequivocal statement of the agency's position and had a direct effect on the regulated party. 801 F.2d at 437-439. *See also Wash. Legal Found.*, 880 F.Supp. at 34 (concluding that because an agency's informal threat of enforcement had the effect of regulating the industry, it was a final agency action). Furthermore, in *Fox Television*, the D.C. Circuit determined that an FCC report in which the Commission voiced its “last word” that the challenged policy was “necessary in the public interest” constituted a final agency action, even though the agency claimed it was not. 280 F.3d at 1038. The agency never takes a final action on any drug since the sponsor is allowed to reapply even a non-approvable (denial) letter. Functionally, there is no difference in net harm to plaintiffs between postponing a decision for two years and making the decision to not approve the drug.

The Complete Response letter that refused either approval or conditional approval was a decision that represented the consummation of the agency's decision making, was definitive and had a direct and immediate effect on the plaintiffs-it barred them from access to Provenge which is at least a potentially life-saving immunotherapy. *Ciba-Geigy*, 801 F.2d at 436. Accordingly, the court should hold that the finality requirement has been met

3. Exhaustion of Administrative Remedies Under the APA

Related to ripeness and finality is the notion that a plaintiff challenging agency action must exhaust all administrative remedies before seeking judicial review. The exhaustion requirement is also found in section 704 of the APA. 5 U.S.C. § 704; *Darby*, 506 U.S. at 138. The exhaustion requirement serves four purposes: (1) it ensures that persons do not flout legally established administrative processes; (2) it protects the autonomy of agency decision making; (3) it aids judicial review by permitting factual development of issues relevant to the dispute; and (4) it promotes judicial economy by avoiding repetitious administrative and judicial fact finding and by resolving some claims without judicial intervention. *Pub. Citizen Health Research Group v. Comm'r, Food & Drug Admin.*, 740 F.2d 21, 29 (D.C.Cir.1984). But, “the exhaustion doctrine *is not jurisdictional in nature* and should *not be applied blindly when the interests that the doctrine protects would not be served.*” *Id.* at 33. Moreover, the Supreme Court has made clear that courts have no discretion to require exhaustion of remedies beyond those clearly mandated by congressional statute or agency regulation. *Darby*, 509 U.S. at 146.

U.S.C. Title 21 section 10 sets forth the requirements for review of an administrative decision of the FDA. It indicates that the Public must file a “Citizen

Petition to challenge an administrative action of the FDA”. With regards to petitions from advocacy groups on behalf of patients, history dictates that the FDA, for all intent and purposes, places such petitions in a circular file. *There are no hard and fast rules for the agencies handling of a citizen petition.* Title 21 section 10 limits the petitioners right to sue until after 180 days from the date of filing the petition, unless the FDA wants more time, in which case the agency is thereafter allowed as much time as they see fit, even if that time period is ten years (45% of the petitions filed in 2004 are still pending). *There is no requirement that the FDA even read the petition, much less give it any further due process at all.* The filing party does not have to have a right to any hearing or to be provided notice of it even if and when the FDA decided without any statutory or regulatory guidance whether a hearing might otherwise be convened to consider the petition, or provide any mandatory procedure at all. Per Title 21 it would be entirely appropriate, as appears often to be the case, that the agency merely files it away indefinitely. The agency has never granted a petition to reconsider a CR or non-approval decision and to the best of Plaintiffs knowledge has never even responded to any advocates petition to provide quicker access to any treatment, whether they are for life threatening conditions or otherwise. Arguably, the most famous petition was that filed by the Abigail Alliance, another patient advocacy group in 2003 which still awaits a response from the FDA. Interestingly the granting of the Abigail Alliance would have meant that the AIPC patients would have already had access to Provenge and may have in fact have resulted in a non irreparable injury as the patients likely would already have at least limited access to Provenge Now, as set forth under the Abigail Alliance proposed Access Act (all drugs and therapies supported by the Abigail Alliance have eventually

been approved at some later time by the FDA). The Abigail Alliance supports approval and access to Provenge now. What is clear is that it is the FDA's refusal to allow early or timely access to safe and effective therapies that has recently cost hundreds of thousands of lives. It's the FDA delays that cost lives and if the delays cannot be attacked many will continue to die while the FDA takes its time. Significantly Title 21 section 10 provide the same 180 days (or what ever extension the FDA wants) for the FDA response whether they actually intend to respond or not and whether the matter being considered concerns a toe fungus cream, a labeling issue or a safe and life saving treatment for late stage cancer patients.

B. The Plaintiffs' Claim is Reviewable

The Defendants argue that because the plaintiffs brought suit before the FDA was required to respond to the plaintiffs' Citizen's Petition, their claim cannot be sustained under the APA insofar as it failed to satisfy the ripeness, finality, and exhaustion requirements. Because the FDA received the plaintiffs' petition on July 27th 2007, it was required under the 180-day response period allowed by 21 C.F.R. § 10.30(e)(2) to respond by January 23, 2008 (unless they want more time then they can take how ever much time they so desire so as to avoid judicial review). The original complaint in this action was filed on July 30, 2007, before the required deadline for agency response. The defendants assert that the Citizen's Petition is a prerequisite to judicial review of an agency policy, (citing 21 C.F.R. §§ 10.25, 10.30, 10.45; *Garlic v. Food & Drug Admin.*, 783 F.Supp. 4, 5 (D.D.C.1992)), an assertion that the plaintiffs deny.

Although the FDA is supposed protect the public, and Title 21 section 10 itself even sets forth that *the FDA does have to answer to the public* (“any concerned citizen” may file a petition and then seek judicial review), it is unclear how the FDA can give the public whose health is at stake, and rights are greater, less due process rights than it does the drug manufacturer. In so much as the Defendants prior treatment of petitions by non drug companies has been non responsiveness, Plaintiff believes that Petition merely exhaust rights designed and written for drug manufacturers and not dying cancer patients. In other words although Title 21 states any citizen can file the FDA looks upon citizen petitions as largely a nuisance and has a history of treating not drug company petitions in such a manner. The FDA gives drug manufactures a right to appeal (and typically notifies the manufacturers of such in the CR letter). The FDA gives no such appeal process to the public or to affected patients. The FDA does not even announce its decision to the public so the public NEVER actually receives a decision from the FDA on any BLA and only obtains this information if disclosed by the applicant company. The public is only notified if the drug manufacturer *decides* to notify them (in the 21st century this seems an archaic scheme in a democratic society). When where and how the FDA decision is announced to the public or that it be announced at all is up to the drug manufacturers, be damned the public. Point being is how can the FDA enforce time requirements of Title 21 section 10 so as to act to insulate them from liability for their arbitrary and capricious actions when they do not even have a responsibility to, and in fact never notify the public of the decisions that might generate the need and desire of a patient, doctor, advocacy group or any other member of the public to file a petition. The public is left to ascertain important public information from other available sources. The public has to go to the

manufacturer for basic information or find it later in a medical periodical. It is difficult for the average citizen/petitioner to meaningfully file such a petition when the agency refuses to announce a decision or provide any rationale for the decisions the petitioner want to direct their petition too.

It is quite true that “no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted.” *McKart v. United States*, 395 U.S. 185, 193, 89 S.Ct. 1657, 23 L.Ed.2d 194 (1969) (quoting *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50-51, 58 S.Ct. 459, 82 L.Ed. 638 (1938)). But surely that requirement pertains only to administrative remedies actually available to a party. There is no support, in law or in logic, for the proposition that “A” can be held to have failed to exhaust remedies available only to “B.” *De Jesus Ramirez v. Reich* 156 F.3d 1273, *1277, 332 U.S.App.D.C. 245, **249 (C.A.D.C.,1998)

1. The Plaintiffs Are Exempted From the Exhaustion Requirement

Plaintiff has claims, which must be taken as true, that individuals within the FDA took unlawful actions, as well as constitutional claims and claims that require legal determinations. Plaintiffs also seek public accountability which issue is unlikely to be addressed in any response to a citizen petition which accountability has been refused since May 9, 2007 and continues to be refused on an ongoing basis. The Plaintiffs are exempt for the following reasons:

a) Constitutional claims and legal issues.

The constitutional claims include; the right to due process of law, patients right to life, the right to be free from arbitrary and capricious conduct by a public agency that

rather than protects the health of patients serves to injure them by denying new safe treatments, the tort claims that rise to the level of constitutional torts which include interference with rescue, the Section 1985 and Section 1986 claims as well as the denial of equal protection claims. Further (see separate memorandum on individual claims) the actions of the individuals rises to the level of constitutional malice and at a minimum were with wanton and willful disregard to the rights of dieing patients (and were at least in part done outside the scope of employment). A constitutional claim, just like any other claim challenging agency action, must challenge final agency action and must be ripe for adjudication. *See e.g., Ticor*, 814 F.2d 731 (holding that a constitutional claim failed either ripeness, finality, or exhaustion); *Wash. Legal Found.*, 880 F.Supp. 26 (holding that the plaintiff satisfied exhaustion and that the constitutional claim was ripe because it challenged a final agency action). Constitutional claims are sometimes exempted only from the exhaustion requirement, but this is not a bright-line rule. *Marine Mammal*, 134 F.3d at 413. The basis for this exception is that agencies do not have the expertise or competence to rule on constitutional issues. *Califano v. Sanders*, 430 U.S. 99, 109, 97 S.Ct. 980, 51 L.Ed.2d 192 (1977). *See. Howard v. FAA*, 17 F.3d 1213, 1218 (9th Cir.1994) (Constitutionality outside the cognizance of the agency and hence exhaustion unnecessary.).The same arguments are involved when legal determinations are required to be made by a court.

Similarly, the Sixth Circuit has rejected an interpretation of the *Williamson* finality requirement to include exhaustion of state remedies. In *Bigelow v. Michigan Dep't of Natural Resources*, 970 F.2d 154 (6th Cir.1992), the court considered whether a plaintiff's takings claim brought pursuant to § 1983 was ripe for judicial review. There,

the plaintiffs were a group of licensed fishermen who challenged the government's restoration of aboriginal fishing rights to Michigan Indians. The plaintiffs argued that such an act amounted to a taking without just compensation under § 1983 and the Equal Protection Clause of the Fourteenth Amendment. Applying *Williamson*, the *Bigelow* court concluded:

What is needed before litigation can proceed in a case such as this is that *proceedings have reached some sort of an impasse and the position of the parties has been defined*. We do not want to encourage litigation that is likely to be solved by further administrative action and we do not want to put barriers to litigation in front of litigants when it is obvious that the process down the administrative road would be a waste of time and money. *We believe that finality, not the requirement of exhaustion of remedies, is the appropriate determinant of when litigation may begin*. By finality we mean that the actions of the city were such that further administrative action by Bannum would not be productive. (Emphasis added).

Bigelow, 970 F.2d at 158 (quoting *Bannum v. City of Louisville*, 958 F.2d 1354 (6th Cir.1992)). In light of the foregoing, that Court concluded that the decision of the BZA was final such that Plaintiff met the finality requirement of *Williamson*. *Cramer v. Vitale* 359 F.Supp.2d 621, *628 -629 (E.D.Mich.,2005).

A constitutional challenge, seeming substantial on its face, creates an exception. *Wilbur v. Harris*, 53 F.3d 542, 545 (2d Cir.1995); *Southern Ohio Coal v. Office of Surface Min.*, 20 F.3d 1418, 1425 (6th Cir.1994), cert. denied 513 U.S. 927, 115 S.Ct. 316, 130 L.Ed.2d 278 (1994), cert. denied 513 U.S. 927, 115 S.Ct. 316, 130 L.Ed.2d 278 (1994) A constitutional challenge to a regulation might avoid the exhaustion requirement.

Also if the damage to a constitutional right could not be remedied by a post-deprivation review in the courts, an exception to the exhaustion requirement is

warranted. *American-Arab Anti-Discrimination Committee v. Reno*, 70 F.3d 1045, 1058 (9th Cir.1995). Many patients right to life will have ended before the exhaustion might occur causing irreparable harm from death.

There is no exhaustion remedy for some claims. Defendants' argument also conflicts with the Supreme Court's decision in *Patsy v. Florida Board of Regents*, 457 U.S. 496, 102 S.Ct. 2557, 73 L.Ed.2d 172 (1982), where the Court held that there is no requirement that a plaintiff exhaust administrative remedies before bringing an action under § 1983. The *Patsy* Court relied on several past cases where the Supreme Court rejected similar invitations to impose an exhaustion requirement before filing a 1983 action. *See Patsy*, 457 U.S. at 500, 102 S.Ct. 2557 (citations omitted). The Court noted that in *Steffel v. Thompson*, 415 U.S. 452, 472-73, 94 S.Ct. 1209, 39 L.Ed.2d 505 (1974), it held. The same legal theory applies when the action to be reviewed was action that occurred that exceeded or was outside the authority of the FDA (including the failure to follow congressional mandates and the faking of the record by impaneling AC committees merely for show or in an attempt to support their previously made decision, which decision could have been made prior to the AC or after the leaked letter conspiracy was undertaken by them). This argument has its greatest force when the allegation is that the agency acted outside of its delegated authority. *Southern Ohio Coal v. Office of Surface Min.*, 20 F.3d 1418, 1424 (6th Cir.1994), cert. denied 513 U.S. 927, 115 S.Ct. 316, 130 L.Ed.2d 278 (1994).

This case also satisfies the ripeness requirements of fitness for review and hardship to the parties. As for fitness, one of the issues raised by the plaintiff-whether the

FDA's prohibition to the access of Provenge to terminally ill patients violates the Constitution-is purely legal. *Atl. States Legal Found.*, 325 F.3d at 284. The alleged injury does not rest on some contingent future event; rather it has already occurred and continues to occur to patients daily only to be remedied if and when a third party that is not accountable to the public at large obtains more data (which date collection is controlled by the FDA) and then choose to submit that data to the FDA. Accordingly, the dispute is fit for review. *Id.* (Exhibit A).

b) Plaintiffs' interest is *so great* and the matter *so extra ordinary* that the Plaintiffs should not have to exhaust remedies set forth in Title 21, section 10.

This matter involves a complete breakdown in due process that resulted in an arbitrary and capricious decision that will seriously affect the rights of the public and the health of dying patients. Because of the *yet unexplained* private over ruling of the public advisory committee by the FDA, men continue to die sooner and with less quality of life then they could if the FDA had afforded basic due process rights to the Provenge BLA. Considering that approximately 80 men die of AIPC every day, the requirement that they exhaust a remedy of waiting 180 days to file litigation (or as much additional time as the agency deems fit) will cause many of them to not have any remedy at all (180 x 80 equals 14,400 patients denied any possible remedy). *Mathews v. Eldridge*, 424 U.S. 319, 330, 96 S.Ct. 893, 900, 47 L.Ed.2d 18 (1976) (plaintiff's interest in having an issue resolved promptly is so great the Court should not defer to agency judgment requiring exhaustion). See *Gibson v. Berryhill*, 411 U.S. 564, 575 n. 14, 93 S.Ct. 1689, 1696 n. 14, 36 L.Ed.2d 488 (1973) (Delay often renders the administrative remedy inadequate.); *Smith v. Illinois Bell Tel. Co.*, 270 U.S. 587, 591–592, 46 S.Ct. 408, 410, 70 L.Ed. 747 (1926) (An

applicant need not wait “indefinitely” before seeking relief.). The citizen petition process contains no definitive decision date for the FDA to make a decision, causing the wait to be what ever the agency decides it wants it to be and this indefinite.

This is an extra ordinary event as the FDA has never before gone against the advise of its advisory panel of experts for a late stage cancer treatment or other treatments for a life threatening condition for which there exists no reasonable alternative treatment. Add to that the severe nature of the COI doctors allowed to infiltrate and corrupt the process and the first time the FDA panel members in the minority took their fight against the treatment, outside the FDA.

c) Irreparable harm exception applies

The Supreme Court's opinion in *McCarthy v. Madigan*, which has become a leading case in this area, the Court found that exhaustion may create undue prejudice to later effective judicial action. McCarthy v. Madigan, 503 U.S. 140, 112 S.Ct. 1081, 117 L.Ed.2d 291 (1992). For instance, waiting for completion of the administrative process may create irreparable harm. See also Komninos v. Upper Saddle River Board of Education, 13 F.3d 775 (3d Cir.1994); Manatee Professional Medical Transfer Service, Inc. v. Shalala, 71 F.3d 574, 581 (6th Cir.1995) (A claim for monetary damages that would be delayed by exhaustion does not generally constitute irreparable harm.); New York v. Sullivan, 906 F.2d 910 (2d Cir.1990) (listing irreparable injury as a requirement to bypass exhaustion). Considering the urgency it is inhumane not to respond in less than 180 days to the citizen petition. The harm to the patients will be death without hope which is surely an irreparable injury. The Defendants propose that this court entertain a

circular argument that the Plaintiffs must prove the patients benefit from Provenge. That is of course an underlying issue and in the long term a goal that is welcomed and achievable by Plaintiffs in this litigation as Plaintiff could bring n a virtually endless stream of experts to prove this. At this stage however all the plaintiffs must prove at a *maximum* is the arbitrary and capricious nature of the Defendants conduct. Since the agency refuses to date to offer any explanation or basis, rational or otherwise for its shocking decision the court could not even rule that their decision was rational when no explanation or reason has been given by the agency. Defendants are careful to set forth possible reasons and hypothetical reasons and not THE reason. Defendnats are content to keep a moving target for as long as they can as they know that Plaintiff is fully prepared to refute any post ad hoc reasons they may suggest to try to justify their decision as soon as they are finally announced (if ever).

Agency procedures sometimes may be challenged without exhaustion where irreparable harm may result from the failure to hear the challenge. McCarthy v. Madigan, 503 U.S. 140, 112 S.Ct. 1081, 117 L.Ed.2d 291 (1992). A growing number of lower court decisions have allowed plaintiffs to avoid the exhaustion requirement when they challenge agency procedures. Coit Independence Joint Venture v. Federal Sav. & Loan Ins. Corp., 489 U.S. 561, 585, 109 S.Ct. 1361, 1375, 103 L.Ed.2d 602 (1989), on remand 874 F.2d 249 (5th Cir.1989); Heldman v. Sobol, 962 F.2d 148, 158–59 (2d Cir.1992); DCP Farms v. Yeutter, 957 F.2d 1183 (5th Cir.1992), rehearing denied 962 F.2d 9 (5th Cir.1992).] Normally, however, the agency must first be presented with allegations of procedural errors in particular cases that could be corrected by the administrative tribunal. Castaneda-Suarez v. INS, 993 F.2d 142 (7th Cir.1993). Since immediately after

May 8, 2007 the agency has been barraged with phone calls, e-mails, faxes, and letters from advocates, doctors, investors, patients and families of patients and *even members of congress*. They have witnessed rallies and half page ads in the Sunday edition of the Washington Post. The issue has been the subject of internet bloggers, medical journals and newsletters, newspaper and magazine articles and even net work TV coverage and finally a citizen petition and a law suit that *called into question the agencies apparent refusal to follow proper procedures in this matter*. Again to date the FDA has offered no explanation counter the accusations that it did not follow appropriate protocol in this matter. The public anxiously awaits a response to the COI issues and leaked letters issues.

Title 21 section 10.

Sec. 10.30 Citizen petition.

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the *category of subject matter*, (ii) the **priority assigned to the petition** considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(i) Approve the petition.....

(ii) Deny the petition; or

(iii) *Provide a tentative response*, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and *may specify when a final response may be furnished*.

The regulation has no real time limit and thus is illusory. It gives the agency as much time as the agency wants. If the agency simply does not want to be sued it merely

says it needs more time, which expanded time period is without limit. The regulation as written merely serves to act as a complete shield against all litigation. Additionally, AIPC cancer patients regard the, to date, refusal of the commissioner to recognize the importance of the matter and to assign a priority designation as a slap in the face. The commissioner (Defendant Andrew von Eschenbach) shall decide the “priority assigned to the petition”. Apparently the priority thus far assigned to this life and death matter is very low.

Agency procedures may be inadequate because they provide no reasonable deadlines and therefore create an opportunity for long delays. Coit Indep. Joint Venture v. FSLIC, 489 U.S. 561, 585–587, 109 S.Ct. 1361, 1375–1376, 103 L.Ed.2d 602 (). The Seventh Circuit will not apply exhaustion to procedural challenges. 503 U.S. at 150–151, 112 S.Ct. at 1089; but see Darby v. Kemp, 957 F.2d 145 (4th Cir.1992), cert. granted 506 U.S. 952, 113 S.Ct. 404, 121 L.Ed.2d 330 (1992), judgment reversed 509 U.S. 137, 113 S.Ct. 2539, 125 L.Ed.2d 113 (1993) (time limits reasonable). Bavido v. Apfel, 215 F.3d 743, 748 (7th Cir.2000). See also, New York v. Sullivan, 906 F.2d 910 (2d Cir.1990) (listing irreparable injury as a requirement to bypass exhaustion).

d) The futility exception applies

Futility is also an excuse for failure to exhaust. In Honig v. Doe, for example, the Supreme Court found that “parents [of students seeking a federal right] may by-pass the administrative process where exhaustion would be futile or inadequate.”Honig v. Doe, 484 U.S. 305, 325–329, 108 S.Ct. 592, 605–607, 98 L.Ed.2d 686 (1988); see also Frutiger v. Hamilton Cent. School Dist., 928 F.2d 68 (2d Cir.1991); W.B. v. Matula, 67

F.3d 484, 495 (3d Cir.1995); Diaz v. United Agricultural Employee Welfare Bene. Plan & Trust, 50 F.3d 1478, 1484 (9th Cir.1995). This exception applies “when following the administrative remedy would be futile because of certainty of an adverse decision.”

Randolph-Shepard Vendors of America v. Weinberger, 795 F.2d 90, 105 (D.C.Cir.1986) (quoting 3 K. Davis, *Administrative Law Treatise* § 20.07 (1958)). An adverse decision can be certain if the agency has articulated a very clear position on the issue which it has demonstrated it would be unwilling to reconsider. *Randolph-Sheppard*, 795 F.2d at 105; *see also Fox Television*, 280 F.3d at 1040 (holding that where the agency had “just determined” in a report “that the rules in question were still necessary to the public interest, it would obviously have been futile for the petitioners to have petitioned the agency for a rulemaking to repeal them.”). A request for an administrative remedy is not futile just because it will “probably fail,” because “most appeals fail.” *Randolph-Sheppard*, 795 F.2d at 106; *Health Equity Res. Urbana, Inc. v. Sullivan*, 927 F.2d 963, 966 (7th Cir.1991). Rather, the appeal must be “clearly useless” and denial of relief must be a “certainty” to excuse failure to exhaust administrative remedies. *Marine Mammal*, 134 F.3d at 413; *Shoshone Bannock Tribes v. Reno*, 56 F.3d 1469, 1476 (D.C.Cir.1995); *Randolph-Sheppard*, 795 F.2d at 105. See also, *Costantino v. TRW, Inc.*, 13 F.3d 969, 974 (6th Cir.1994) (Finding that exhaustion in such cases is futile). It appears that 45% of the petitions filed in 2004 are still pending with the agency.

<http://www.fda.gov/ohrms/dockets/CITPETS/04citpetlist.htm>. The agency has a history of not responding to citizen petitions that are from advocate groups and typically responds only to petitions by drug companies (which drug and pharmaceutical companies happen to provide funding to the FDA). Plaintiff has been unable to find an

instance wherein the FDA reconsidered a NDA or BLA upon request of an advocacy or similar group.

While reviewing the fact that the FDA seemed firm of mind the District Court in Washington DC recently ruled in the Abigail Alliance Case on this issue and stated:

Given this FDA proclamation, any further administrative procedure, like a Citizen's Petition, was "clearly useless," because it made clear that the agency had a "preconceived" and "unyielding" stance on the issue. *Randolph-Sheppard*, 795 F.2d at 107. Without ruling on the question of whether FDA regulations *require* an aggrieved party to file a petition before gaining judicial review, Defs.' Mot. at 10, 19, 22, the court concludes that the plaintiffs are exempted from the exhaustion requirement because further recourse to the FDA would clearly have been futile

Futility exception to exhaustion of administrative remedies:

- ? The FDA is currently operating in a dysfunctional manner and is unable to timely respond to citizens petitions.

The FDA cannot keep up with the petitions it has pending and they have admitted that it sometimes takes as long as five years to respond to a petition. The agency has given Plaintiffs no reason to think that this petition is going to be moved to the front of the line, despite the importance of the issue to late stage cancer patients. The commissioner has not indicated that the FDA considers the matter of utmost importance or even urgent. In fact just the opposite seems true. The agency has gone out of its way to show that they are firm of mind with regards to this decision and that they will not reconsider the decision.

Immediately following the decision not to approve Provenge announced by way of a Complete Response Letter to the applicant, the FDA was barraged with public outrage at its decision. The FDA phones rang, the faxes went off and

the e-mails started pouring into the agency. This happened beginning on May 9th and increased in intensity culminating in the first rallies that were held in Chicago and Washington DC in early June 2007.

At the Washington Rally on June 4, 2007 advocates voiced their concerns in a face to face meeting with FDA commissioner Andrew von Eschenbach. This rally was attended by CareToLive members. Commissioner von Eschenbach was asked to reconsider and he clearly and unequivocally indicated they would not reconsider. The commissioner was firm of mind. He also did not even make a suggestion that the advocates file a citizen petition assumingly because he knew such effort would be a waste of time and resources of the advocates and the FDA.

Meeting with FDA Commissioner - June 4th

Organizers of the rally, Jan Manarite, Raise A Voice, Dr. Mark Moyad, University of Michigan, Jim Kiefert, Us TOO, Thomas Kirk, Us TOO and Thomas Farrington, Prostate Health Education Network, drove to Rockville, MD on June 4 to meet with FDA commissioner Dr. Von Eschenbach for a face to face meeting to discuss FDA's decision. Dr. Paul Shellhammer joined the group for the meeting.

> In this meeting Dr. Von Eschenbach emphasized that the FDA was a science-based and science led organization and that drug approval decisions would be based on scientific evidence. His implication was that Provenge did not meet the FDA's criteria without further evidence. He emphasized that the advisory committee's recommendation was never intended to be the final decision.

ProvengeNow coalition members, three of whom presented at the March 29th

advisory committee meeting, assured Dr. Von Eschenbach that they were fully aware that the advisory committee recommendation was not to be the final decision, however, they pointed out that they felt two members of the advisory panel politicized and corrupted the decision making process with their public campaigning against Provenge after the panel meeting. Their comments were also a catalyst for further comments and speculation within the financial community, thus creating an appearance that the final FDA decision was influenced by outside forces. It was also pointed out that by the FDA not commenting on "leaked" letters which it received from those two advisory committee members, that there is also a public perception that elements within the FDA could have been complicit in the politicizing.

Dr. Von Eschenbach was firm in the FDA's decision to request more Provenge data and not grant immediate approval

Considering the firmness of the decision by the FDA, the fact that the public was upset about it and the public communicated this outrage to the FDA commissioner himself and considering that they have know there was public outrage not later then May 20, 2007 (as of 10/19/07, 183 days ago) their failure to give any indication what so ever that they *might reconsider* makes further petitioning and requests futile.

? The FDA has a history of unresponsiveness to Citizen Petitions.

The petition process is also futile as the agency has a history of never responding to advocacy petitions. Interestingly, Defendants motion questions the reliability of this assertion but they do not deny it either. The records are with the Defendants, unable to

be received by Plaintiff because of the agency refusal and/or backlog in responding to FOIA requests. Exhaustion is not required where, as here, it is highly unlikely the agency would change its position. Costantino v. TRW, Inc., 13 F.3d 969 (6th Cir.1994); Tataranowicz v. Sullivan, 959 F.2d 268 (D.C.Cir.1992), cert. denied 506 U.S. 1048, 113 S.Ct. 963, 122 L.Ed.2d 120 (1993); Bethesda Hospital Association v. Bowen, 485 U.S. 399, 405, 108 S.Ct. 1255, 1259, 99 L.Ed.2d 460 (1988); Atlantic Richfield Co. v. United States DOE, 769 F.2d 771, 782 (D.C.Cir.1984) (“[E]xhaustion is not required where, as here, it is ‘highly unlikely that the [agency] would change its position ...’”). All indications from the FDA is that they are not and will not reconsider and through Defendants pleadings it appears that they are even attempting to sweep the wrongdoing of the COI doctors as well as the leaked letters debacle under the rug.

Since June 4th the advocacy efforts increased. Since June 4th, numerous press reports on national television and in major newspapers as well as magazines, internet sites and even peer reviewed journals discussed the reported irrational conduct of the FDA in this matter. The Plaintiff, CareToLive even directed advocacy action directly against the FDA by placing a half page advertisement in the Washington Post that ran on July ___th. To fund this advertisement the group raised \$26,000.00 for the advertisement mostly from small contributions from numerous supporters. On July 27th CareToLive filed the Citizen Petition. Along with other advocacy groups CareToLive participated in yet another rally on September 18th outside the FDA offices in Rockville Maryland. Because of advocacy efforts directed towards congress numerous House members and Senators have expressed their concern regarding this matter directly to the FDA. One Senator was even “no commented by the FDA”. This matter has tested the resolve of the

agency in every conceivable manner and to date they have not given one iota or scintilla of evidence that they are reconsidering the matter. Further exhaustion of remedies is futile.

e) Challenge of bias or prejudgment

The McCarthy Court stated, exhaustion is not necessary where the agency is biased or has predetermined the issue. McCarthy v. Madigan, 503 U.S. 140, 112 S.Ct. 1081, 117 L.Ed.2d 291 (1992). Evidence of prejudgment may come from several sources. Lower courts have also frequently held that when the administrative consideration is clearly controlled by a regulation, exhaustion of further administrative challenges to an individual determination may be futile so as to justify a failure to exhaust. Costantino v. TRW, Inc., 13 F.3d 969 (6th Cir.1994); Tataranowicz v. Sullivan, 959 F.2d 268 (D.C.Cir.1992), cert. denied 506 U.S. 1048, 113 S.Ct. 963, 122 L.Ed.2d 120 (1993); Bethesda Hospital Association v. Bowen, 485 U.S. 399, 405, 108 S.Ct. 1255, 1259, 99 L.Ed.2d 460 (1988); Atlantic Richfield Co. v. United States DOE, 769 F.2d 771, 782 (D.C.Cir.1984) (“[E]xhaustion is not required where, as here, it is ‘highly unlikely that the [agency] would change its position ...’.”). The individuals at the FDA are biased and have indicated they are biased towards the applicant and more importantly have taken actions for their own self interest ignoring the health and welfare of the patient population that are there to protect.

f) To further equity or fairness

The Supreme Court in *Bowen v. New York*, suggested that a district court could make an *ad hoc* determination that equities may justify waiver of the exhaustion requirement. *Bowen v. New York*, B476 U.S. 467, 106 S.Ct. 2022, 90 L.Ed.2d 462 (1986) Generally, that justification included the inability of the claimant to know that the administrative scheme was not being faithfully executed. 476 U.S. at 480, 106 S.Ct. at 2030. Practical arguments supporting the exhaustion doctrine, the Court said, “merely serve to remind us why exhaustion is the rule in the vast majority of the cases; they do not aid the Court in deciding when exhaustion should be excused.” 476 U.S. at 486, 106 S.Ct. at 2033

g) Unreasonable delay

The Supreme Court has not required exhaustion when unreasonable administrative delay has rendered the administrative remedy inadequate. *Gibson v. Berryhill*, 411 U.S. 564, 575 n. 14, 93 S.Ct. 1689, 1696 n. 14, 36 L.Ed.2d 488 (1973) (Delay often renders the administrative remedy inadequate.) In the case of a treatment for a group of patients with an average life expectancy of 19 months after diagnosis with AIPC, a six month or longer delay in their pursuit of Provenge helps assure an inadequate remedy. The delay will insure that many patients who could benefit will not ever have the chance. The fact that the agency can extend the 180 day requirement for as long as they see fit means that they could delay a terminal patient population until they have all passed away and there is no real time period, making the process time indefinite. *Smith v. Illinois Bell Tel. Co.*, 270 U.S. 587, 591–592, 46 S.Ct. 408, 410, 70 L.Ed. 747 (1926) (An applicant need not wait “indefinitely” before seeking relief.). See also *Southwestern Bell Telephone Co. v. FCC*, 138 F.3d 746, 750 (8th Cir.1998) (“The

FCC's record of delay in this matter may not, as we have said, invalidate its action, but it does render an administrative remedy manifestly inadequate.”).

C. Title 21 section 10 is unconstitutional or unconstitutional as applied

This court likely having found in favor of the Plaintiffs on the above issues will not have to consider this part as the constitutionality of a statute need only be determined if necessary to a fair resolution of this matter.

Title 21 section 10 is unconstitutional or at least unconstitutional as applied to late stage cancer patients. A statute that gives the agency 180 days to respond and which provides for no type of due process to late stage cancer patients is a denial of due process and equal protection under the law and will assure that many patients will not be able to obtain a remedy.

The statute is also impermissibly vague and, therefore, unconstitutional under the due process clause. The Supreme Court has long recognized that a legislative enactment “which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law.” Connally v. General Constr. Co., 269 U.S. 385, 391, 46 S.Ct. 126, 127, 70 L.Ed. 322 (1926) (citations omitted).

In determining whether a legislative enactment is unconstitutionally vague, the court must acknowledge that the Constitution does not require, nor does the English language lend itself to, mathematical precision. Broadrick v. Oklahoma, 413 U.S. 601, 608, 93 S.Ct. 2908, 2913-14, 37 L.Ed.2d 830 (1973) (noting that “[w]ords inevitably contain

germs of uncertainty”). When, as here, a party asserts a claim of unconstitutional vagueness outside the First Amendment context, the party must demonstrate that the legislative enactment is vague as applied to its own conduct. In other words, “vagueness challenges ... which do not involve First Amendment freedoms must be examined in the light of the facts of the case at hand.” United States v. Mazurie, 419 U.S. 544, 550, 95 S.Ct. 710, 714, 42 L.Ed.2d 706 (1975). FN2. “No person shall ... be deprived of life, liberty, or property, without due process of law[.]” U.S. Const. amend. V. “No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.” U.S. Const. amend. XIV, § 1.

So long as a court is faithful to legislative intent, the court may issue a declaratory judgment and an injunction prohibiting the statute's unconstitutional application. *Ayotte v. Planned Parenthood*, 546 U.S. 320 (2006). When a state law is challenged on due process grounds, courts inquire “whether the state has deprived the claimant of a protected property interest, and whether the state's procedures comport with due process.” *Lujan*, 532 U.S. at 195. Courts examine the procedural safeguards built into the statutory or administrative procedure effecting the deprivation, and any remedies for erroneous deprivations provided by statute. *Lowe v. Scott*, 959 F.2d 323, 340 (1st Cir.1992).

Title 21 section 10 does not set forth a “set standard” for weighing evidence, it provides for no hearing or opportunity to be heard, it has no real time requirements and places no requirements of due process on the agency what so ever. There is no requirement that the agency even read the petition much less consider it in any

meaningful way. A law will be void for vagueness if persons “of common intelligence must necessarily guess at its meaning and *differ as to its application...*” *Connally v. General Constr. Co.*, 269 U.S. 385, 391, 46 S.Ct. 126, 70 L.Ed. 322 (1926). The statute sets forth some things the agency *can do* but it sets forth no requirements for the agency to do anything substantially to determine the issue raised in a Citizen Petition.

Ultimately, FDA management decides whether to grant a petition. But first, agency staffers evaluate it, a process that may take several weeks to more than a year, depending on the issue's complexity. After FDA grants or denies the petition, the agency will notify the petitioner directly. If not satisfied, the petitioner can take the matter to court.

For more information on submitting petitions, and sample formats, consult Title 21 of the Code of Federal Regulations, [Sections 10.30](#), [10.33](#), and [10.35](#).

Besides accepting public comments and petitions, FDA also schedules public meetings and hearings to discuss and explain its proposals. These usually are held with industry representatives or consumer groups, but anyone interested may attend and, with advance notice, may comment on a proposal. Meetings often are held in the Washington, D.C., area, but sometimes are set in other areas across the country. Meetings for the public to present views are announced in the Federal Register.
<http://www.fda.gov/opacom/backgrounders/voice.html>

There is no evidence to suggest that the FDA has taken any of those steps. More importantly none of those steps is required by the statute (they all appear to be discretionary). The statute is unconstitutional as applied to AIPC patients.

D. Standing and Related Issues

DEFENDANT’S RED HERRING DEFENSE

This action is brought by CareToLive, a not for profit corporation on behalf of the public and the citizens of this country; groups include advocates, investors, doctors, patients and families of patients. The arbitrary and capricious decision of the FDA to not approve Provenge is felt throughout the country as it affects the future development of all cancer therapies and thus directly or indirectly almost every citizen of the US. There

is virtually nobody that is not directly or indirectly touched or who will not be touched past or future by cancer, so they are all affected by unlawful actions of the FDA. The decision not only effects the health and welfare of all those whose families cancer effects but it effects the whole infusion of monies into future biotech funding and research, and effects the speed at which the industry as a whole can bring their novel new products to market.

Dr. von Eschenbach in 2007 spoke about the FDA needing to be a bridge and not a barrier to get innovative new cancer treatments to patients who need them and that the goal of the FDA was to make cancer a treatable condition rather than a dreaded killer of a disease. The Commissioner cannot deny that the failure to approve Provenge, a first of its kind immunotherapy, has significantly set back the goal to make cancer a treatable condition by 2015.

Due to the surprising FDA decision in this matter (those without inside sources at the FDA, such as several investment companies and hedge funds had) investors lost money invested in the stock of a company whose product is safe and effective yet denied marketing due to capricious actions of the FDA, the public lost faith in a government agency (FDA), Doctors were denied the chance to prescribe Provenge to their patients and most importantly the patients waiting on it have been denied the treatment, so they are left with no other viable alternative other than to accept death without a fight, without even the hope that they might be helped, leaving their families without them. Who is damaged by the private unlawful actions of the FDA that were contrary to the public perception painted by the FDA of what was happening with the Provenge process.

- ? The Public (Citizens).
- ? Families of patients.
- ? Patients.
- ? Doctors.
- ? The Government itself
- ? Investors.

THE PUBLIC

The FDA cannot deny that it has a duty to the public. At the very least they have a duty of accountability. Even if they argue that their decision herein was not arbitrary and capricious and they actually attempt to announce a rational reason for their conduct and provide the information sought under the FOIA, then they still have a duty to explain their decision, which at bare minimum at least arbitrary and capricious in the eyes of the citizenry.

Almost every household in the United States is affected in some way by the ravages of cancer. One in 6 men will get prostate cancer. They and their loved ones are effected. Roughly one in every three person will get some kind of cancer. By the time baby boomers become of age there is expected to be over 280,000 new case of prostate cancer diagnoses every year. Plaintiffs represent the public and the citizenry.

FAMILIES OF PATIENTS

Somewhat surprisingly the Defendants assert that the families of prostate cancer patients have no damages and this have no standing. This is demonstrative of the lack of understanding and compassion of the FDA. Even the COI doctor herself, Maha Hussain,

recognizes the suffering of the families of prostate cancer victims. Attached hereto as “Exhibit B” is that article describing the effect on families of prostate cancer patients. In addition the Prostate Cancer Foundation reports on the devastating affects on the family of cancer patients:

Prostate Cancer Difficult For Wives As Well
Wives report as many, or more, problems with quality of life

http://www.prostatecancerfoundation.org/site/c.itIWK2OSG/b.3468637/k.151D/Prostate_Cancer_Difficult_For

CareToLive member Marilyn Fish (letter attached as Exhibit H to Plt. Reply to memo contra inj. Rel) certainly recognizes the effects of her husband John Fish’s battle with prostate cancer. CareToLive member Stephen Study’s father suffers from late stage prostate cancer and his father even went to Mainilla to obtain a treatment similar to Provenge at the cost of \$80,000.00 (after he failed in an efforts to get Provenge access through the FDA programs). Stephen’s father wants Provenge and Stephen wants it for him. The evidence of Stephen and his fathers struggles and full plight to obtain Provenge is attached hereto as “Exhibit D”

THE PATIENTS

Attached hereto as “Exhibit E”, is the signed letter by Howard Cassell who is an AIPC patient in Ohio who seeks Provenge now. Howard is very ill and in late stage of prostate cancer. He hopes that if he can’t get Provenge in time to help him that he can at least help others to receive it. John Fish (letter attached to Plt mot. for inj, exhibit H), also from Ohio is a late stage cancer patient who wants Provenge now. CareToLive member

Ted Girgus is a late stage prostate cancer patient who wants access to Provenge. Ted's letter is attached hereto as "Exhibit F". Ted could benefit from Provenge Now and says his doctor would prescribe it to him if the FDA allowed it.

Prostate Cancer patient Jim Lanpher was waiting on Provenge and he, as did other patients, expected it to be approved by May 15, 2007. Jim Lanpher, is 60 years old and dieing from the cancer; interviewed by ABC after the June 4th Rally, <http://video.yahoo.com/video/play?vid=617207> Mr. Lanpher stated upon learning that the FDA did not approve Provenge: "Oh, no! Oh, please no!"

Harry Petersik late stage prostate cancer patient was fortunate enough to have received Provenge in a clinical trial previously said: "I never felt sick, not once," says Harry Petersik. "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

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.

Steve Fleischmann is a late stage 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!"

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

CareToLive member Bruce Tower received Provenge as part of a trial over 5 years ago. Bruce is able, even today, to travel as he did to attend the rally held outside the FDA offices on September 18th (speech at <http://www.youtube.com/watch?v=RmlDsIJjQIw>) because he received Provenge in a trial. Mr. Tower would be eligible for a much desired booster shot of Provenge if it were approved.

David Friedline, a high school teacher in New Hampshire, joined CareToLive because he wants to help CareToLive fight the FDA for his life. David is AIPC and could benefit from and qualifies for on label usage of Provenge. David's desperate plea for help is attached hereto as "Exhibit G". If David cannot get Provenge before it is too late he wants to fight for others to receive it as soon as is possible.

Stephen H. Study, the father of before mentioned Stephen Study, is a CareToLive member and a patient with late stage prostate cancer. He is 66 years old. He served 4 years in the air force after high school stationed at Bergstrom Air Force base in Austin TX as B29 mechanic and met future wife (Mary Jo) in Austin and married in 1962. After military service he stayed in Texas and went to work for IBM in the office product division. He and his wife raised two sons. He worked 25 years with IBM and achieved the position of lead copier technical specialist in Central Texas region and took an early retirement at age 55 after a short transition of the division to Kodak. For the next 10 years, he traveled some around the country with his wife and took a few temporary/part

time jobs with IBM but mostly enjoyed his retirement and his grand children. On Dec 6th, 2006 he lost his wife, after a 6-month illness, to lung cancer. In Feb 2007, he was diagnosed with prostate cancer that had already spread outside his prostate. He was intensely hoping for Provenge this past May. He ended up going out of the country to get some immunotherapy.

CareToLive, board member Peter McGrath has Prostate cancer and wants Provenge approved not only for his benefit but for the benefit of all prostate cancer patients and their families now and in the future.

THE DOCTORS

Doctors also have rights not only as members of the public but as doctors who fight for their patients. They have a right to assert patient rights and have a right to assert their own individual rights. Doctors are being directly denied the right to prescribe Provenge to patients who they believe would benefit from it. The Defendants cannot possibly deny that their actions have caused Doctors, to be denied the right to prescribe it when they believe it will help their dieing patients.

Just recently President George Bush stated that health care decisions should be made between doctors and their patients and not in Washington (see page 3 of this interview at <http://www.cnbc.com/id/21249783/>). Doctors and patients who want Provenge could not agree more.

CTL member Dr. Patrick Bennett is a physician active in the US army and he wants Provenge for patients including active service men and veterans (affidavit attached

to Plt. Mot. for inj rel ex. J). Dr. Robert A Rostock is a practicing Oncologist and Chairman of Oncology at Geisinger South Wilkes Barre, Chairman of the Institutional Review Board and Chairman of Radiation Oncology at Wyoming Valley Health Care. Doctor Rostock's letter is attached hereto as "Exhibit H". Dr. Rostock says he has approximately 25 patients he would prescribe Provenge to now. He is being denied that opportunity by the FDA. Dr. Rostock, a CTL member, has also worked diligently through lobbying of congress to get a congressional investigation of the FDA's handling of this matter. Dr. Rostock believes in Provenge and fights hard for his patients to receive it.

Doctor Crescenzo Calise's letter is attached hereto as "Exhibit I". Dr. Calise is a member of a group of urologists who would prescribe Provenge.

Other Doctors that want Provenge for patients include Dr. Petrylak, Dr. David Penson, Dr. David Samadi, Dr. David Allen, Dr. James Mule, Dr. Alexander, Dr. Mathew Allen, Dr. Michele Calos, Dr. Jeffrey Chamberelin, Dr. Stephen Dubinett, Dr. Farshid Guilak, Dr. Larry Kwak, and Dr. William Tomford, just to mention a few. Two more rather surprising Doctors whose patients would benefit from having Provenge approved for use by their patients are Dr. Howard I. Scher and Dr. Maha Hussain. *Both of them would prescribe Provenge to their patients if it was available to be prescribed now.* This is absolutely undeniable.

It is clearly the action of the FDA in unexpectedly denying approval to Provenge on May 8, 2007 that causes the doctors not to be able to prescribe Provenge to their patients, which hurts the Doctors individually and as advocates of the patients and hurts

the patients being denied this treatment which hurts their families. It is a questionable strategy of the Defendants rather than to recognize the standing of CareToLive and its members and the public at large, to challenge and invite the interested parties to file individual suits throughout the country, which strategy would only insure that there are hundreds of law suits pending across the country versus just this one (which the government would just move to consolidate into one).

THE GOVERNMENT

The agency actions herein hurt the government itself. As more fully set forth in Plaintiffs Reply to Defendants Memorandum Contra Plaintiffs Motion for Injunctive Relief the FDA has acted publicly with regards to Provenge completely differently than they did privately and their ongoing refusal to account for their inconsistent actions to the public has harmed the government in that the public lose confidence in them. The individual Defendants Scher, Pazdur and von Eschenbach actions have hurt the agency and thus the government itself.

INVESTORS/ADVOCATES

Some of Plaintiffs members are investors turned advocates. It just so happens that a large part of the public that follows innovative new treatments on a daily basis is investors. Arguably investors are more quickly fine tuned to the latest technology than most other groups. It was investors that first understood the misconduct by the FDA and helped educate others as to the injustice. Advocacy groups such as Provenge Now and

CareToLive arose instantly to the discovery of misconduct. Many investors knowing that an injustice occurred became advocates and now fight for something much more meaningful than mere money.

Investors not privy to the inside information that funnels out of the FDA operated at a disadvantage to those that receive inside information from the agency and thus have also been hurt by the conduct of the FDA. The friends of the Dr. Scher's of the world have an advantage over other investors and investors have thus been damaged by the unlawful actions of the FDA, and the commissioner Andrew von Eschbach, by not taking action against employees that leak information to the investment community, has by not doing something in affect condoned the leaking of information from FDA employees to the financial industry, making the playing field unfair. There is no impugnable conflict in having investors fund a company that innovates in medicine and having an alignment of interests with patients wronged by bureaucratic omissions or misdeeds. Further discussion of just a few of the supporting advocacy groups is set forth below.

Standing exists when there is injury in fact, the injury is caused by the defendant, and the court can redress the injury. *Center for Individual Freedom v. Carmouche*, 449 F.3d 655, 659 (5th Cir.2006). Patients are dieing without hope that access to Provenge would provide. They ask that the FDA stop their nonsense and at least give them hope. The FDA's attitude that they are too busy and important to be bothered by a bunch of old men (patients) to even acknowledge the important of this matter is not understandable by the patients, their doctors and their family. That access is unreasonably and arbitrarily being denied by the FDA who is sworn to protect the public health and welfare and they

won't even act with a sense of urgency in addressing the mistake they have made is also met with astonishment from the patients. The Court should not accept the red hearing defense of the Defendants that suggests that Plaintiffs must at this stage prove the effectiveness of Provenge in order to show damages although Plaintiff has the ability to do so at a hearing and upon presentation of the administrative record. The courts focus at this stage of the proceedings should remain on whether the FDA decision is, or even just appears to be arbitrary and capricious. At this point all factual assertions of Plaintiff must be taken as true. Plaintiffs assert that Provenge is safe and effective and that the denial of Provenge is causing Plaintiffs needless pain and suffering and further that the actions of the FDA affect virtually the entire citizenry of this Country. The FDA may not have originally caused the patients' disease but there is an excellent chance it caused, through omission, its continuation.

In a case brought under the APA, standing has two components: a constitutional component and a prudential component. *Dismas Charities, Inc. v. U.S. Dep't of Justice, Fed. Bur. of Prisons*, 401 F.3d 666, 671 (6th Cir.2005). To satisfy the constitutional component of the standing inquiry, the plaintiff must demonstrate that it suffered “injury in fact,” that the injury is “fairly traceable” to the actions of the defendant, and that the injury is likely to be “redressed by a favorable decision.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Under the first prong of the standard, the injury must be “concrete and particularized” and must be “actual or imminent” rather than “conjectural or hypothetical.” *Bennett*, 520 U.S. at 167. *As this issue is before the court on a motion to dismiss, the bar for establishing the elements of standing is relatively modest. See id. at 167-68.* The harm alleged in this case may be redressed by a favorable decision in this

action. Provenge, despite the many obstacles thrown in its path by the FDA did all it was required to do to gain approval which is provide substantial evidence of efficacy and show that it is safe. That has been done.

To satisfy the prudential component of the standing inquiry, the plaintiff must demonstrate that it is “*arguably* within the zone of interests” intended to be protected or regulated by the statute. Bangura, 434 F.3d at 499 (citing Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co., 522 U.S. 479, 487-90 (1998)). The key question in this inquiry is “not whether the overall statute in question furthers goals shared by the plaintiff, but whether the particular statutory (or regulatory or constitutional) provision relied upon by the plaintiff to win in court protects the interests of someone in the plaintiff's position.” Dismas Charities, 401 F.3d at 673-74 (citing Bennett, 520 U.S. at 175-76). The FDA has completely ignored the Public's right in this matter and by their unlawful, arbitrary and capricious conduct is costing not only quality of life but life itself. The Defendants have not and cannot deny the FDA owes a duty to protect the health of the Public. Under former FDA commissioner McClellan the duty to the public was even raised:

McClellan symbolically signaled his new assertiveness overall when he changed the FDA's motto. Instead of the traditional 'protecting America's health,' it was now "protecting and advancing America's health." The FDA was not just reactive, inspecting the drugs and foods that were brought to it; it would also be proactive, helping drug companies develop new drugs more efficiently, helping generic drugs get on the market faster, helping doctors prescribe more effectively, and helping consumers stay healthy by eating right." Inside the FDA, Id. at p. 299

The FDA now has as part of its mission statement to get new innovative treatments to market more rapidly to improve the health of the public. Jesse Goodman,

head of CBER at the FDA also says that the FDA has to keep rethinking the way it approves drugs and biologics, including the use of smaller trials and different endpoints, *Inside the FDA, Fran Hawthorne, John Wiley & Sons, Inc. 2005 at p. 247*. The FDA is not being responsive to the public it serves. As the plaintiff has alleged facts to establish both constitutional and prudential standing, jurisdiction is appropriate.

§ 702. Right of review (See also section 706)

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.

The defendant FDA has set forth this idea that individual Plaintiffs must show specific hardship, although the plaintiffs allege no specific acts of enforcement by the FDA resulting in injury, such an allegation is unnecessary in this instance. The challenged decision is of such a nature that it need not be enforced against those in the class of the plaintiffs, that is, terminally ill patients, to affect their rights. Because the policy prohibits Dendreon from marketing and distributing Provenge, it bars *all patients* access even without any particular enforcement or threat against them directly. THE FDA actions cause Provenge to not be able to be prescribed, and distributed to them and the assertion that Dendreon would decide not to bring the product to market as soon as it possibly could, as it has repeatedly stated its intention to be, and forgo billions of dollars of sales is ludicrous. The Plaintiffs need not challenge a specific instance of enforcement against them. Furthermore, the defendants do not question the plaintiffs' assertion that the FDA's policy has had the effect of denying Provenge to the public or members CTL or all 100,000 estimated AIPC patients in the US. For these reasons, the case would benefit little if at all from the development of a particular factual setting. *See e.g., Wash. Legal*

Found., 880 F.Supp. at 36 (holding that whether an FDA policy violates the First Amendment is primarily a legal rather than a factual inquiry). Whatever minor benefit might emerge from a more concrete setting is more than offset by the alleged hardship the plaintiffs face upon delay of review-further denial of Provenge. *Abigail Alliance for Better Access to Developmental Drugs v. McClellan* L 3777340, *2 -8 (D.D.C.,2004). *Abigail Alliance for Better Access to Developmental Drugs v. McClellan* L 3777340, *2 -8 (D.D.C.,2004)(Court finding that the Abigail Alliance has demonstrated organizational standing and representational standing that are sufficient to survive a motion to dismiss).

Article III standing is a fundamental prerequisite to any exercise of our jurisdiction. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). A showing of standing requires, at the “irreducible constitutional minimum,” *id.*, that the litigant has suffered a concrete and particularized injury that is actual or imminent, traceable to the challenged act, and redressable by the court. *See Allen v. Wright*, 468 U.S. 737, 750-51, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984); *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 37-38, 96 S.Ct. 1917, 48 L.Ed.2d 450 (1976). An organization can have standing on its own behalf, *see Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378-79, 102 S.Ct. 1114, 71 L.Ed.2d 214 (1982); *Warth v. Seldin*, 422 U.S. 490, 511, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975), or on behalf of its members, *see United Food & Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 544, 553, 116 S.Ct. 1529, 134 L.Ed.2d 758 (1996); *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343, 97 S.Ct. 2434, 53 L.Ed.2d 383 (1977). At each stage of trial, the party invoking the court's jurisdiction must establish the predicates for standing “with the manner and degree of evidence required **at** **that stage of trial.** *Defenders of Wildlife*, 504 U.S. at 561, 112 S.Ct. 2130. *At the motion to dismiss stage*, “general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we ‘presum[e] that general allegations embrace those specific facts that are necessary to support the claim.’” *Id.* (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 889, 110 S.Ct. 3177, 111 L.Ed.2d 695 (1990)).

CTL alleges standing on its own behalf and on behalf of its members. The standard for representational standing is well-established:

[A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

United Food & Commercial Workers, 517 U.S. at 553, 116 S.Ct. 1529 (quoting *Hunt*, 432 U.S. at 343, 97 S.Ct. 2434).

Many CareToLive members would have a right to sue on their own behalf including the terminally ill patients (AIPC), their families and the doctors (and the John Doe Plaintiff should one of the members or other patient in Ohio pass away from AIPC after having been denied Provenge). CareToLive has made an adequate showing of standing, both as an organization and as a representative of its members to remedy any possible shortcomings in its original or amended complaint.

The patients have no other medically-feasible options, and due to FDA misconduct, the ignoring of congressional mandates and the refusal to approve Provenge has been denied access to a therapy, that has saved others' lives such as Bruce Tower, Ray Matyshyn, Eduardo Garcia, and Harry Petersik, just to name a few.

In so much as this Court wants the CTL standing assertion further identified in the pleadings themselves (complaint) the Plaintiffs would request leave for 7 days to so amend. *See* 28 U.S.C. § 1653; FED. R. CIV. P. 15(a). In addition the Plaintiff reminds the court that the allegations of the failure of the FDA to comply with the Freedom of Information Act (FOIA) is an actionable cause in its own right. Because of the weight of Plaintiffs amended complaint Plaintiff has not sought to further complicate the matter by seeking leave to amend to add that count but rather brought it by way of motion (Docket no. ____) pending before this court. If the court deems it necessary the FOIA claim can

be added as a count in the complaint at this time then again the Plaintiff seeks leave for 7 days to so amend the complaint (the FOIA claim alone is sufficient basis for the court to have jurisdiction as set forth in the FOIA and allow Plaintiff to move forward with some discovery and an injunctive hearing. The non compliance with the FOIA by the FDA is an action that by statute specifically vests this court with authority to hear it.

ORGANIZATIONAL AND THIRD PARTY STANDING

Plaintiff CareToLive is a not for profit corporation. It organized and began advocacy efforts almost immediately after the FDA actions complained of herein (shortly after May 8, 2007) (it was later incorporated as a not for profit corporation in Columbus, Ohio). It has a board a duly elected board of directors that includes directors and members who attended the June 4th rally in Washington DC and some of whom attended congressional briefings. One of the board members is Pete McGrath a prostate cancer survivor who upon any relapse would want Provenge and who may qualify for off label use of Provenge now. CareToLive has many members from all referenced groups who all have the goal of justice and reform at the FDA that starts with initial goal of approval of Provenge Now. CareToLive also has supporters throughout the country who are not members but who have funds donated to CareToLive and actively support and work to advance the activities of CareToLive including numerous other advocacy groups. One of CareToLives supporters is the Cancer Cure Coalition (<http://www.cancercurecoalition.org/>) founded by Charles Reinwald also a CareToLive member, who himself has prostate cancer and who delivered a compelling speech at the September 18th rally at the FDA (speech attached hereto as “Exhibit J”). Charles is also a

retired attorney who would like Provenge now. Provenge is also a therapy that the Abigail Alliance is currently advocating for access to.

There are currently an estimated 96,000 AIPC patients in the US. All of those patients would be eligible for Provenge according to the Dendreon proposed on label prescribed use. All of those patients should have at least the right to have Provenge after consultation with their doctors. That's 96,000 immediately affected by the FDA actions.

Plaintiff CareToLive contends that the actions of the FDA have caused the member group as an organization to suffer cognizable injuries that will continue without this court's intervention. "There is no question that an association may have standing in its own right to seek judicial relief from injury to itself and to vindicate whatever rights and immunities the association itself may enjoy." *Warth*, 422 U.S. at 511, 95 S.Ct. 2197. CareToLive seeks to help educate patients, doctors, families and the world about Provenge. CareToLive is expending much time and resources to educate and to help gain access to Provenge by the patients now. CareToLive and its members have been unable despite their efforts to obtain Provenge or even obtain rationale from the FDA why it denied Provenge and what role the undisclosed conflicts of interest and "leaked letters" played in the FDA decision for patients though they have been trying since May of 2007 to obtain it. CTL members continue to try to provide prostate cancer patients with information regarding Provenge and the availability and dynamics of Provenge and continue to educate patients. Until they learned it from CTL many patients thought that Provenge had in fact been approved and were surprised to find out otherwise. So long as the FDA continues to act in a dysfunctional and confidential manner CTL will seek to obtain accountability. CTL is currently still advocating to congress and seeking

congressional action as well. They also are in the process of educating doctors and specifically urologists about Provenge. On behalf of doctors and patients who cannot obtain information from, the FDA, CTL seeks that information for them and seeks to gain access to patients and doctors to Provenge so as to improve and extend their lives. The FDA's refusal to approve Provenge, although it has been proven safe and effective cause and refusal to account to the public means groups such as CTL must continue to expend resources that might be used in other patient advocacy and support.

The Defendants' conduct in this matter has frustrated CareToLives efforts to both assist its members and the public in accessing the safe and life-saving therapy called Provenge and obstructed its, advocacy, and educational services. Some patients have even gone to other countries in an effort to obtain immunotherapy. CTL engages in counseling, referral, advocacy, and educational services

The Supreme Court in *Havens Realty* found allegations of standing sufficient to withstand a motion to dismiss where an organization that provided counseling and referral services for home-seekers claimed that the defendants' actions led it “ ‘to devote significant resources to identify and counteract the defendant's [sic] racially discriminatory steering practices.’ ” 455 U.S. at 379, 102 S.Ct. 1114 (quoting plaintiff's complaint); see also *Metro. Wash. Airports Auth. v. Citizens for the Abatement of Aircraft Noise, Inc.*, 501 U.S. 252, 264-65, 111 S.Ct. 2298, 115 L.Ed.2d 236 (1991).

The courts have applied *Havens Realty* to justify organizational standing in a wide range of circumstances. See, e.g., *Fair Employment Council of Greater Wash., Inc. v. BMC Mktg. Corp.*, 28 F.3d 1268, 1276 (D.C.Cir.1994); *Haitian Refugee Ctr. v. Gracey*,

809 F.2d 794, 799 (D.C.Cir.1987); *Action Alliance of Senior Citizens v. Heckler*, 789 F.2d 931, 936-39 (D.C.Cir.1986). The court has distinguished between organizations that allege that their activities have been impeded from those that merely allege that their mission has been compromised. *See Nat'l Treasury Employees Union v. United States*, 101 F.3d 1423, 1429-30 (D.C.Cir.1996). CTL has met this threshold by alleging that it actively engages in “counseling, referral, advocacy, and educational services; *see also Competitive Enter. Inst. v. NHTSA*, 901 F.2d 107, 122 (D.C.Cir.1990); *Action Alliance*, 789 F.2d at 938 & n. 7. Moreover, CTL alleges that this injury is directly attributable to FDA policies and practices, *see Rainbow/PUSH Coalition v. FCC*, 396 F.3d 1235, 1240-42 (D.C.Cir.2005).

The FDA presents no good arguments that counsel against finding that the CTL's allegations of organizational standing are sufficient.

Abigail Alliance for Better Access to Developmental Drugs v. McClellan L 3777340, *2 -8 (D.D.C.,2004).

Although the FDA suggests that holding the Abigail has standing would allow “public interest organizations to bring legal challenges at will to any and all regulations (and statutes) that they dislike,”regarding Article III Standing at 3, our holding does not relax the standing requirements. For standing to be based upon injury to the organization's activities there must still be a direct conflict between the defendant's conduct and the organization's mission. *See Nat'l Treasury Employees Union*, 101 F.3d at 1430.

Significantly this case has several arguments that make the CTL organizational standing argument much more compelling in this case. 1) First, CTL is not challenging an administrative policy in general rather it challenges specific unlawful and arbitrary and

capricious conduct of the FDA. CTL challenges conduct which is as far as can be determined an action that is first of its kind. This is unprecedented. There has never before been a factual basis of wrong doing at the FDA the likes of what is demonstrated herein. 2) *Second, the CTL seeks to represent all 96,000 AIPC cancer patients and asserts that these patients are unable to affectively represent themselves.* The average AIPC patient is a 70 year old man that has an average life expectancy of 19 months from the date of diagnosis. As set forth in Plaintiffs amended complaint these men are the sickest of sick. This is not AIDS or breast cancer or some other life threatening condition where there are various age and conditions of individuals. These men at this age and infirmity are unable to effectively fight the FDA individually and be expected to individually hire an attorney, fund complex litigation, attend court hearings and depositions, educate counsel on all the issues and otherwise proceed on their own. This class of 96,000 AIPC patients is quite different then some other classes of non-terminal patients. Many of the patients if they now had to file individual law suits against the FDA to obtain the relief sought, will have passed away before they could obtain any relief. The cost of these individual suits (that the FDA would then move to consolidate) would be enormous and AIPC patients would be unable to obtain relief due to their infirmities and the cost. Not only is this an elderly and very sick group of patients they generally are men with a disease that men do not like to discuss or even publicly acknowledge. This is one of the reasons the FDA thought they could get away with treating this class unequally. It makes no sense seeing that it may take an order from this court to help many of the 96,000 AIPC patients.

Our jurisprudence recognizes third-party standing under certain circumstances. *Campbell v. Louisiana*, 523 U.S. 392, 397-98, 118 S.Ct. 1419, 140 L.Ed.2d 551 (1998); *see also Hodel v. Irving*, 481 U.S. 704, 711, 107 S.Ct. 2076, 95 L.Ed.2d 668 (1987) (acknowledging general rule that party must assert own interests is “subject to exceptions”). For instance, doctors may be able to assert the rights of patients; lawyers may be able to assert the rights of clients; vendors may be able to assert the rights of customers; and candidates for public office may be able to assert the rights of voters. *See, e.g., Caplin & Drysdale, Chartered v. United States*, 491 U.S. 617, 109 S.Ct. 2646 (1989) (holding lawyer could bring Sixth Amendment lawsuit on behalf of criminal defendant); *Singleton*, 428 U.S. 106, 96 S.Ct. 2868, 49 L.Ed.2d 826 (conferring standing on physicians on behalf of patients to challenge a statute that excluded funding for abortions from Medicaid benefits); *Craig*, 429 U.S. 190, 97 S.Ct. 451, 50 L.Ed.2d 397 (allowing vendor to challenge statute that prohibited males under age of twenty-one from buying beer); *Mancuso v. Taft*, 476 F.2d 187 (1st Cir.1973) (permitting candidate for public office to raise voters' rights).

In particular, if a course of conduct “prevents a third-party from entering into a relationship with the litigant (typically a contractual relationship), to which relationship the third party has a legal entitlement,” third-party standing may be appropriate. *United States Dep't of Labor v. Triplett*, 494 U.S. 715, 720, 110 S.Ct. 1428, 108 L.Ed.2d 701 (1990); *see also Munson*, 467 U.S. at 954-58, 104 S.Ct. 2839 (fundraiser had third-party standing to challenge statute limiting fees charitable organizations could pay because law infringed on organizations' right to hire fundraiser for a higher fee). Typically AIPC patients are 70 year old men with 19 months or less to live. They generally depend on to

others to help them in day to day activities are severally depressed and do not wish to disclose or discuss their condition with others.

The Supreme Court has found that the principles animating these prudential concerns are not subverted if the third party is hindered from asserting its own rights and shares an identity of interests with the plaintiff. *See Craig*, 429 U.S. at 193-94, 97 S.Ct. 451; *Singleton*, 428 U.S. at 114-15, 96 S.Ct. 2868; *Eisenstadt v. Baird*, 405 U.S. 438, 443-46, 92 S.Ct. 1029, 31 L.Ed.2d 349 (1972). More specifically, third-party standing requires the satisfaction of three preconditions: 1) the plaintiff must suffer injury; 2) the plaintiff and the third party must have a “close relationship”; (such as doctor-patient)(added) and 3) the third party must face some obstacles that prevent it from pursuing*289 its own claims. *Campbell*, 523 U.S. at 397, 118 S.Ct. 1419; *Powers*, 499 U.S. at 411, 111 S.Ct. 1364; *The Pitt News*, 215 F.3d at 362. It remains for courts to balance these factors to determine if third-party standing is warranted. *Amato*, 952 F.2d at 750. *See, Pennsylvania Psychiatric Soc. v. Green Spring Health Services, Inc.* 280 F.3d 278, *287 -293 (C.A.3 (Pa.),2002):

Although the Pennsylvania Psychiatric Society itself has not suffered direct injury, it is uncontested that it properly pleaded that defendants' policies and procedures have economically injured its member psychiatrists and undermined their ability to provide quality health care. Thus, while the Society does not itself stand in an appropriate relationship to the patients' claims to directly assert them, its members may have third-party standing to do so.^{FN11} And because plaintiff seeks to establish standing on the basis of its members' standing to bring these claims, the members are the appropriate focus of inquiry for these purposes.

The District Court held-and the dissent argues-that the Pennsylvania Psychiatric Society could not raise these claims because it did not itself suffer injury. Injury to the Society, however, is not relevant to the issue of the psychiatrists' standing to bring the patients' claims. Because of the Society's posture, that is the initial question to be resolved. Only after it is determined that the member psychiatrists

would have third-party standing over these claims do we assess whether the Society can bring its members' third-party claims.

We next turn to whether the psychiatrists and their patients have a sufficiently “close relationship” which will permit the physicians to effectively advance their patients' claims. To meet this standard, this relationship must permit the psychiatrists to operate “fully, or very nearly, as effective a proponent” of their patients' rights as the patients themselves.^{FN12} *Powers*, 499 U.S. at 413, 111 S.Ct. 1364 (quoting *Singleton*, 428 U.S. at 115, 96 S.Ct. 2868).

Courts have generally recognized physicians' authority to pursue the claims of their patients. *Am. Coll. of Obstetricians & Gynecologists v. Thornburgh*, 737 F.2d 283, 290 & n. 6 (3d Cir.1984) (collecting cases where physicians allowed to assert patients' claims); see also *Planned Parenthood v. Farmer*, 220 F.3d 127, 147 & n. 10 (3d Cir.2000).

The patients' relationships with their psychiatrists fulfills this requirement. See *supra* note 12. In *Singleton v. Wulff*, the Supreme Court granted physicians third-party standing on behalf of their patients to challenge a statute prohibiting Medicaid funding for certain abortions. 428 U.S. 106, 96 S.Ct. 2868, 49 L.Ed.2d 826. Because of the inherent closeness of the doctor-patient relationship, the plurality found the physicians could efficaciously advocate their patients' interests. *Id.* at 117, 96 S.Ct. 2868 (noting “abortion decision is one in which the physician is intimately involved”). The relationship forged between psychiatrists and their patients is equally compelling.

.....

Finally, we examine whether the mental health patients face obstacles to pursuing litigation themselves. This criterion does not require an absolute bar from suit, but “some hindrance to the third party's ability to protect his or her own interests,” *Powers*, 499 U.S. at 411, 111 S.Ct. 1364. In other words, a party need not face insurmountable hurdles to warrant third-party standing.^{FN14} *Id.* at 415, 111 S.Ct. 1364 (holding excluded juror's limited incentive to bring discrimination suit satisfied obstacle requirement for criminal defendant to merit third-party standing); *Singleton*, 428 U.S. at 117, 96 S.Ct. 2868 (recognizing lawsuit's invasion of patient's privacy and “imminent mootness” of pregnancy sufficiently impeded patient from bringing suit herself). The District Court found the patients' mental health problems did not significantly hinder them from suing. We disagree.

FN14. One treatise insists that “cases do not demand an absolute impossibility of suit in order to fall within the [impediment] exception. At the other end of the spectrum, a practical disincentive to sue may suffice, although a mere disincentive is less persuasive than a concrete impediment.” 15 James Wm. Moore et al., *Moore's Federal Practice* § 101.51 [3][c].

.....

Because the third-party claims asserted by the Pennsylvania Psychiatric Society do not implicate any constitutional rights of the psychiatrists' patients, the MCOs contend that granting third-party standing is unwarranted. While successful third-party standing claims have involved alleged violations of third parties' constitutional rights, *Singleton* and its progeny have not stipulated that constitutional claims are a prerequisite.^{FN15} It is true that the rule against third-party standing “normally bars litigants from asserting the rights or legal interests of others in order to obtain relief from injury to themselves.” *Warth*, 422 U.S. at 509, 95 S.Ct. 2197. Furthermore, the Supreme Court has noted that courts must consider “the relationship of the litigant to the person whose rights are being asserted; the ability of the person to advance his own rights; and the impact of the litigation on third-party interests.” *Caplin & Drysdale*, 491 U.S. at 623 n. 3, 109 S.Ct. 2646. But the Court has not held that a constitutional claim must also be alleged, *see, e.g., Powers*, 499 U.S. at 410-11, 111 S.Ct. 1364, and absent further guidance, we will not impose this requirement. For these reasons, we hold the Pennsylvania Psychiatric Society's member psychiatrists would have third-party standing to assert the claims of their patients.

STANDING SUMMARY

This is not a tenuous standing case alleging vague aesthetic or environmental harms. CTL's members are suffering pain, shortened lives, and death as a direct and natural result of being denied access to Provenge that may very well help them (no viable alternatives). For standing to be proper, it must be that the injury “fairly can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party not before the court.” *E. Ky. Welfare Rights Org.*, 426 U.S. at 41-42, 96 S.Ct. 1917. The FDA claims that CTL members have not properly sought individual-use approval and that their inability to access Provenge cannot be attributed to the FDA. Stephen Study's letters are an example of just that kind of effort.

CTL's terminally-ill members cannot be required to apply for individual-use approval from the agency when the FDA procedures they challenge are "effectively inoperative," (an affidavit or testimony from others on this issue such as Steven Walker co-founder of the Abigail Alliance can be presented at a hearing of this matter or supplemented), and make success virtually impossible. Such statement will indicate that the process (as well as the petition process above), requests for individual use "are in all material and regulatory aspects clinical trials that effectively cannot be requested or initiated by any patient or any physician." The net result is that for this approach to succeed, a sponsor must have a preexisting program approved by the FDA, an Institutional Review Board must grant its approval, and the patient must meet the restrictive eligibility requirements of the sort that fail time and again. See also above referenced letter from Stephen Study. The efforts of Stephen and his father are an example of the fundamental failings of the agencies access programs and it was only with Stephen's help that his Dad was even able to make the effort he did to get help from the FDA. Most 70 year old dying AIPC patients lack the will, knowledge, expertise and assistance required to try cut through the FDA bureaucratic red tape. Not to mention they often suffer from extreme and debilitating depression. Furthermore, the FDA has an acknowledged "private stance on expanded access" that, unsurprisingly, pharmaceutical companies awaiting approval are unwilling to violate. The CTL members cannot obtain Provenge until the FDA approves it.

The FDA challenges redressability on the grounds that, even if its regulations were changed, it is merely speculation that Dendreon would sell Provenge to members of the CTL. Here, it would be in the drug companies' pecuniary interests to sell

Provenge, particularly if the FDA allows them to charge market prices. This makes the question of redressability a hardly-speculative exercise in naked capitalism. The FDA also maintains that elimination of the regulation would not change the FDA's alleged hostility to access or the drug companies' fear of reprisal, but the agency's perceived hostility to access will no doubt diminish if it rescinds the regulation that sets up the barrier to compassionate use programs in the first place.

All AIPC patients have exhausted all standard treatments for earlier stages of prostate cancer. Their injury-in-fact is their inability to obtain a potentially life-saving treatment that is stipulated to be safe by the FDA.

Even if CTL did not supply a particular terminally-ill member, at each moment, who has exhausted all conventional treatments but has not died, this is a classic case of a situation “capable of repetition, yet evading review.” *S. Pac. Terminal Co. v. ICC*, 219 U.S. 498, 515, 31 S.Ct. 279, 55 L.Ed. 310 (1911). By the very nature of its membership, the CTL has a reasonable expectation that its members will continue to suffer the same short-lived injuries that this doctrine addresses. *Cf. Weinstein v. Bradford*, 423 U.S. 147, 149, 96 S.Ct. 347, 46 L.Ed.2d 350 (1975) (per curiam); *Sosna*, 419 U.S. at 402, 95 S.Ct. 553. CTL members also suffer individual injury in fact.

DUE PROCESS

The Plaintiffs seek enforcement of a narrowly defined constitutional finding of this Court but submits since Courts are not supposed to make constitutional rulings until

they are absolutely necessary that at this stage of the proceedings the Court need not make constitutional decisions. Although the Plaintiffs seek a constitutional finding, narrowly defined, that there is a fundamental right of due process to late stage cancer patients who have no reasonable alternative treatments available where their only alternative to the treatment is death without hope, that have a right to access to a proven safe and effective treatment. Although Abigail, supra, might be headed to the Supreme Court (giving this court more guidance in the future or the broader issue general labeled as a right to life the CTL seeks more of a basic determination of a right to survive). More narrowly and specifically the question posed is: “Do late stage cancer patients with no viable treatment options have a right to meaningful access to safe and potentially life saving treatment?”. Plaintiffs say yes.

A fundamental constitutional right of survivorship is long recognized and existed even before written law. The right is as old as it gets. CTL also claims that they have actions based on intentional constitutional torts, denial of equal protection, interference with a third parties attempts to provide aid to those in peril, as well as relief under the APA, FOIA and section 1985 and 1986 questions (which contrary to Defendant assertions involve state action as the states regulate and license the doctors and the states will not let the doctors prescribe Provenge unless it is first approved by the FDA). The court can find in favor of Plaintiffs without reaching the constitutional question.

Such decisions to be made by terminally ill patients with no approved treatment options have a constitutionally protected right to decide for themselves whether to pursue access to Provenge that the FDA concedes is safe. These decision whether to use such a

treatment should be made between a doctor and his patient and not by the government in Washington.

The Plaintiffs are at the very least entitled to have a procedural due process, which process not be arbitrary and capricious, before they are denied a possibly life saving and life enhancing therapy. Plaintiffs will prevail no matter if the determination is that merely a rational basis is required to justify the agencies decision or whether the stricter standard is applied because Plaintiff asserts that it can and will demonstrate that the agencies action was arbitrary and capricious.

Further evidence on the denial of equal protection claims and procedural due process claims can be presented after discovery. The injury, is to these patients' liberty and privacy-not just to their health. But even if this Court requires allegations of injury to life or health, such injuries are abundant here and directly result from the FDA's actions. The FDA's speculations are inconsistent with its other arguments in this case, legally inappropriate, factually wrong, and completely intertwined with the merits. *Clinton v. City of New York*, 524 U.S. 417, 433 n.22 (1998); *see also, e.g., Northeastern Fla. Ch., Associated Gen. Contractors of Am. v. Jacksonville*, 508 U.S. 656, 666 (1993) (“The ‘injury-in-fact’ in an equal protection case of this variety is the denial of equal treatment resulting from the imposition of the barrier, not the ultimate inability to obtain the benefit.”).

Should the Court be interested in what Plaintiff consider is a premature constitutional determination then it offers the following: In a long line of cases, courts have held that, in addition to the specific freedoms protected by the Bill of Rights, the

“liberty” specially protected by the Due Process Clause includes the rights to marry, **394 *137 *Loving v. Virginia*, 388 U.S. 1, 87 S.Ct. 1817, 18 L.Ed.2d 1010 (1967); to have children, *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 62 S.Ct. 1110, 86 L.Ed. 1655 (1942); to direct the education and upbringing of one's children, *Meyer v. Nebraska*, 262 U.S. 390, 43 S.Ct. 625, 67 L.Ed. 1042 (1923); *Pierce v. Society of Sisters*, 268 U.S. 510, 45 S.Ct. 571, 69 L.Ed. 1070 (1925); to marital privacy, *Griswold v. Connecticut*, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965); to use contraception, *ibid.*; *Eisenstadt v. Baird*, 405 U.S. 438, 92 S.Ct. 1029, 31 L.Ed.2d 349 (1972); to bodily integrity, *Rochin v. California*, 342 U.S. 165, 72 S.Ct. 205, 96 L.Ed. 183 (1952), and to abortion, [*Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992)]. We have also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment. *Cruzan* [*v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990)].

The Supreme Court precedent on liberty indicates that the right claimed by CTL can be inferred from the Court's conclusion in *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 278, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990), that an individual has a due process right to refuse life-sustaining medical treatment, *id.* at 279, 110 S.Ct. 2841. Here, the claim implicates a similar right—the right to access safe and at least potentially life-sustaining medication where there are no alternative government-approved treatment options. *In both instances, the key is the patient's right to make the decision about her life free from unwarranted government interference.*

The Due Process Clause of the Fifth Amendment to the United States Constitution provides that “[n]o person shall be ... deprived of life, liberty, or property, without due process of law.” U.S. CONST. AMEND. V. The Supreme Court has held that the Clause “guarantees more than fair process” and accords substantive protection to the rights it guarantees. *See Troxel v. Granville*, 530 U.S. 57, 65, 120 S.Ct. 2054, 147 L.Ed.2d 49 (2000) (plurality opinion); *Glucksberg*, 521 U.S. at 719, 117 S.Ct. 2258; *Flores*, 507 U.S. at 301-02, 113 S.Ct. 1439. Substantive due process claims can present difficulties for courts. *See Michael H. v. Gerald D.*, 491 U.S. 110, 121, 109 S.Ct. 2333, 105 L.Ed.2d 91 (1989) (plurality opinion); *Moore v. City of East Cleveland*, 431 U.S. 494, 502, 97 S.Ct. 1932, 52 L.Ed.2d 531 (1977). In a case of first impression where fundamental rights may be at stake, determining the limits of the government's authority over an individual's freedom to make certain personal decisions unavoidably entails a careful and possibly arduous assessment of that personal decision's objective characteristics in order to determine whether it warrants protection under the Due Process Clause. *Cf. Roberts v. U.S. Jaycees*, 468 U.S. 609, 620, 104 S.Ct. 3244, 82 L.Ed.2d 462 (1984).

It appears the Supreme Court has employed two distinct approaches when faced with a claim to a fundamental right. In some cases, the Court has discerned the existence of fundamental rights by probing what “personal dignity and autonomy” demand. *See Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 851, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992) (citations omitted). In other cases, the Court has derived fundamental rights by reference to the Nation's history and legal tradition, *see, e.g., Glucksberg*, 521 U.S. 702, 117 S.Ct. 2258. The line of cases beginning with *Griswold v. Connecticut*, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965), and continuing

through *Eisenstadt v. Baird*, 405 U.S. 438, 92 S.Ct. 1029, 31 L.Ed.2d 349 (1972), *Roe v. Wade*, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973), and *Casey*, 505 U.S. 833, 112 S.Ct. 2791, Although it is relevant to the substantive due process analysis that the government has never prescribed the desired conduct, this is not dispositive. The absence of regulation could be attributable to a liberty interest that is deeply rooted in this Nation's history and tradition, and therefore characterized by a history of liberty from governmental interference, but there may be another explanation. For example, a lack of regulation might indicate only that the technology of yesteryear did not warrant it.

Contrary to Defendants assertions drugs were unregulated for most of our Nation's history, and the added condition of substantial evidence of efficacy is historically very recent. *Glucksberg* supports CTL's due process claim.

A right of control over one's body has deep roots in the common law. The venerable commentator on the common law William Blackstone wrote that the right to "personal security" includes "a person's legal and uninterrupted enjoyment of his life, his limbs, his body, [and] his health," as well as "the preservation of a man's health from such practices as may prejudice or annoy it." WILLIAM BLACKSTONE, 1 COMMENTARIES *125, *130. This right included the right to self-defense and the right to self-preservation. "For whatever is done by a man, to save either life or member, is looked upon as done upon the highest necessity and compulsion. "As recognized throughout Anglo-American history and law, when a person is faced with death, necessity often warrants extraordinary measures not otherwise justified. Indeed the principle holds even when that action impinges upon the rights of others. *See, e.g., Ploof v. Putnam*, 81 Vt. 471, 475, 71 A. 188 (1908) ("This doctrine of necessity applies with

special force to the preservation of human life.... One may sacrifice the personal property of another to save his life or the lives of his fellows.”) (internal citation omitted); *Mouse's Case*, 77 Eng. Rep. 1341, 1342 (K.B.1609) (deciding that it is lawful to throw overboard property of another for safety of lives of passengers); RESTATEMENT (FIRST) OF TORTS § 197 (1934); *see generally* George C. Christie, *The Defense of Necessity Considered from the Legal and Moral Points of View*, 48 DUKE L.J. 975 (1996). *But see The Queen v. Dudley and Stephens*, 14 Q.B.D. 273 (1884) (holding that the defense of necessity did not justify taking of innocent life). Barring a terminally ill patient from the use of a potentially life-saving treatment impinges on this right of self-preservation.

Such a bar also puts the FDA in the position of interfering with efforts that could save a terminally ill patient's life. Although the common law imposes no general duty to rescue or to preserve a life, it does create liability for interfering with such efforts. Section 326 of the Restatement (First) of Torts, first published in 1934, explained that one who, without a privilege to do so, intentionally prevents a third person from giving to another aid necessary to his bodily security, is liable for bodily harm caused to the other by the absence of aid which he has prevented the third person from giving.

While infrequently invoked, this common law rule is of venerable vintage. *See id.*; *see also Soldano v. O'Daniels*, 141 Cal.App.3d 443, 190 Cal.Rptr. 310, 313, 316-18 (1983); *Miller v. Arnal Corp.*, 129 Ariz. 484, 632 P.2d 987, 993 (App.1981).^{FN12}

Due to the weight and importance of this case, this court should not expect perfection in the pleadings. Because this case is in the early stages no prejudice would be caused to Defendants should any amendments to the complaint be necessary or later required including the FOIA claims. 28 U.S.C. § 1653 expressly provides that “[d]efective allegations of jurisdiction may be amended, upon terms, in the trial or appellate courts.” Nothing set forth herein or in the Plaintiffs’ other motions and memorandums is inconsistent with the allegations in Plaintiffs’ amended complaint. Leave should always be freely allowed “so as to effectuate Congress’ intent in enacting [Section] 1653-to avoid dismissals on technical grounds.” *Miller v. Davis*, 507 F.2d 308, 311 (6th Cir. 1974); *see also Goble v. Marsh*, 684 F.2d 12, 17 (D.C. Cir. 1982). This court is reminded of the doctrines of Equity and fundamental fairness.

It is well settled that the loss of certain rights can constitute sufficient injury-in-fact without a showing of additional practical consequences stemming from the violation. For instance, in the Equal Protection context the Supreme Court has repeatedly observed that “a denial of a benefit in the bargaining process can itself create an Article III injury, irrespective of the end result.”¹ Plaintiffs challenging affirmative action programs need not show that they would have been admitted but for the program, because the injury is not the loss of a job or education but loss of the right to be considered fairly. *See Price Waterhouse v. Hopkins*, 490 U.S. 228, 265 (1989) (O’Connor, J., concurring in judgment)

Similarly “the loss of a procedural right ‘is itself an injury’ sufficient to provide standing ‘without any requirement of a showing of further injury.’ *Wessel v. City of Albuquerque*, 299 F.3d 1186, 1193 (10th Cir. 2002) (quoting *Bertulli v. Indep. Ass’n of Cont’l Pilots*, 242 F.3d 290, 295 (5th Cir. 2001); *see also Zivotofsky v. Sec’y of State*, 444

F.3d 614, 620 (D.C. Cir. 2006) (“Although it is natural to think of an injury in terms of some economic, physical, or psychological damage, a concrete and particular injury for standing purposes can also consist of the violation of an individual right conferred on a person by statute.”).

If violations of rights sounding in equality and procedural fairness constitute sufficient injury, without more, then the same must be true of constitutional rights, like this one, sounding in the protected interests of liberty and privacy. Forcing patients to beg for permission from FDA officials is a fully realized violation of their constitutionally protected liberty and autonomy sufficient to satisfy Article III, without regard to what the FDA or the drug company decides to do. A statute vesting in some official the substantive discretion to deny wedding licenses on the ground that the bride and the groom are of a different race is unconstitutional on its face even if that discretion is never exercised. The same would be true (although on Due Process rather than Equal Protection grounds) if the statute conferred discretion to deny licenses on the ground that the official thinks the couple is not a good match. This case presents a similar injury.

Properly understood, that injury to liberty and privacy is self-evidently caused by the regulations challenged here, and would be redressed by a favorable decision. The FDA's speculation about what drug companies would do if the FDA ceased its interference is irrelevant. It is also inappropriate. As Judge Bork observed in *Haitian Refugee Center v. Gracey*, 809 F.2d 794, 801 (D.C. Cir. 1987),

When the Supreme Court has granted standing to a litigant who claims injury to his ability to act together with a third party not before *7 the court, the litigant typically has challenged a statute that produced injury by placing him under a legal prohibition against engaging in conduct together with the third party. This

legal prohibition causes an injury to the litigant sufficient to confer standing apart from any prediction about the third party's actions.

Judge Bork drew support from the Supreme Court's decisions in *Craig v. Boren*, 429 U.S. 190 (1976), where the Court held that a beer vendor had standing to challenge a statute prohibiting the sale of beer to nineteen year-old men without allegations or proof that the vendor would have nineteen year-old male customers absent the ban, and *Doe v. Bolton*, 410 U.S. 179 (1973), where the Court granted standing to physicians challenging an abortion ban without requiring that they show that patients would request abortions in the absence of the ban. The case for standing here is even stronger than in *Craig v. Boren* and *Doe v. Bolton*, because these patients are not asserting a third party's interests, but their own.

That is not simply speculation. Provenge was voted overwhelmingly to be safe and effective by the expert advisory committee and Provenge is specifically designed to target the particular disease afflicting CTL members. This case cannot be dismissed on causation or redressability grounds without giving CTL a chance to obtain discovery and make its case. If the pleading requirements were set so high that the allegations and averments now in the record do not suffice, plaintiffs would be unfairly deprived of the opportunity to test the allegations at the fact finding stage. *Cf. Am. Library Ass'n v. FCC*, 401 F.3d 489, 493 (D.C. Cir. 2005) (noting that overly stringent pleading rules “would waste, rather than conserve, judicial resources and place an unnecessary burden on litigants”).

The FDA invites this court to speculate that the real barrier to access for these patients is not the FDA, but instead is either their own failure to request a discretionary exemption from the FDA under the “treatment IND” program, or a drug company's unwillingness to make the drugs available no matter what the FDA says. As explained above, when a statute prohibits a party from dealing or acting jointly with a third party, courts do not require the litigant to prove what the third party would do but for the

prohibition. And, of course, such speculation is inconsistent with the FDA's own representations to this court.

It is no more speculative to accept that drug companies are in the business of making medicines available for a reasonable profit, if not prohibited from doing so, than it was for the Supreme Court to assume in *Craig v. Boren* that nineteen year old men will choose to purchase beer if permitted. Courts refuse to respect allegations of injury only where a plaintiff relied upon “unadorned speculation” to draw the causal link between the injury and the challenged conduct. *See, e.g., Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26 (1976); *Warth*, 422 U.S. at 504. If anyone is speculating here, it is the FDA not Plaintiffs.

Procedurally the FDA has made the contention that the Plaintiffs’ “propounded interrogatories to members of FDA’s advisory committee”. What the Plaintiffs did was seek to obtain affidavits of favorable testimony from stipulated expert witnesses to assist in presenting facts and opinions to this court to in order to assist this court in deciding the issues herein. The effort was to impose minimal burdens on thirteen (13) expert plaintiff witnesses, who all believe Provenge is safe and effective. Those efforts, as well as other efforts of the Plaintiffs to obtain its evidence, has been stymied and blocked by Defendants. Defendant also state they “do not question the legitimacy of their desire for access to safe and effective alternative treatments”. Isn’t that precisely what Defendant seek to do?

The Federal Food Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 321 *et seq.*, provides a systematic scheme for the approval of new drugs and new drug formulations

intended to be marketed for use in interstate commerce. Under the FDCA, a new drug product cannot be marketed unless the FDA approves the product and determines that it is safe and effective for its intended use. *See* 21 U.S.C. § 355(a). There is no full access until FDA approves Provenge.

Here the Plaintiffs seek access to a specific therapy that has completed phase one, phase two and two phase three studies and which was over whelming approved by a panel of 17 experts selected by the FDA and has been proven to be safe and effective for use by terminal patients with no other viable alternative then death. The agencies specific unlawful, arbitrary and capricious actions are at issue here no matter the standard applied.

Next, defendants argue that the court should abstain from deciding this case in deference to the “primary jurisdiction” of the FDA. The doctrine of primary jurisdiction is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties and applies where a claim that is originally cognizable in courts “requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body,” *United States v. Western Pacific R.R. Co.*, 352 U.S. 59, 63-64, 77 S.Ct. 161, 1 L.Ed.2d 126 (1956). In deciding whether to apply the primary jurisdiction doctrine, a court should take into account the doctrine's two primary interests: resolving technical questions of fact through an agency's specialized expertise prior to judicial consideration of the legal claims and consistency and uniformity in the regulation of an area which Congress has entrusted to a specific agency. *See, e.g., Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290, 303-04, 96 S.Ct. 1978, 48 L.Ed.2d 643 (1976). In the past, the doctrine has been applied in matters that required the FDA's special expertise to resolve an issue in the

first instance. *See, e.g., Rutherford v. Am. Med. Ass'n*, 379 F.2d 641 (7th Cir.1967); *Tutoki v. Celebrezze*, 375 F.2d 105 (7th Cir.1967). In this case, it is unclear what issues, if any, defendants want the FDA to resolve. Both the FDA and now this court has the AC hearing transcript and thus the opinion of 17 experts to help it decide. The FDA had many chances to pass on Provenge but they *accepted the data as sufficient* at every step right through the AC hearing. Then inexplicably denied it shortly after the AC hearing stating they wanted even more data that they had presumably on several occasions already decided was sufficient enough to empanel an expert advisory committee. It demonstrates that the FDA already had an opportunity to pass on the issue in the first instance but instead took Provenge through public process successfully only to derail it in private (instead of passing at any step they had a hearing and then issued a CR letter that was inapposite to the hearing results). The failure to even offer a rational explanation renders Defendants argument that their decisions anything but capricious, a nullity. This court should find that the doctrine of primary jurisdiction is applicable due to the facts of this case, and defendants' motion to dismiss should be denied with respect to their request that the court abstain from hearing this case in deference to the FDA.

Finally, the Defendants argue that Provenge is a new drug subject to FDA regulation. Plaintiffs assert that the decision on this particular issue must be made by the FDA alone and that that sole issues must be returned to them with an order for such a determination *Rutherford v. U.S.* 582 F.2d 1234, *1236 (C.A.Okl.,1978).

Immunity

Under the APA and FOIA the government has specifically waived immunity. This action is brought under the APA and FOIA and alleges intentional torts that rise to the level of constitutional malice. There is also equal protection claims that must be accepted as true at least at this stage of the proceedings.

There is no immunity for intentional conduct done with malice that rises to the level of a constitutional tort inside or actions outside the scope of employment. Neither the government itself nor the government officials Dr. von Eschenbach, Dr. Scher and Dr. Pazdur have immunity from being sued. Qualified immunity provides that government officials are shielded from liability in their individual capacity “for civil damages insofar as their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known.” *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982). A qualified immunity defense “provides ample protection to all but the plainly incompetent or those *who knowingly violate the law*.” *Malley v. Briggs*, 475 U.S. 335, 341 (1986).

The guidelines for determining whether Congress has waived sovereign immunity as to a particular agency were developed in the trilogy of Supreme Court opinions in *Keifer & Keifer v. R. F. C.*, 306 U.S. 381, 59 S.Ct. 516, 83 L.Ed. 784 (1939); *F. H. A. v. Burr*, 309 U.S. 242, 60 S.Ct. 488, 84 L.Ed. 724 (1940), and *R. F. C. v. Menihan Corp.*, 312 U.S. 81, 61 S.Ct. 485, 85 L.Ed. 595 (1941); See also *Standard Oil Div., American Oil Co. v. Starks*, 528 F.2d 201 (7th Cir. 1975). In *Keifer & Keifer*, 306 U.S. at 388, 59 S.Ct. at 517, the Court established that “the government does not become the conduit of its immunity in suits against its agents or instrumentalities merely because they do its

work.” In *F. H. A. v. Burr*, 309 U.S. at 245, 60 S.Ct. at 490, the Court stated that, in the absence of a contrary showing, “(I)t must be presumed that when Congress launched a governmental agency into the commercial world and endowed it with authority to ‘sue and be sued,’ that agency is not less amenable to judicial process than a private enterprise under the circumstances would be.” And in *Menihan Corp.*, 312 U.S. at 85, 61 S.Ct. at 487, the Court announced, “We apply the farther (sic) principle that the words ‘sue and be sued’ (in the statute creating the R.F.C.) normally include the natural and appropriate incidents of legal proceedings.” See also *Buchanan v. Alexander*, 4 How. (U.S.) 20, 11 L.Ed. 857 (1846); *Scott, The Government as a Garnishee*, 16 Ind.L.J. 545 (1941). The FDA also has the ability to sue others and has done so and routinely takes enforcement actions much like a police agency.

In Butz v. Economou, 438 U.S. 478, 98 S.Ct. 2894, 57 L.Ed.2d 895 (1978), and our decision in *Kwoun v. Southeast Mo. Prof. Stands. Rev. Org.*, 811 F.2d 401 (8th Cir.1987), *cert. denied*, 486 U.S. 1022, 108 S.Ct. 1994, 100 L.Ed.2d 226 (1988). In *Butz* the Supreme Court rejected the argument that federal officials are broadly entitled to absolute immunity for executive and administrative actions. Instead, the Court limited absolute immunity to those who participate in agency adjudications, where such immunity is appropriate because “federal administrative law requires that agency adjudication contain many of the same safeguards as are available in the judicial process.” 438 U.S. at 513, 98 S.Ct. at 2914. Under *Butz*, absolute immunity in the Executive Branch is reserved for hearing officers, administrative law judges, agency trial attorneys, and “agency officials performing certain functions analogous to those of a prosecutor.” See 438 U.S. at 512-17, 98 S.Ct. at 2913-16.

The Supreme Court adhered to the principle that qualified immunity is the norm and absolute immunity the limited exception in *Cleavinger v. Saxner*, 474 U.S. 193, 206, 106 S.Ct. 496, 503, 88 L.Ed.2d 507 (1985), where it conceded that “the line between absolute immunity and qualified immunity often is not an easy one to perceive and structure,” and again in *Malley v. Briggs*, 475 U.S. 335, 342-43, 106 S.Ct. 1092, 1096-97, 89 L.Ed.2d 271 (1986),

While addressed by separate memorandum this court cannot ignore in the context of the facts asserted herein, which must be considered true at this stage of the proceedings, that suggest the behaviors was so outrageous and so beyond the scope of any authority the individuals herein named possessed that the actions are not immune.

Equity Jurisdiction

This court should also exercise its power of equity jurisdiction. “Equity jurisdiction is proper if (1) the plaintiff has no adequate legal remedy; (2) the threatened injury is real, not imagined; and (3) no equitable defenses preclude jurisdiction.” *Northeast Women's Center, Inc. v. McMonagle*, 665 F.Supp. 1147, 1152 (E.D.Pa.1987) (citing 11 C. Wright & A. Miller *Federal Practice and Procedure* §§ 2942-44 (1973)). A legal remedy is inadequate “if the plaintiff’s *injury is a continuing one* where the best available remedy at law would relegate the plaintiff to filing a separate claim for damages each time it is injured anew.” *Id.* Furthermore, “*the continuing violation of constitutional rights constitutes irreparable injury*,” and is, therefore, real. *Walters v. Thompson*, 615 F.Supp. 330, 341 (N.D.Ill.1985) (citing C. Wright & A. Miller *Federal Practice and*

Procedure, § 2948 at 440; *cf. Elrod v. Burns*, 427 U.S. 347, 373, 96 S.Ct. 2673, 2689-90, 49 L.Ed.2d 547 (1976)). *Robbins v. Budke* 739 F.Supp. 1479, *1484 -

1485 (D.N.M.,1990). While the Defendants assert the record should be limited to the administrative record the court should note that Title 21 defines administrative record to be “..... particular administrative action on which the *Commissioner relies* to support the action”. That record would be an empty file since Defendants contend that the commissioner has not reviewed or decided anything. If it is true that the Commissioner has not considered or decided such an important issue as this is then such conduct is at least negligent and probably even wanton and willful and thus reckless misconduct.

In relevant part, the APA provides:

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party.

5 U.S.C. § 702 (2000). This provision does not independently confer subject matter jurisdiction, *Califano v. Sanders*, 430 U.S. 99, 105 (1977) (“[T]he APA is not to be interpreted as an implied grant of subject matter jurisdiction to review agency actions.”); *Dixie Fuel Co. v. Comm'r of Soc. Sec.*, 171 F.3d 1052, 1057 (6th Cir.1999), but it does have a bearing on the proper exercise of jurisdiction, in that it functions to waive

sovereign immunity and provide for judicial review of an agency action where a plaintiff seeks non-monetary relief in a suit against the United States. *See Capitol Park Ltd. Dividend Hous. Ass'n v. Jackson*, 202 Fed. Appx. 873, 877 (6th Cir.2006) (“The [APA] waives sovereign immunity for claims for equitable relief against federal officials.”); *United States v. City of Detroit*, 329 F.3d 515, 520-21 (6th Cir.2003) (holding that court had jurisdiction over suit against Army Corps of Engineers because, under Section 702, “[t]he government has waived its immunity with respect to non-monetary claims”). The Supreme Court has stated that the judicial review provisions embodied in Section 702 should be given “generous” and “hospitable” interpretations, *Abbott Labs. v. Gardner*, 387 U.S. 136, 140-41 (1967), *overruled on other grounds, Califano*, 430 U.S. at 105, and that the purpose of the provision is to “broaden the avenues for judicial review of agency action by eliminating the defense of sovereign immunity in cases covered by the amendment,” *Bowen v. Massachusetts*, 487 U.S. 879, 891-82 (1988). As the Plaintiff here does not seek monetary relief from the government, the waiver of sovereign immunity evinced in Section 702 applies.

Defendants also suggest that Plaintiff does not seek a remedy that would address the wrong. The footnotes to Federal Rule of Civil Procedures (2007) Rule 57 states: “... when coercive relief is sought but is deemed ungrantable, or inappropriate, the court may sua sponte, if it serves a useful purpose, grant instead a declaration of rights” see *Hasselbring v. Koepeke*, 1933, 248 N.W. 869, 263 Mich. 466 A.L.R. 1170.

WHEREFORE, this court should deny the Defendants motion to dismiss.

Respectfully submitted,

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CERTIFICATE OF SERVICE

It is understood that since this document was e-filed with the court that the clerk will transmit a copy by e-mail to all counsel of record in this matter this 19th day of October, 2007.

S/Kerry M. Donahue

Kerry M. Donahue

APPENDIX ONE

FACTUAL SUMMARY

The FDA, through a jumble of improper trial design guidance, blatant conflicts of interest, and apparent internal political manipulation, has quashed the release of Provenge, a safe immunotherapy treatment, missing a chance to improve the odds of survival—and quality of life—for Androgen Independent Prostate Cancer (AIPC) patients. For some, Provenge still has a chance to extend and improve their quality of life. For others, like Coach, Provenge was not available to him, as the FDA failed to grant the approval of Provenge by May 15, 2007, as expected by the public.

I've been talking this week with a number of people who were friends of a local legend of a coach that died last week of prostate cancer. Coach was 60 and weighed about 120 lbs when he died. He was diagnosed just 7 years ago with prostate cancer and was in decent shape until the last year. The androgen deprivation therapy had taken its toll. It's tough for a guy that's been in top shape all his life to begin to have no energy, gain weight and develop tits. About 6 months ago he started having back fractures to the point that he had to have a "wire cage" as he described it wrapped around part of his backbone. He was in rehab to try to get healthy enough to undergo chemo, which I imagine meant Taxotere, at Johns Hopkins when suddenly things took a turn for the worse. He's gone now. Posted by Geoff Morrow/The Patriot-News September 21, 2007 22:47PM

Mid-Penn Conference high school football teams suffered an enormous loss Friday night when longtime Mechanicsburg coach Rich Lichtel died.

A gregarious, fun-loving and supremely respected head coach for the Wildcats since 1981, Lichtel died at 7:01 p.m. at Harrisburg Hospital, according to Mechanicsburg athletic director Andrea Teeter.

Lichtel, who suffered from prostate cancer, was 60 years old. He is survived by his wife, Beverly; two sons, Jeff and Jason; a daughter, Megan; and two grandchildren. Information on memorial services and funeral will be announced later.

At least he waited until after kickoff," said Teeter. The Wildcats kicked off their Keystone Division scrap against rival Middletown at 7 p.m. Two of his assistants, Chris Hakel and Jeff Costello, have been serving as co-head coaches in Lichtel's absence.

He was such a part of all of us, not just the football program but the entire community," Teeter said. "Even though he wasn't on the sidelines, he was with all of us and will be forever. He is Mechanicsburg football."

A standout player at Shamokin High School and Bloomsburg University, Lichtel played minor league football and coached at Bloomsburg before joining Mechanicsburg prior to the 1981 season. He compiled a 160-121-3 record through 2006.

Lichtel learned of his prostate cancer in 2000 but continued coaching until this season.

"I was able to stop by [Friday] morning and say goodbye to him," said longtime Hershey head coach Bob "Gump" May. We said we love him, and he put his thumb up. Now he's pain free, and that's the important thing."

Many more patients, who could both extend their lives and improve the quality of life that they have left, have been denied Provenge due to the wrongful actions of the FDA. Between May 9, 2007 (Black Wednesday) and October 15, 2007, over 12,000 men have died of prostate cancer. CareToLive represents them, their families and the estimated 96,000 other men who currently are AIPC patients and joins with the Doctors who seek Provenge for their patients.

After the FDA took the surprising, history making, first of its kind action in deciding not to follow its own self convened and self selected advisory panel of experts advice regarding a treatment for a terminal condition where no viable alternatives exist, a former medical officer in the FDA Office of Oncology Products, Dr Mark Thornton, denounced the FDA's decisions, and stated,

"May 9, 2007, should be cited in the annals of cancer immunotherapy as Black Wednesday."

"Within an eight-hour period that day," Dr. Thornton continued, "the FDA succeeded in killing not one but two safe, promising therapies designed and developed to act by stimulating a patient's immune system against cancer."

"FDA's hubris will affect the lives and possibly the life spans of cancer patients from nearly every demographic, from elderly men with prostate cancer to young children with the rarest of bone cancers."

Experts say the new immunotherapies hold promise for many forms of cancer. The FDA decision was a devastating blow to the entire field of immunotherapy and biotechnology.

The Advisory Committee panel conducted by The FDA's Cell Tissue and Gene Therapy Committee's (CTGT) Center for Biologics Evaluation and Research (CBER) on March 29th clearly and overwhelmingly endorsed the approval of Provenge for this fatal stage patient population, voting 17-0 it is safe and 13-4 in favor of its efficacy. Until May 8th, the FDA had never before overruled a positive advisory committee panel vote for a life threatening cancer treatment, when there were no other viable options for the patient. Given that Provenge provided a 200% three year survival advantage (34 vs.11%), over

the control arm, despite side effects limited to fever and chills lasting 1-2 days, at least conditional approval contingent on continued monitoring of an ongoing confirmatory phase III trial should have been granted; yet inexplicably, the FDA forestalled such approval. A *post approval* 3,000 patient surveillance program was proposed to be continued by the applicant, after discussion between FDA staff, CTGT and Dendreon (further evidence of the public expectancy of approval).

Currently, the only FDA-approved treatment of AIPC is Taxotere, a cytotoxic chemotherapy drug with side effects so severe that half of patients decline treatment. These side effects include: hair loss, low white blood cell count (increasing the risk of infection), low red blood cell count (anemia), fluid retention, peripheral neuropathy (numbness in fingers and toes), nausea, diarrhea, mouth sores, hair loss, fatigue and weakness, infection, nail changes, vomiting, muscle/bone/joint pain (myalgias and arthralgias), low platelet count, **and a 2% incidence of premature death attributable to the treatment itself** (note the safety profile of this *approved* treatment).

The FDA's own chairman, Dr. Andrew Von Eschenbach, spoke glowingly of cancer immunotherapies in the months leading up to the AC panel. So why then would the FDA powers-that-be deny a desperate patient population access to such as powerful and safe treatment? They offer no reason to the public or this court but their counsel sets forth a few speculative rationales. Part of their speculation or hypothetical rationale is that that it just missed hitting "statistical significance", ($p=.052$ vs. $.05$), on its primary trial endpoint, Time to Tumor Progression (TTP) (D9901a).ⁱ In laymen terms this means that there was only a 94% chance the survival evidence was not due to chance rather than 95% (which would have made it statistically significant by anyone's standards). Stated another way there is a 1 in 40 chance that Provenge is not effective.

The truth is the FDA had admittedly been struggling, until recently, with the relevance of TTP. Indeed, until May 15th 2007 they had advised drug sponsors such as Dendreon to use TTP as the primary endpoint; Provenge was no different. Its trial was designed in 2000 with TTP as the primary and survival as the secondary endpoints. TTP endpoints have traditionally been used to measure the effectiveness of quick acting, yet nonetheless systemically toxic, chemotherapy agents. Immunotherapies and chemotherapies work in *very* different ways. Dr. Scott Gottlieb, the former FDA Deputy Commissioner, had this to say about the FDA's evaluation methodology for cancer immunotherapies:

*When it comes to completely novel products like immune-boosting vaccines, the agency stumbles, forcing square pegs into round holes as it tries to adapt familiar regulatory models to technologies it doesn't fully understand...*ⁱⁱ

Provenge (and others) build up to full strength over a period of several weeks or months, while chemotherapy and radiation are strongest at the moment of treatment. Because Provenge takes a while to begin working and because the ongoing phase III study designed by the FDA is flawed in that the placebo arm is permitted to cross over and use Provenge if they get sufficiently sick and thus Provenge ends up competing against itself,

yet the FDA still decides to hold Provenge to a higher standard versus the standard used to evaluate other treatments, such as deadly chemotherapeutic agents. Combine that fact with the fact that the FDA only allowed Provenge to be tested in its trials on the sickest of the sick; late stage androgen independent prostate cancer patients (AIPC), so despite the fact that Provenge had numerous road blocks thrown in its path, it still amazingly succeeded.

Consistent with this reality, CBER issued new guidelines for evaluating immunotherapy agents on May 15, 2007 (perhaps coincidentally the same day as the Provenge PDUFA date); ***just six days after the FDA delayed and deferred the approval of Provenge until more data could be accumulated and submitted in a new application.***ⁱⁱⁱ Clearly, using these new guidelines, approval of Provenge should be a rubber stamp exercise given it meets the quality of life and overall survival precepts as outlined therein. Survival has been identified as the “gold standard” in immunotherapy evaluation. Those guidelines identify other trial endpoints, such as TTP, as surrogates and not replacements for survival. This is not surprising given the nature of cancer immunotherapies like Provenge. Both Dr. Scher and Dr. Pazdur, himself, now admit that survival is the best measurement of efficacy. Pazdur said as much in a radio interview:

Even so, there is a hierarchy of established end points. “Survival is the gold standard of end points because it is the most meaningful to all people,” Pazdur said. “There can be no misinterpretation when the end point concerns survival: the patient is either dead or alive.”^{iv}

The only problem with survival being the end point for immunotherapies like Provenge when it comes to the approval process is that it takes a “death event” before the FDA will consider the data. In other words the FDA refuses to consider the quality of life the patients who received Provenge are now enjoying. Provenge actually takes longer to collect data on, because it works so well that it causes people to live longer and if they live they supply no “data” for the FDA. In other words, what the FDA told Dendreon was come back after more people have died and we will look at the additional data. The success of Provenge serves to actually work against it and to deny Provenge, considering *all* the evidence is demonstrative of an FDA operating more like a computer, without a human element and without any compassion or common sense. Provenge was even set up to fail by another handicap dictated by the FDA as the trials (and thus the data obtained) were only permitted to be obtained from the sickest of the sick, i.e., those that were in the final stages of the deadly disease called cancer (AIPC). The trials were not permitted on earlier stage patients that would have stronger immune systems and would be healthier whereby it would be even more likely that the immunotherapy would have an even better chance of success.

Dendreon was encouraged by the FDA to file the Biologic License Application for Provenge based on its demonstrated survival advantage.^v Nonetheless, it appears a few *conflicted doctors*, at least in the case of Provenge, insisted on harping about trial design and TTP. To that point, Drs. Brent Blumenstein^{vi} and Kurt Gunter^{vii} pointed out during the Advisory Committee (AC) panel that Dendreon should not be penalized for

having chosen TTP as the primary endpoint in 2000 since this was the trial design guidance as issued by the FDA at the time (www.fda.gov/cder/guidance/7478f1.htm).

FDA Spokesperson, Dr. Celia Witten, told the panel, and Dr. Hussain in particular, that FDA does not ask sponsors to go back and redesign those trials.^{viii}

Despite the unfair handicaps, Provenge still came very close to achieving statistical significance on its original (though ill advised) FDA-mandated primary TTP endpoint in its largest phase III completed trial to date. Despite the hurdles the data is surprisingly strong given the circumstances and the late stage and generally poor condition of those that received it. Yet the FDA has allegedly speculated that it may have denied Provenge approval over a very minute statistical miss on a superfluous endpoint. Clearly, Provenge has shown an impressive overall survival benefit. Even the conflicted doctors on the AC panel had to admit to that fact and voted it 17 to 1 safe. If the FDA would visit the patients they would have even more evidence of the quality of life of Provenge recipients from observing the fortunate men who have received Provenge and discussing how they feel and how they are enjoying life, or more simply, by listening to the doctors who have had their patients in the trials, like Dr. Penson, who speak glowingly of its success, the FDA would have an actual human element.

With the approval of the new therapies, the profits, along with the horrendous side effects of the only treatments now available, could become a thing of the past. "One day current treatment approaches such as surgery, radiation and chemotherapy, which often kill most but not all of a cancer, could be made obsolete by a potent immune response that eradicates the cancer cells and provides subsequent protection against return and relapse," Dr Thornton wrote:

As such, the new therapies pose a grave threat to the cancer industry as a whole, and the lost profits would not be limited to the sale of products. The pharmaceutical giants have spent a small fortune to gain control of every segment of the industry, from researchers to government regulators, and every year, billions of dollars flow through a nationwide network of research institutions and treatment providers under the guise of finding a cure for cancer.

However, the profits up for grabs have become so enormous that critics say the goal of industry-controlled research is no longer focused on finding a cure for cancer to save lives. Instead, the focus is on thwarting the development and approval of new therapies in order to protect the profits of the treatments already on the market.

The FDA's refusal to approve Provenge has caused major outrage in the cancer community. Provenge supporters have sent thousands upon thousands of letters and other correspondence to the FDA, members of Congress, the Department of Justice and others in pursuit of justice.

Provenge is designed to stimulate the patient's own immune system to specifically attack only cancer cells, unlike chemo drugs that attack any fast-growing line of cells. The only other AIPC treatment approved, actually gained FDA approval although it has

horrendous side effects including death (2%). In contrast, the Provenge safety profile is so good that nobody has died from it and less than one in four patients experience side effects consisting of mild flu-like symptoms that last for one or two days.

Conflicts of Interest among AC Panel Members

Two members of the panel requested and received conflict of interest waivers from the FDA to sit on the panel. Dr. Maha Hussain, of the University of Michigan, and Dr. Howard Scher of the Memorial Sloan-Kettering Cancer Center were both granted waivers despite the fact they both lead clinical trials on Taxotere.^{ix}

Dr. Hussain's husband owns and operates a clinic in Ann Arbor, MI that administers Taxotere trials.^x In addition, he owns the stock of three companies with products competing with Provenge.^{xi} The waiver of conflicts of interest granted by the FDA to Dr Hussain, which allowed her to sit on the panel, reveals that she is the lead investigator on a research contract awarded by a company that competes with Dendreon, and her husband owns stock in three competing companies valued at between \$15,000 and \$300,000.

Another undisclosed conflict of interest for Dr. Hussain is her role as Principal Investigator of a phase II study of Cilengitide in Patients with Nonmetastatic Androgen-Independent Prostate Cancer.^{xii}

An even more egregious conflict, and one not identified by Dr. Scher on his waiver, is his involvement as a board member for Proquest Investments.^{xiii} Proquest is a venture capital company which was provided seed funding of \$45 million by the infamous Michael Milken. Proquest was the initial investor in Novacea, Inc. Novacea has a compound, Asentar, in a phase III study for use as a combination treatment to mitigate Taxotere's hideous side effects. Taxotere is the treatment that could be replaced by Provenge. Certainly, the approval of Provenge would impact Asentar. All told, Dr. Scher has at least *sixteen* conflicts of interest.

Novacea announced a \$500 million partnership agreement on Asentar with Schering Plough, Inc. on May 30, 2007, just **days** after the approval of Provenge was denied.^{xiv} Dr. Scher was certainly aware of a pending half billion dollar deal involving Novacea only two months earlier, when completing his COI waiver for the Provenge AC panel, since he is a board member at Proquest and is the principle investigator and leads the clinical trials for Asentar trials for Novacea. Surely, he must have been aware of his Novacea connection, given his comments on Asentar on January 7, 2007. Dr. Scher stated: "obviously I think it (Asentar) has potential because I am running the phase III trial."^{xv} Nonetheless, this relationship was not accounted for in his conflict of interest application filed with the FDA seeking to sit on the Provenge AC panel. Dr. Scher violated the law and perpetrated a fraud upon the FDA.

Dr Scher has an interest in ProQuest Investments, which stood to make money from the its investment in the Provenge competitor Novacea (attached hereto as “Fact Exhibit One” is and spreadsheet titled The Race to Approval: Novacea vs. Dendreon which sets forth the time table of the two competing treatments). Because Taxotere is the only approved drug, Sanofi would have suffered the greatest immediate loss had Provenge been approved. According to the firm's 2006 Annual Report, Taxotere was the company's 4th best-selling product in 2006.

Dr Scher, Memorial Sloan-Kettering Cancer Center, is a scientific advisor and lead trial investigator for the competitor of Dendreon called Novacea. Under faculty disclosures at the University of Michigan, Dr Hussain is listed as an advisory board member of Novacea, and she receives research funding from Sanofi. Novacea stood to and in fact did reap windfall profits soon after Dr. Hussian and Dr. Scher helped to assure that Provenge was not approved.

The ProQuest fund was established with a specific focus on prostate cancer, and SEC filings show that ProQuest and its principals are major shareholders of Novacea. Dr. Scher is a "ProQuest Executive" and "member of the Board of Directors". ProQuest reaps millions of dollars investing in prostate cancer companies based on advice from doctors and *insiders such as Dr. Scher*, and ProQuest own stock in direct competitors including Novacea. Dr Scher receives compensation from ProQuest as a “scientific advisor” (provider of inside information) recommending investments *and* for conducting clinical trials that result from the investments. He also holds an ownership interest in ProQuest. Dr. Scher cashed in at least three ways financially and numerous more ways politically, from the non approval of Provenge on May 8th.

Dr Scher is on the board of Directors of Sloan Kettering who receives research support from the Prostate Cancer Foundation (Sloan Kettering is in fact one of the PCF's most funded entities along with Dr. von Eschenbach's MD Anderson Center), as well as financial benefits, as one of a consortium of members who reviews new research on cancer drugs to determine which grants should be awarded by the Prostate Cancer Foundation and which companies Proquest which appears to be an arm (extension) of the PCF invests in. On March 29th and May 8th Proquest held no Dendreon stock but did own competitors stock. Dr. Scher and Proquest had a dog in the fight and Dr. Scher interfered to see that his dog got a little unlawful help.

The PCF is one of the largest sources of funding for the National Cancer Institute and government research programs. A following of the tangled web involved in the PCF reveals that Dr Jonathan Simons, President of the Foundation, Dr Stuart Holden, Medical Director, and Dr Howard Soule, an Executive Vice President of the Foundation, are all “scientific advisors” to ProQuest.

Another research arm found to be infested with several of the same insiders is the Prostate Cancer Research Program, within the Department of Defense, which since 1997 has been appropriated a total of \$730 million by Congress. According to a PCRFP report,

"Today, the PCRP is the second leading source of extramural prostate cancer research funding in the United States." Its political influence cannot be understated.

The PCRP funds a Clinical Consortium Award to support the creation of a major multi-institutional clinical trial resource, "to speed development of novel therapeutics that will ultimately decrease the impact of the disease."

Here, too, Dr Scher is listed as the leader of the consortium, and the list of participating clinical sites and lead investigators includes none other than Dr Hussain. Dr Simons is listed as developing new clinical therapeutics for late-stage prostate cancer, but a review of upcoming research listed in the report shows immunotherapies are not in the cards.

These consortium members are invaluable to the industry and investors due to their unique access to insider information about clinical trials and influence over the FDA approval process. Evidence of this claim came on May 30, 2007, less than 3 weeks after approval for Provenge was denied, when Novacea announced an agreement with Schering-Plough worth over \$450 million, in which Schering agreed to jointly fund and develop Asentar, a competing prostate cancer drug, for which Dr. Scher just happens to be the lead investigator.

Founded in 1998, ProQuest Investments is a healthcare venture capital firm with over \$875 million under management., partnered by Jeremy Goldberg and Jay Moorin. Mr. Moorin owned 1,910,988 shares of Novacea stock at the time of a May 15, 2006, SEC filing, and the ProQuest document mentions an investment from Domain Associates, "whose general partner, Jim Blair, has also worked with the fund to plot its investment strategy.

As it turns out, Mr. Blair and Mr. Moorin were both members of Novacea's board of directors when the Schering deal was set up. However, apparently their services are no longer needed, because on August 30, 2007, Novacea announced the resignation of James Blair and Jay Moorin, effective September 4, 2007, and September 19, 2007, respectively.

The whole deal could have gone up in smoke had Provenge been approved, because there would have been a drastic drop in the enrollment of late-stage cancer patients in clinical trials as soon as they learned that there was a new vaccine that could not only increase their survival rate but allow them to live out their final days without the agonizing side effects of chemotherapy. This, along with the other financial and political reasons, contributed to Dr. Scher and Dr. Hussain's post AC panic mode which caused them to sign the fraudulent "leaked letters" (see below).

Provenge's approval also would have caused many patients currently participating in trials to drop out. Novacea's 2006 Annual Report filed on April 2, 2007, less than 2 months before the Schering announcement, warned that the "clinical development and regulatory approval processes inherently contain significant risks and uncertainties." The report shows Novacea was going broke trying to keep the Asentar trials running,

with research and development expenses associated with the drug of \$12.9 million for the year ended December 31, 2006, up from \$7.3 million for the year ended December 31, 2005. The \$5.6 million increase was due primarily to the Phase 3 Asentar trial, and the filing warns that Novacea could experience *many delays in getting its product to market due to problems in trials including, "patient enrollment may be slower than expected at trial sites due to factors including the limited number of, and substantial competition for, suitable patients with the particular types of cancer required for enrollment in our clinical trials"*. It also notes that there "is a limited number of, and substantial competition for, suitable sites to conduct our clinical trials; clinical trial sites may terminate our clinical trials"; "patients and medical investigators may be unwilling or unable to follow our clinical trial protocols;" and "patients may fail to complete our clinical trials once enrolled."

In addition, another ongoing trial is evaluating Asentar as part of a combination therapy for AIPC patients with Sanofi's Taxotere. If safety or efficacy issues arise with Taxotere, *the annual report warns*, Novacea could experience significant regulatory delays, and the clinical trial may need to be terminated or redesigned. Even if Asentar were to receive FDA approval, Novacea would continue to be subject to the risks that could arise with Taxotere or that *Taxotere may be replaced as the standard of care for AIPC*. "This could result in Asentar™ being removed from the market or being less commercially successful," the report states.

Ironically, in one of 3 derogatory letters sent to the FDA urging the non-approval of Provenge and leaked to the media following the failed efforts to rig the advisory panel vote, Dr Scher discussed the same fatal effects that the approval could have on the "research industry".

An approval recommendation has far reaching implications beyond making the product available that the data simply do not support or justify," he wrote. Approval would provide the Agency's endorsement of Provenge as a "standard of care" for men with AICP, he said, and by extension, elevate Provenge "to a position of being the new 'control' arm for future randomized phase 3 trials that are being designed for the regulatory approval of any new experimental agent or approach."

In other words, all the billions of dollars invested in the clinical trials now underway, or set to begin, conducted in hopes of gaining FDA approval for a new AIPC treatment, could go right down the drain if Provenge is approved as the first-line treatment for this patient population. Dr Scher is probably more aware of this fact than anybody. On February 26, 2007, MedPage Today reported that in a satellite symposium titled, "Improving Upon Current Standards: The Integration of Novel Therapies in the Treatment of Androgen-Independent Prostate Cancer," sponsored by Novacea, Dr Scher said Taxotere-based combination therapy is being investigated in a dozen clinical trials for AIPC patients, and he reported receiving grants and research support from both Novacea and Sanofi.

Under new FDA conflict of interest guidelines in the FDA PDUFA legislation recently passed by the U.S Senate and House of Representatives, neither of these doctors would have been eligible to sit on the Provenge AC panel even considering just their *disclosed* conflicts. The FDA has refused to date to explain why such conflicted doctor's participation in such an important matter such as Provenge was allowed and why they have taken no remedial action since learning of the undisclosed conflicts. The action of these doctors after the AC was inexcusable and when considered in conjunction with their COI's, blatantly unlawful, and at minimum, ethically challenged.

By comparison, an *expert on immunotherapy*, Dr. Glen Dranoff of the Dana-Farber Cancer Center in Boston, was invited to join the AC panel as a guest, allowing him to comment during the proceedings *but not to vote* since he has an interest in another immunotherapy treatment (he declined). Drs. Hussain and Scher were offered special dispensation in this respect and given voting privileges due to improper maneuvering by Richard Pazdur.

There should be no question as to why Dr. Scher did not disclose his interests in Proquest and Novacea, an obvious violation of Executive Orders 12674^{xvi} and 12731^{xvii}. He has clear professional and financial interests in their success. Interests not disclosed in his conflict of interest waiver application.^{xviii}
The view of a respected lawmaker on such conflicts of interest:

When members of the advisory committee have conflicts of interest, it not only hurts the public, but it also destroys the credibility of the committee's recommendations," said US Representative Edward Markey (7th district-MA). *"The FDA should not allow individuals with conflicts of interest to vote on decisions and the FDA should significantly limit conflicted individuals' participation, in order to preserve the integrity of the process."*^{xix}

The Conspiracy

The Defendants Dr. Scher and Dr. Pazdur engaged in a conspiracy to prevent the approval of Provenge. Dr. Pazdur purposely located two conflicted oncologists who he was sure for a variety of reasons would be anti-Provenge and he instructed them to help him to derail the approval of Provenge. By choosing Dr. Scher, and also Dr. Maha Hussain, to serve on the advisory panel, Dr. Pazdur undoubtedly found two of the most conflicted oncologists (not immunologists, rather doctors who financially profit by prescribing the current standard of care, chemotherapy) in the country to sit in judgment of Provenge, and who would both assuredly continue his plot to lobby others at the FDA to vote for non-approval. At the behest of Dr Pazdur, and for their own future political and monetary gain, "these two oncologists did everything they could think of to obstruct and impede the approval of Provenge. The result of the actions of the conspiracy was that, on May 9, 2007, the FDA denied terminally-ill patients' access to Provenge, even though the FDA Advisory Committee recommended approval, found the vaccine safe by a 17-0 vote and found there was "substantial evidence" of efficacy with Provenge by a 13-4 vote. Because the prostate cancer advocates are much less powerful then the other

cancer advocates such as those for breast cancer, the conspirators figured they could get away with profiting or politically benefiting from denying these elderly men equal protection under the law. Because they saw these elderly men as a group that would be unable to challenge their misconduct and because they knew that it would be financially beneficial to Proquest, an arm of the Prostate Cancer Foundation, they figured they could discriminate against elderly men without consequence. Dr. Scher and Dr. Pazdur saw this elderly group of very sick men and thought it presented to them an opportunity for a political and/or monetary gambit.

During the AC meeting, as part of the conspiracy and in an attempt to derail an approval recommendation by the panel, and prior to the vote on efficacy, Dr. Pazdur and his co-conspirators changed the statutory question regarding efficacy from 'substantial evidence' to 'absolute certainty' of efficacy, in an effort to obtain a 'no' vote on Provenge. However, during the voting, this manipulation was discovered and promptly corrected by the FDA's Dr. Celia Witten and Dr. Jesse Goodman, and subsequently in an overwhelming majority, the panel voted "yes" to the corrected efficacy question.

When the conspirators were unsuccessful in their attempts to derail Provenge at the AC meeting they panicked and made the mistake of taking their conspiracy outside the scope of their employment in order to try to derail Provenge by writing insincere and contradictory letters, and misrepresenting the science so as to paint Provenge in a negative light, and it was done for the sole purpose of derailing Provenge. They were aided by Dr. Thomas Fleming who is a known ally of Dr. Pazdur. This effort was in part taken by Howard Scher for the purpose of financial gain that he would realize because of his involvement with ProQuest Investments. This action was taken with the aid of Richard Pazdur and other employees at the FDA, under his direction.

The actions of the conspirators were done by agreement between them for their own political and/or financial gain and were meant to deny the class of elderly men a safe and effective cancer treatment in violation of their right to equal protection under the law. The actions served to deny the patients this treatment so that other treatments that were more financially and/or more politically appealing could be advanced by them, and for their own political aspirations.

AC Panel Doctors Leaked Letters to the FDA

Drs. Scher and Hussain went out of their way to obstruct the approval of Provenge, but that end had limited success through the AC meeting. Following their unsuccessful efforts to lobby the other experts on the AC (despite their covert success in lobbying a weaker CBER), both wrote letters to the FDA post-AC meeting to indicate their disagreement with its approval (even though the majority of people believed approval was forthcoming based on the overwhelmingly favorable AC vote). Both of these letters were subsequently leaked to and published by The Cancer Letter, a non-peer reviewed journal. These letters were written to be leaked, as is obvious by the unnecessary biographical introductory cover letters included with Dr. Scher and Dr. Hussain's letter respectively, both of whom the FDA already knows very well. Dr. Scher

later admitted that he had help writing his letter (he said he signed it but he didn't write it).

Dr. Pazdur was previously involved in another unauthorized FDA leak in the case of the biologic agent Erbitux (for colorectal cancer) in which there was an approval delay. The leak resulted in Sam Waksal, the sponsor Imclone's CEO going to jail for insider trading, and Martha Stewart landing in jail for obstruction of justice, after they traded on leaked information that Erbitux would not be approved. Pazdur, the head of the FDA's OOD division, was later identified by a Capitol Hill source as being the cause of the leak.^{xx} Dr. von Eschenbach has done nothing to end the flood of insider information that flows from the FDA employees to the financial community.

Erbitux was finally approved by the FDA for colorectal cancer victims around the world but not soon enough to save the 80,000 colorectal cancer victims that died while awaiting approval. The Abigail Alliance was a leader in that fight.

Dr. Pazdur was unhappy that his OOD division of the FDA was not given the Provenge decision and vowed that neither it nor any other immunotherapy would be approved that was not assigned to his division of the FDA. Dr. Pazdur even threatened CBER to take the political infighting public if they approved Provenge, which they were set to do, before his interference.

DENDREON

The targeted population of Provenge is very, very sick men. They are all terminal and have an average life expectancy of 19 months (from time they become AIPC). Their one remaining hope is a treatment like Provenge. Since the FDA says they can't have it they just suffer and die without any hope at all. Dendreon sought approval for Provenge only for AIPC patients, patients whose prostate cancer has usually gone into remission and then returned, spreading to other parts of the body including the bones, lymph nodes, bladder, rectum, liver and lungs. All men who do not die of other causes first, progress to the final stage where the cells no longer respond to hormone therapy. Provenge is intended for use by this certain class of patients who have already failed other types of therapy.

What does Dendreon say?

Our Business

We are a biotechnology firm focused on the discovery, development and commercialization of novel therapeutics that harness the immune system to fight cancer. Our portfolio includes active immunotherapy, monoclonal antibody and small molecule product candidates to treat a wide range of cancers. The product candidates most advanced in development are active immunotherapies designed to stimulate a patient's immune system for the treatment of cancer. Our most advanced product candidate is Provenge (sipuleucel-T), an active cellular immunotherapy that has completed two Phase 3 trials for the treatment of asymptomatic, metastatic,

androgen-independent (also known as hormone refractory) prostate cancer. We own worldwide commercialization rights for Provenge.

In September 2005, we announced plans to submit a biologics license application (“BLA”) to the U.S. Food and Drug Administration (“FDA”) to market Provenge. This decision followed a pre-BLA meeting in which we reviewed safety and efficacy data with the FDA from our two completed Phase 3 clinical trials for Provenge, D9901 and D9902A. In these discussions the FDA agreed that the survival benefit observed in the D9901 study in conjunction with the supportive data obtained from study D9902A and the absence of significant toxicity in both studies was sufficient to serve as the clinical basis of our BLA submission for Provenge. Provenge was granted Fast Track designation from the FDA for the treatment of asymptomatic, metastatic, androgen-independent prostate cancer patients, which enabled us to submit our BLA on a rolling basis.

On August 24, 2006, we submitted the clinical and non-clinical sections of our BLA and on November 9, 2006, we submitted the chemistry, manufacturing and controls (“CMC”) section, completing the submission of our BLA to the FDA for Provenge. On January 12, 2007, the FDA accepted our BLA filing and assigned Priority Review status for Provenge. The goal for reviewing a product with Priority Review status is six months from the filing date.

The FDA’s Cellular, Tissue and Gene Therapies Advisory Committee (the “Advisory Committee”) review of our BLA for the use of Provenge in the treatment of patients with asymptomatic, metastatic, androgen-independent prostate cancer was held on March 29, 2007. The Advisory Committee was unanimous (17 yes, 0 no) in its opinion that the submitted data established that Provenge is reasonably safe for the intended population and the majority (13 yes, 4 no) agreed that the submitted data provided substantial evidence of the efficacy of Provenge in the intended population.

On May 8, 2007, we received a Complete Response Letter from the FDA regarding our BLA. In its letter, the FDA requested additional clinical data in support of the efficacy claim contained in the BLA, as well as additional information with respect to the chemistry, manufacturing and controls (“CMC”) section of the BLA. In a meeting with the FDA on May 29, 2007, we received confirmation that the FDA will accept either a positive interim or final analysis of survival from our ongoing Phase 3 D9902B IMPACT (Immunotherapy for Prostate AdenoCarcinoma Treatment) study to support licensure of Provenge. These analyses are event driven, rather than time specific. We anticipate that interim results will be available from our IMPACT study in 2008.

Statement released 10/12/07

<http://investor.dendreon.com/EdgarDetail.cfm?CIK=1107332&FID=891020-07-292&SID=07-00>

FINAL FACTS

Having Hussain and Scher on the Provenge panel at all, since they are oncologists and experts in the use of chemotherapy, and not biologic agents, was akin to having foxes in the hen house.

The fact is Taxotere showed only a 2.4 month median survival advantage over placebo (Phase III TAX327 trial) vs. Provenge's 4.5 month median and stellar 200% (34 vs. 11%) survival advantage over three years (Phase III D9901a) combined with the fact that Taxotere causes the death of 2% of those that use it, is it rational that Taxotere could be approved and Provenge not approved based on the current date for each.

Dr. Scher did not want Provenge, a first in its class immunotherapy, to shake up the status quo in terms of what, for him, are career-defining adjuvants in Taxotere and Asentar.

President George Bush recently stated that questions regarding patient health should be decided between doctor and patient and not by Washington

"I'm for private medicine. I want decisions to be--being made between doctor and patient, not between people here in Washington, DC."

(<http://www.cnbc.com/id/21249783/site/14081545/page/3/>).

Yet the FDA wants to tell Doctors that they cannot prescribe an undeniably safe Provenge for patients because there is a 1 in 40 chance that it is not effective. Questions of treatment modality should be answered by doctors and patients in the medical marketplace, not the FDA. And the FDA would not necessarily require that future trials of competitive compounds be compared to Provenge as the control arm; those would be separate matters altogether to be later addressed at the time of new trial design. This argument is clearly a red herring made by Dr. Scher, a conflicted doctor; and one that appears to be almost Stalin-esque in his approach to markets.

Dr. Scher later lied to The Wall Street Journal journalist Marilyn Chase about his conflicts of interest in an interview on May 11th:

"I try to keep to the high ground," Scher said, adding that he doesn't work with any companies in direct competition with Dendreon.^{xxi}

This was of course an out and out lie as evidence above. After the undisclosed conflicts of interest were disclosed by the public Dr. Scher spoke:

Dr. Scher also was reluctant to comment, saying "This is a situation I've never been in before." But he seemed distressed that other doctors were not rallying to his support. "There's no one else standing up and saying this is ridiculous," he said. <http://www.nytimes.com/2007/06/04/health/04drug.html>.

It was a surprise only to himself that the others would not stand up for him once his misconduct was exposed to the public.

Inconsistencies in the Logic of the FDA

Perplexingly, Dr. Hussain made this comment in 2005 during the FDA AC panel for Tarceva, a non-cytotoxic drug used in combination therapies for lung and pancreatic cancer:

I think the approval of the drug would allow an informed conversation with the doctor and the patient, and I don't think that it is fair for us to make the judgments for the patients that if they get a rash they should not get the drug" and "Not to minimize at all the side effects, but there are a lot of drugs out there that do cause significant serious, life-threatening side effects but they are being used daily because of an informed conversation between the patient and the doctor. So, I think that the quality of life at least is no worse. That is an important fact".^{xxii}

Compare her comments regarding Tarceva with those from the Provenge AC panel:

Now, in the context in looking at this is that when I sit down Monday to talk to patients, I have to feel maybe not 100 percent, but 90 percent confident that everything that was presented today is related to the treatment, and that this is the best drug for Mr. Smith, who I'm going to see Monday morning if it's available on the market, and that I have to feel confident in advising him about that. And I guess the answer is I'm not sure"... "and as I read this , it is clear that there is a survival difference, so we're not disagreeing that the survival difference is related to a therapy effect"... "So the first thing I want to point out, that no one disagrees that survival ought to be the key fact. However, it's the spirit of how that survival has been looked at, not an after-effect, or afterthought, it's intended in the first place to be looked at."^{xxiii}

Interestingly, the FDA's own statisticians have determined that there is a 97.5% probability that the survival advantage demonstrated by Provenge can be solely attributed to the treatment and not to unrelated factors.^{xxiv} In fact, Provenge has met the standard outlined by Dr. Hussain at the Provenge AC panel. Yet she wrote a letter to the FDA, after the panel hearing, opposing its approval? Perhaps she missed that very relevant statistic presented by FDA biostatistician, Dr. Bo Zhen. Her opinion appears to be a moving target.

Another inconsistency is revealed in her comments when voting on the "does Provenge demonstrate substantial evidence of efficacy" question during the AC panel:

"So, to me, 'substantial' and 'establish' are the same, and no to either. So no to both".^{xxv}

It appears that she misunderstands the nuance between "establish substantial efficacy" and "establish efficacy"; she did not answer the question as it was asked. This was just one example of the inconsistency Dr. Hussain demonstrated repeatedly at the AC panel.

She later illogically commented that Provenge **did demonstrate a distinct survival advantage**:

And as I read this, it is clear that there is a survival difference, so we're not disagreeing on that ^{xxvi}

Yet she later attacked the survival advantage based on the trial design. ^{xxvii} So, exactly which is it? Dr. Hussain hasn't said.

Tarceva, by the way, had demonstrated a nearly inconsequential two week survival advantage for pancreatic cancer patients yet received her support. Dr. Hussain ought to take notice of comments such as these from a doctor that actually conducted a Provenge trial site regarding the quality of life and effectiveness provided by Provenge:

"When a drug improves survival, it's a hallelujah event," Dr. Paul Schellhammer said. He said he has patients who were treated with Provenge *"who are still alive with minimal other therapies, which just defies the odds."* *"No patient withdrew because of the side effects, which is virtually unheard of in an advanced cancer treatment trial,"* said Schellhammer, who is director of the Virginia Prostate Center at Eastern Virginia Medical School and incoming president of American Urological Association. ^{xxviii}

In Dr. Hussain's mind, a serendipitous finding such as survival extension is irrelevant because it was not specified as the primary endpoint (even though it was a secondary endpoint). The new CBER guidelines for immunotherapy trials should be read as saying "survival trumps all others". However, it is abundantly clear that Hussain and Scher have different rulebooks for evaluating chemotherapy and biologic compounds and use different analysis depending on their own best interest.

Differences of opinion are one thing, but complete breakdowns in logic by persons with vested interests in competing drugs, are indicative of such obvious bias, that their input should not be allowed. Dr. Hussain did not see offering Provenge to terminal patients on an expanded access (i.e. free) basis as being problematic; in fact, she encouraged it. ^{xxix} Dr. Hussain vocalized that making Provenge available to patients was perfectly acceptable to her if Dendreon would give it to them free of charge, and she would be all for that. This fact in particular calls into question the motives of the conflicted doctor. To date the FDA has refused to take any action to correct the injustice caused.

In addition, Dr. Mark Frohlich of Dendreon outlined their plans for a *post-approval pharmovigilance study* for Dr. Hussain and she was duly impressed. ^{xxx}

It is ironic to note that Dr. Scher, too, commented on the vagaries of drug evaluation just a month before the Provenge AC panel and indicated that *common sense* should be introduced into the drug approval process:

It may be time we focus less on statistical significance alone, and more on patient benefit. ^{xxxi}

This was his view at a Novacea Symposium. Please note the lack of consistency between his comments in the leaked Provenge letter and those on Asentar, for which he is the primary investigator and, via his connection as a board member at Proquest, holds a financial interest.

Dr. Scher, in the same spirit demonstrated by Dr. Hussain during the panel, contradicted himself in regard to Provenge's survival advantage:

...three years later a survival analysis is reported, it is observed and there's no question that this is the gold standard by which we live."^{xxxii}

Inexplicably, he later contradicted his own words in saying:

So you know, if you ask me the question does this drug prolong life, I just don't know at this point in time."^{xxxiii}

One has to wonder which is truly Scher's opinion? Why would he comment if he doesn't know? Why not leave it to the experts in the field of immunology to decide instead of embarking on a crusade to derail the approval process? The only logical rationale is that you are an extremely conflicted doctor who should not have been invited to join the panel.

Obviously, in Drs. Scher and Hussain's minds, what is good for the chemotherapy "goose" is not good for the biological "gander". But, given their obvious conflicts, should anyone be surprised? The public is not.

It is relevant to note that the FDA has approved two chemotherapy drugs in recent years (Gemzar for ovarian cancer and Iressa for lung cancer) offering **no survival benefit whatsoever** and despite AC Panel recommendations *against* their approval. It appears today's FDA has been hijacked by forces dedicated to the approval of chemotherapy compounds for terminal cancer patients despite very specious efficacy results and toxic side effects.

Provenge has demonstrated a 200% three year survival advantage with very few side effects, mostly flu-like fever and chills for a day or two, yet was denied approval.

Power Struggle at the FDA and Obstruction of Due Process

Dr. Richard Pazdur, head of the FDA's Office of Oncology Drugs (OOD), typically constructs the composition of the Oncology Drugs Advisory Committee (ODAC) panels for chemotherapy drugs. Puzzlingly, he attended the Provenge AC panel conducted by CTGT. Why? Immunotherapies fall under the auspices of the FDA's Cell Tissue and Gene Therapy Committee (CTGT) which conducts their CBER AC panels, not the OOD.

Pazdur was there in furtherance of the conspiracy to subvert or stop what he believed to be the imminent FDA approval of Provenge? He had reportedly fought an internal battle within the FDA to have control of the Provenge application (via his OOD)

but lost; reportedly fought the FDA to have a joint OOD/CTGT Provenge AC panel but lost; fought and won by having token representation (Hussain and Scher) on the Provenge AC panel; but lost again when they failed to influence the other panel members to see it Pazdur's way and vote no.

Believing Provenge approval was now hanging threateningly over his head, Pazdur, in addition to orchestrating much of Drs. Hussain and Scher's panel presentations, also assisted in the scripting of the letters to the FDA, letters that were intended to be leaked. And, given his previous involvement in unauthorized leaks of confidential information in the Erbitux scandal that found its way to the same non peer journal, it is easy to believe that he was involved once again.

Those in attendance at the Provenge AC panel on March 29th watched as Drs. Hussain and Pazdur passed notes back and forth. Given Dr. Pazdur's alleged history of leaking confidential FDA information, one can only speculate as to what the contents of those communications entailed. It is not a stretch to say that any investigator looking into the source of the three letters leaked to The Cancer Letter would first look at Dr. Pazdur. It appears he, together with Drs. Hussain and Scher, are at the heart of a power struggle within the FDA over which individuals and bureaucracies will control the fate of prospective cancer treatments (his OOD vs. CTGT).

Ironically, Provenge is not a drug in the traditional sense of the word at all. Nonetheless, we had the head of the Office of Oncology Drugs reportedly scheming to torpedo it. Not coincidentally, Patricia H. Harley, the FDA's Consumer Safety Officer, recently sent this as a reply to a Provenge advocate:

Often we call upon independent outside experts for their advice. In this instance, we sought the advice of an FDA advisory committee. The majority of the advisory committee members indicated that the data submitted for Provenge supported its effectiveness; however, several members expressed significant concerns about the strength of these data."(read Scher and Hussain.)

It is clear to the reasonable man that these conflicted members of the panel had an undue impact on the outcome and commandeered the decision making process. These doctors are by no means experts in immunotherapy. Urologist Dr. Mark Moyad, Director of Preventive and Alternative Medicine in the Department of Urology at the University of Michigan, an internationally known expert on prostate cancer treatments and a prostate cancer patient advocate, has spoken out in favor of Provenge approval and strongly disagrees with Dr. Hussain (see Pltf. Mot. for Inj Rel).

The FDA not only ignored the thirteen members of the AC panel that voted in favor of Provenge but it also ignored noted experts like Dr. Schellhammer, Dr. Hy Levitsky, and their own Drs. Miles Braun and Celia Witten. Drs. Pazdur, Hussain, and Scher effectively "lynched" Provenge under the guise of "statistical correctness". The FDA appears to operate in a shadow universe running parallel to our democracy?

Drs. Hussain and Scher's testimony should be stricken from the AC panel record and the issue of approval re-evaluated by CBER and Dr. von Eschenbach alone without influence and political pressure from Dr. Pazdur.

The Provenge Patient Experience

In the final analysis, it is the patients and their needs that should drive the decision making process. We have already seen a testimonial from Dr. Paul Schellhammer outlining his very favorable impressions of Provenge. In addition, please consider these comments from an AIPC patient, Eduardo Garcia, who took part in the Provenge D9901a trial in 2001:

It not only helped me control the prostate cancer, it helped me live six years...And I'm talking about living normally, you know...My opinion is the FDA approved chemo 30 years ago, which has definitely not proved to cure anybody... You lose your hair, you feel terrible, and your way of life completely changes. Anybody who took chemo is not the same after that, which is completely different if you take Provenge. You know, when you take it, the reaction is so mild, like if you have a very mild cold, you know...And then, after awhile you start feeling the energy. Now I have bone cancer, and every three months my doctor sends me (for a bone scan) and every time he measured, and he congratulated me because the cancer is still there. It's in my hips. It's in some of the bones in my back, but it has not gone out to the rest of the things. And the main thing, the most important thing, I have no pains, and I can move. Right now I am doing exercises. I went to a gym, and I do exercises on certain machines. You know, with the bicycles and stuff like that. So, at 82 years old, I think that's excellent, you know, to have that much.”^{xxxiv}

Interestingly enough, it is possible that what Eduardo's doctors believe are stubborn tumors could indeed be nothing more than the remnants of dead tumors:

“So why, in trial after clinical trial, doesn't this reaction eliminate the tumor? Dr. Glenn Dranoff, an immunotherapy expert at Boston's Dana-Farber Cancer Institute, says there is evidence immune cells infiltrate the tumor and kill it from within, leaving a ball of scar tissue the same size as the malignant growth. ‘You don't see a visible change in the size of the tumor, but the composition has been dramatically altered.’”^{xxxv}

This is yet another reason why the TTP endpoint should be viewed as being a largely meaningless measure of efficacy when evaluating immunotherapy treatments.

Author's note: Provenge was given both orphan and fast track status by the FDA for clinical trials only on late stage, AIPC patients. Presently, as previously noted, those patients do not have a treatment option outside of Taxotere. However, it is quite logical that Provenge would be more effective if it was given to earlier stage patients (we don't get our measles vaccine *after* contracting the disease, after all). Prostate cancer is typically slow-growing and treated by urologists until patients advance to the AIPC stage. While AIPC takes **30,000 lives** every year, **220,000 men will be newly diagnosed** with

prostate cancer in 2007. One in every six men in the US will be afflicted with prostate cancer during their lives. It is truly a matter of epidemic proportion.

Life for these earlier stage patients is no walk in the park, either. Prostate cancer affects men from all walks and in the prime of their lives. Consider these treatment modalities and their dehumanizing side effects:

Treatment	Side Effects
Prostatectomy (surgery)	Pain; lethargy; impotence, incontinence; no semen production; death (2-3%).
Radiation Therapy	Diarrhea; frequent and uncomfortable urination; treated area to become red, dry, and tender; impotence; hair loss in the pelvic area; rectal bleeding.
Hormone Therapy(Orchiectomy*; LHRH agonists; Estrogen) *Chemical castration.	Reduced testosterone levels; impotence; tumor flare; nausea; vomiting; tenderness and swelling of the breasts.
Brachytherapy	Urinary urgency and frequency. Rectal bleeding. Impotency.

Operation Without Transparency

The FDA is omnipotent. It answers to nobody, operates in secrecy , and does what it wants impervious to criticism. It sounds like the old communist Russia. It seeks to avoid public accountability at all costs.

A more transparent and publicly accountable FDA is needed. The FDA needs to disclose more about its drug reviews, as guidance to both investors and patients. People shouldn't have to wait for leaked letters to understand what the bureaucracy is up to. The FDA will not do so without judicial order as congress has proved to be ineffective against the awesome power that is the FDA. The FDA regulations prohibiting disclosure of proprietary information were intended to protect corporate trade secrets and financial information. This prohibition has created an impenetrable shield behind which the FDA and drug companies hold their discussions.

If the FDA halts cancer research on patients for whatever reason, current regulations permit the FDA to communicate only with the drug's sponsor, usually a company or academic institution. The patients can get their information only from the drug company /

institution. The FDA cannot correct misinformation or offer their perspective on the problems in the clinical trial to anyone without the drug company's permission. Peter Barton Hutt, former counsel for the FDA and regulatory law expert from Harvard University wrote an article years ago that laid out some basic principles for sound government regulatory policy. They are:

1. *To protect the public from harm.*
2. *To preserve maximum individual freedom of choice.*
3. *To guarantee meaningful public participation in the decision making process.*
4. *To promote consistent and dependable rules that are equally applicable to everyone.*
5. *To provide prompt decisions on all of the issues that arise in a regulatory context.*

The Defendants cite the FDA's guidance document often. That is inconsistent and irrelevant because Congress mandated that one trial and supportive data is sufficient for approval. Who cares that FDA guidance is for two trials? At this point it matters little whether the decision is that the FDA failed to follow congressional mandate or whether their rules and regular conduct amounts to an ongoing refusal to follow congressional mandates. The FDA wants to hide behind their rules, but they do not follow their own rules. There is barely anything discernable as precedent when it comes to oncology approvals. About the only thing that *was* hard and fast was the FDA, in terms of oncology approvals, never overruled an advisory committee and delayed a drug in a life threatening situation, when no viable alternatives exist. They've approved drugs with much less compelling evidence than that demonstrated by Provenge and for less compelling needs.

It seems the FDA needs a fall guy and that person's name is Dr. Ashok Batra. It almost seems like they are trying to say that Dr. Batra had no authority to approve or not approve....he just signed the non approval letter without authority or review from anyone above him. The FDA seems to be suggesting that no decision has been made and since someone without authority signed the CR Letter that it's not a decision. Strange way to approach this matter, all things being considered.

Following the FDA's logic the agency never takes a final action on any drug since the applicant is allowed to reapply even after a non-approvable letter. Functionally, there is no difference in net harm to plaintiffs between postponing a decision for two years and making the decision to not approve the drug.

While the FDA remains too busy to reply to an advocates petition in a matter of extreme importance or to reconsider its historical refusal to follow an expert advisory committee relative to a treatment for a deadly cancer, it does have time to work on other important issues: Early this year, the Food and Drug Administration approved the first prescription drug to help overweight dogs. Called Slentrol, the drug reduces appetite and fat absorption in round hounds (Pfizer).

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

ⁱⁱⁱ Guidance for Industry, Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics, FDA (CBER/CDER), May 2007

^{iv} <http://wncmarket.com/GHC-CancerTruths-Drug-Testing.html>

^v FDA Center for Cellular, Tissue, and Gene Therapy Advisory Committee transcript; March 29, 2007; page 189.

^{vi} FDA Center for Cellular, Tissue, and Gene Therapy Advisory Committee transcript; March 29, 2007; pages 330-339.

^{vii} FDA Center for Cellular, Tissue, and Gene Therapy Advisory Committee transcript; March 29, 2007; page 339.

^{viii} FDA Center for Cellular, Tissue, and Gene Therapy Advisory Committee transcript; March 29, 2007; page 185.

^{ix} Hussain: <http://www.med.umich.edu/intmed/hemonc/staff/hussain.htm>

Scher: <http://www.clinicaltrials.gov/ct/show/NCT00273338;jsessionid=0FA581A8EA524B3CA46C460A2DC55EEB?order=1>

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^{xi} FDA Center for Biologic Research Memorandum, February 5, 2007

^{xii} http://www.cancer.gov/ncicancerbulletin/NCI_Cancer_Bulletin_032707/page6

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^{xxii} Tarceva AC Panel Transcript, page 25:

<http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4174T1-Part4.pdf>

^{xxiii} FDA Center for Cellular, Tissue, and Gene Therapy Advisory Committee transcript; March 29, 2007; page 307-310.

^{xxiv} Provenge BLA Briefing Documents.

^{xxv} FDA Center for Cellular, Tissue, and Gene Therapy Advisory Committee transcript; March 29, 2007; page 382.

^{xxvi} FDA Center for Cellular, Tissue, and Gene Therapy Advisory Committee transcript; March 29, 2007; page 307.

^{xxvii} FDA Center for Cellular, Tissue, and Gene Therapy Advisory Committee transcript; March 29, 2007; page 307-316.

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