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

CareToLive, et al.,

Plaintiff,

Case No. 2:07 CV 729

vs.

Judge Frost

Andrew von Eschenbach,
et al.,

Magistrate Judge King

Defendants.

PLAINTIFF'S MEMORANDUM CONTRA
DEFENDANT SCHER'S AND DEFENDANT PAZDUR'S MOTION TO DISMISS
PLAINTIFF'S AMENDED COMPLAINT

Now comes Plaintiffs and hereby offers the following memorandum contra the individual Defendant's motion to dismiss. Plaintiff has set forth causes of action against Howard Scher and Richard Pazdur in their individual capacities as government employees and as individuals who exceeded the scope if their employment by unlawfully and purposely sabotaging a proven safe and effective treatment for AIPC prostate cancer sufferers, resulting in the denial of that treatment to patients who were and are hoping to receive it and to their doctors that wish to prescribe it. Plaintiffs incorporate all arguments from their other memorandum contra the Defendant's motion to dismiss.

MEMORANDUM

FACTS

DEFENDANT PAZDUR

Richard Pazdur is the head of the Office of Oncologic Drugs (OOD) division of the FDA which is a division of the Department of Health and Human Services. Dr. Pazdur also controls the Oncologic Drugs Advisory Committee - ODAC. Since

Provenge is an immunotherapy and not a drug it was assigned to the Cellular, Tissue and Gene Therapies Advisory Committee - CTGT. Dr. Pazdur was upset with the decision to give the control over Provenge to CTGT and its advisory panels run by the Center for Biologics Evaluation and Research - CBER. Dr. Pazdur knew that the next era of cancer treatments and the next front line on the war on cancer was going to be in the area of immunotherapies (there are numerous immunotherapies currently in development). Provenge was the first immunotherapy that looked like it was going to gain approval for the treatment of cancer patients. Since the future of cancer treatments was going to be in this realm it was very disturbing to Richard Pazdur that his division OOD/CDER was not being given authority and control over the Provenge BLA. This decision meant that OOD and CDER were losing control/power to CBER and CTGT. This was a sign that all future immunotherapies were going to go to the division over which Richard Pazdur is *not supposed to* have control or influence upon, thus divesting and weakening his own power within the agency and limiting his ability to control or otherwise interfere with the future of cancer therapies. This angered Richard Pazdur. Richard Pazdur made the decision then that if his division of the FDA was not going to get control over these treatments then none of them were going to be approved. Richard Pazdur then decided he was going to make a power play that either failed to consider or intentionally refused to consider the actual best interests of the AIPC class of elderly men. The patients came to be but a mere pawn in his game.

Richard Pazdur lobbied for all immunotherapies to come through his CDER controlled AC panels, which were controlled by his OOD division. He lost. He then wanted his controlled CDER panels to be the ones to advise the FDA regarding

Provenge. He lost. Richard Pazdur then fought for the right to place two of his CDER panelists on the CBER Advisory Committee. He won. Then he found two severely conflicted oncologists who he knew would be willing to follow his instructions because they had everything to gain and nothing to lose by the non approval of Provenge. The two Oncologists he hand picked and placed on the AC were Dr. Maha Hussain and Dr. Howard Scher. These oncologists had both disclosed and undisclosed conflicts of interest and Dr. Pazdur knew they would be receptive to his request to help him to derail Provenge, in that they both would personally benefit by the non-approval of Provenge.

Dr. Pazdur then pressured other AC panel members to vote against the approval of Provenge. Although Pazdur had no business even being <u>at</u> the Provenge AC hearing he attended anyway in hopes that his mere presence would sway Committee votes. Commissioner Dr. von Eschenbach did not attend. Dr. Pazdur then spoon fed ideas to Committee members Maha Hussain and Howard Scher during breaks in the AC meeting, even passing hand written notes to Dr. Hussain, presumably to assist her in making arguments attacking Provenge.

Prior to the AC meeting, Pazdur, Scher and Hussain had discussed the plan and all were aware that Pazdur had altered the key question that was to be voted on by the panel of experts to reflect a standard that was higher than the congressionally approved standard. Pazdur tried to raise the bar in an effort to obtain a "no" vote. The question was changed by Pazdur to "has efficacy been established". The votes started to come in as "no's" but CTGT head Celia Witten and CBER head Jesse Goodman realized the question had been changed to one that asked for a standard higher than that set forth by regulation as decided by Congress. The question was then restated to the congressionally

mandated requirement “is there substantial evidence of efficacy”. The AC panel responded “yes” by a vote of 13-4. Two of the 4 “no” votes were Dr. Hussain and Dr. Scher. One of the other two “no” votes was the statistician who determined that the FDA guidelines suggested that there was a one (1) in forty (40) chance that the survival data was obtained by mere chance (the FDA statisticians generally like there to be only a one in 1600 chance that the results are by chance). Dying cancer patients do not care if a safe immunotherapy has a 1 in 40 chance of not helping them. They correctly focus on the 39/40 chance it will help them. That Scher and Hussain had a pre hearing agenda is easily demonstrable by the AC transcript itself, which also makes it obvious that they had been tipped off and ready for the “loaded” question. They were both confused about how to respond when the question was properly fixed and then elected to just answer the first wrongly phrased question. Mrs. Hussain took the route that she was going to consider “establish” and “substantial” to be the same standard (this was the perverted way she had to justify in her mind a “no” answer to the substantial evidence of efficacy question because otherwise she knew this was wrong as she knew that there absolutely was substantial evidence of efficacy demonstrated). Mr. Scher actually said no to the first question and yes to the second indicating that he believed if the question was asked as congressionally mandated to be asked then Scher was in fact admitting that the correct answer to the question whether there was substantial evidence of efficacy was YES. In reality even both Dr. Scher and Dr. Hussain can’t deny that Provenge is both safe and shows substantial evidence it is effective. Note: the fourth “no” vote came from Dr. Richard Chappell who also chose to ignore the fact the question was properly restated

and chose to answer the first question instead (he seemed confused about what question he was answering). This is all clearly demonstrated on the AC hearing transcript.

When the pressure exerted on the panel by Richard Pazdur did not work and when the efforts of Scher and Hussain to sway the panel did not work, and when their "change the question trick" did not work, Richard Pazdur, who had no business being at or involved in the Advisory Committee meeting to begin with, decided that in order to implement his vow that no immunotherapy that did not come through OOD would ever be approved, he needed to take more extreme measures. He then encouraged Dr. Hussain, Dr. Scher, and a known cohort of his, Dr. Richard Fleming to write letters to Janet Woodcock, Jesse Goodman and Commissioner Dr. von Eschenbach, in order to lobby them further to delay and/or deny the pending Provenge approval.

Richard Pazdur, along with help from FDA employees and other employees of the NCI division of HHS, including but not limited to Alison Martin, concocted a plan to send three letters to be signed by Scher, Hussain and Fleming, and which were written and purportedly sent to Dr. Woodcock, Dr. Goodman and Dr. von Eschenbach. Richard Pazdur's post AC plan to derail the expected Provenge approval was discussed at a meeting wherein both NCI employees and OOD were present. Present at that meeting was another NCI employee, who Plaintiff will not name at this time. At this point NCI employees directed by FDA employee and OOD head Richard Pazdur, helped the three doctors write their letters with the designed goal of derailing Provenge approval. Then, Richard Pazdur, conspiring with other HHS employees, and conspiring with Scher, Hussain, and Fleming, purposefully "leaked" a copy of each of the letters, on different dates, to a non peer reviewed journal called The Cancer Letter (perhaps not

coincidentally the very same non peer reviewed journal that Pazdur "leaked" the Imclone/Erbitux information to) which journal published all three letters. Investment funds, hedge funds, analysts and others who were short the stock and who had inside information from FDA employees then "piled on", contributing to CBER's pressure which was now being felt by CBER from both within and outside the FDA. First CBER was bullied by Pazdur prior to the AC, then CBER was pressured by Pazdur, Scher and Hussain during the AC, and then CBER was pressured by letters written by Scher, Hussain and Fleming, with the help of Pazdur and other taxpayer paid government employees after the AC. Then more pressure from Pazdur himself and then CBER was pressured by actions of NCI and finally was pressured by way of the outside pressure that came as a result of the "leaked letters".

The sordid actions did not end here. CBER was still set to go ahead and approve Provenge anyway. However, Richard Pazdur had one final trick up his sleeve. Richard Pazdur then threatened that a public demonstration would be carried out by his CDER division, to again take the issue outside the FDA (having done that already with the "leaked" cancer letters which paved the way by bringing the argument to the outside world). The threat was to take the FDA's dirty laundry and political infighting outside the FDA. This final unlawful action by Richard Pazdur succeeded in persuading CBER to finally cave in and issue a non-approval letter rather then the approval letter they were preparing to send to the applicant (Dendreon). The CR letter was unusually convoluted and hard for even the applicant to understand (requiring weeks to interpret along with a translation from the FDA, to fully decipher). It appeared to have been written as a conditional approval letter which was hurriedly changed into a non-approval CR letter.

The government (docket no. 43 p. 9) says Plaintiff's allegations are not entirely clear. So that they are clear to this Court, the allegations as to Defendant Pazdur are as follows: Richard Pazdur exceeded the scope and the authority of his office when for his own political career and ambitions, he did unlawfully and knowingly engage in the following activities that served to deny substantial and procedural due process to the Plaintiffs:

Controlling the AC panel.

Conspiring with AC two (possibly three) members to achieve a pre determined result.

Pressuring both the committee and members of CBER.

Changing the CBER statutory question on efficacy.

Bringing in oncologists with severe conflicts of interest.

Conspiring with these same oncologists to hide the true extent of their conflicts of interest.

Recruiting other employees of HHS for help with the "leaked" letters

Again pressuring and threatening CBER members post AC, after they had decided to approve Provenge.

Approved the use government resources to take unlawful actions that were outside the scope of their employment and using government equipment to pursue his own personal agenda.

Betraying the letter and spirit of Congressional rules governing the approval of products like Provenge.

Defendants assert that the Plaintiffs have no evidence of the facts asserted but nowhere do they say that the allegations are not the truth. At this point in the proceedings all allegations must be taken as true, therefore the contention of Defendants in that regard is not relevant during this stage of the proceedings. In addition, the Defendants have taken extraordinary steps to deny access to the evidence. Not only has the FDA refused to provide documents to Plaintiffs which were demanded under the Freedom of Information Act but they requested that other witnesses not talk to Plaintiffs and not provide documents to Plaintiffs.

The Plaintiff made two FOIA requests. One to the FDA, for which no documents have yet been provided (pending motion to enforce FOIA Dct. No. 29 that may become amended count of complaint) and one to the National Institute of Health (NIH) which has been recently responded to. That response and the documents provided are attached hereto as "Exhibit A". The document appears to be a (v3) "third version" of the Scher "leaked" cancer letter. Accompanying e-mails and the other versions were not provided to Plaintiffs by the author of version three, which author was Alison Martin, a current employee of the National Cancer Institute (NCI) and a former employee of the FDA. This letter, subsequently signed and sent not by Ms. Martin, but by Defendant Howard Scher as his own work product, came off the government computer of Alison Martin and was written and/or edited by her as an employee of NCI. This is an earlier version of the draft and indicates that what they had set out to accomplish had already been decided, and that now they were just trying to articulate reasons for non approval to present to both the decision makers at the FDA and to the media at large. They were now fabricating the means to try to justify the desired ends. HHS Secretary Michael Leavitt

clearly has given up control over the HHS when his NCI employees are assisting rogue FDA employees in improperly attacking a BLA for an advanced cancer therapy, post AC meeting, but prior to the decision by the FDA (which they succeeded in having changed at the last moment). Alison Martin was now onboard and assisting Pazdur and Scher in their efforts to improperly influence and pressure CBER, including writing and/or editing letters and intentionally leaking them to the press.

Dr. Pazdur being the head of OOD and CDER had no business being involved in or interfering with the Provenge approval process since it was not assigned to his CDER division of the FDA but resided in the CBER division instead. Outside of insisting the two COI oncologists be on the AC panel, (which may have been itself outside his scope of authority) any further action was clearly beyond the scope of his employment. His sole purpose in sticking his nose into the business of the BLA for Provenge was to seek to derail approval. He had no business whatsoever being involved in the Provenge approval process. He had no business improperly pressuring employees of the FDA, pressuring the AC experts, trying to change the efficacy question to a higher standard of approval, recruiting doctors to write letters to the FDA decision makers, assisting in the writing of the letters, recruiting NCI and other HHS employees to help with the writing of the letters and then assisting the "leaking" of all three letters, each on a different day, to the press. Why was he even involved in reviewing the BLA in the first place? Clearly some if not all of these action were outside the scope of his employment as head of OOD of the FDA.

DEFENDANT SCHER

Defendant Scher disclosed several conflicts on his conflict of interest waiver request form which he was required to file with the FDA in order to be eligible to serve on the Advisory Committee. Although it was mandatory to disclose all his conflicts he did not do so. He had many undisclosed conflicts. The total number of conflicts is believed to be 16 or 17. Defendant Scher did not tell the FDA that he was the lead investigator for Asentar the Novacea late stage prostate cancer treatment or that there was a pending deal on the table to sell an interest in Novacea to Schering Plough for 440 million dollars. The deal between Novacea and Schering Plough was announced a few weeks after the non approval of Provenge. He did disclose to the FDA that the 440 million dollar deal between Novacea and Schering Plough would not go through if Provenge was approved. Not only was Scher the lead investigator for Asentar but as a Scientific Advisor, Director and a top Executive for ProQuest Investments, he stood to profit from the Novacea deal. Proquest Investments owned a significant number of shares in Novacea at the time Scher sought to derail the Provenge approval. Scher had at least 16 other conflicts of interest that made him inherently biased, and should have disqualified him from sitting on and voting during the AC. He was in a position to profit financially, politically and historically by the non-approval of Provenge on May 8th, including securing his place as the lead doctor in other prostate cancer trials competing with Provenge and hoping to be "first to market", a coveted position. There also was concern by the NCI and Scher that the approval of Provenge would make it harder to recruit prostate cancer patients for pc trials including the pending taxotere trial

enrollments, as it would set a new standard to compete against without all the toxic side effects.

Mr. Scher was a special government employee (SGE). His role was to serve as an advisor to the FDA, in this instance the CBER division, as a panelist on the Advisory Committee. This was an open hearing wherein there was a record (transcript), and any real (as opposed to imaginary) concerns could be discussed with the other advisors and with FDA staff. At the close of the AC his role as government employee was finished. At that point further conspiring with Richard Pazdur, Alison Martin and others was outside the scope of employment.

The "leaked" letter signed by Scher which was written with the help of HHS employees is full of disingenuous and inaccurate assertions that were not even believed by him. A glimpse of version 3 alone, that is attached hereto (Exhibit A), demonstrates the goal of finding a possible reason to argue for non-approval. This version 3 draft sought opinions and other help in justifying Scher's position which he had already taken at the AC. In addition, the "leaked" draft and final letter contained contradictions to Scher's position at the AC where he voted Provenge safe, rendering the safety vote unanimous. Now in his "leaked" letter he contradicts himself from just a few days earlier and questions the safety of Provenge. The inconsistencies of Defendant Scher are pointed out in "Appendix one" and "Appendix two", attached hereto. Appendix one, is an analysis of Scher's letter by Biotech Research Expert David Miller and Appendix two is a letter with analysis by a group of twelve (12) doctors and four (4) research scientists that were both written soon after Scher's leaked letter appeared. Since the writers did not have the same access to the authorities as did Howard Scher it is unknown if anyone with any

decision making authority at the agency ever considered it, at this stage of the proceedings.

These actions by Scher were taken by him at the urging of others including Pazdur. *Not even Scher, himself, believed what was written in the letter* he signed, that helped to derail Provenge. Mr. Scher wrote the letter with the help of HHS employees and at the urging of Pazdur with the intention that the letters be sent to Dr. von Eschenbach, Janet Woodcock and Jesse Goodman and also that they be "leaked" to the press with full knowledge that they were going to be used to persuade CBER not to approve Provenge. He even castigated CBER in the process. As set forth by Scher himself CBER is a bit weaker and more likely to be influenced or manipulated by others then CDER. The post AC actions of Defendant Scher were outside the scope of his employment as a special government employee as the scope of his employment was to advise the FDA during the AC meeting. Once the AC meeting was over his role was completed. There is not supposed to be a second hearing in some back room outside the view of the public with selected biased participants to promote their own agenda. It was not his role to use his special government employee status to conduct a post AC lobbying effort via a letter to CBER, CDER, the Commissioner and the press to deny an applicant's BLA. Question: Why was he fighting so hard for non approval? Answer: Because he personally benefited by it. *None of the other 13 doctors who did not have conflicts and voted that there was substantial evidence of efficacy wrote any post AC letters*. Only the two severely conflicted "no" voters who were unable through their other chicanery to derail Provenge prior to and at the AC, wrote post AC letters (as did non-panelist Dr. Fleming who is a known cohort of Richard Pazdur).

After the letter became public Scher commented that while he did not write the letter, he did sign it. We now know, that the v3 draft of Scher's letter was written in part with at least one helper who is an employee of the National Cancer Institute (NCI), a division of HHS.

ARGUMENT

Defendants argue that the individuals do not need to be parties to this action for the court to grant the relief sought by the Plaintiffs. If this court orders the FDA to grant some kind of approval to Provenge based on the fact that the applicant demonstrated substantial evidence of efficacy and that Provenge is safe then Defendants are indeed correct. However if this court returned this matter to the FDA with an order that fair, reasonable and duly protected procedural due process be afforded the BLA which was not previously done within a very set and limited number of days, it would still be possible for Mr. Scher and Mr. Pazdur to again interfere and derail the process. As a part of any such order this court would need to order the individuals not to take any action in degradation of the procedural due process ordered by this court. The court can only enforce an order over those persons if they are parties. While the Federal Agency must act, this time it must act without the improper influence of these conflicted individuals. The question of qualified immunity is just that, it is only qualified. Whether the individuals even have qualified immunity is only relevant to activities taken within their scope of employment. *See* *Miller v. City of Anderson*, 777 N.E.2d 1100, 1104-05 (Ind.Ct.App.2002) ." *Miller*, 777 N.E.2d at 1103, Flynn v. Mills 361 F.Supp.2d 866, *877 (S.D.Ind.,2005). The allegations taken in a light most favorable to Plaintiffs at the

least indicate that the issue of whether the actions taken by Scher and Pazdur were within the scope of their employment requires a factual determination by the court. Qualified immunity also only covers negligent acts and not intentional acts committed with constitutional malice as alleged by Plaintiffs. Qualified immunity does not protect them from actions taken outside their scope of employment. Both Scher and Pazdur acted outside the scope of their authority. Scher's job description was to review the Provenge BLA including all the briefing documents and then offer advice to the FDA at the public advisory hearing. Pazdur, being in a different division of the FDA than the one reviewing the Provenge BLA, should not have been involved at all and especially should not have been involved after the AC meeting. It appears Scher also committed a violation 18 U.S.C. section 208 and perpetrated a fraud on the FDA when he failed to disclose all his conflicts of interest to the FDA prior to the AC hearing. Such actions take him outside the protection afforded by qualified immunity. Clearly Scher did or should have known his actions were unlawful and deprived Plaintiffs from their dignity and personal autonomy guaranteed under the Constitution. Pazdur should not have misused his authority and his public office in such a manner. Regardless, the fact that Defendant may have subjectively believed that his actions were lawful is not relevant to the qualified immunity analysis-rather, the standard is one of objective reasonableness. *See O'Brien,* 23 F.3d at 999. That being said Scher clearly realized that his combination of undisclosed conflicts of interest, misuse of FDA insider information was against the law, as was misuse of his status as a special government employee to conduct post AC defamation of Provenge with the assistance of public employees.

Defendants bear the burden of establishing that they enjoy qualified immunity. *See Ryan v. Burlington County,* 860 F.2d 1199, 1204 n. 9 (3d Cir.1988). The Supervisor Defendant has not carried that burden. Any reasonable person would have known that acting in the alleged manner would violate the Plaintiff's well-established rights to bodily integrity and equal protection of the laws.

Further, while an agency's employees generally enjoy qualified immunity to the same extent as does the agency itself, employees do not have such protection where their actions constitute "willful misconduct". "While 'willful misconduct' generally refers to intentional torts, it can also mean ... misconduct 'whereby the actor ... was aware that [a result] was substantially certain to follow, so that desire [that a particular outcome results] can be implied.' " *DiSalvio,* 158 F.Supp.2d at 564 (citing *Owens v. City of Phila.,* 6 F.Supp.2d 373, 394-95 (E.D.Pa.1998)). Based on the allegations of the Complaint, Defendants have not carried their burden of showing that they enjoy qualified immunity for their actions, or failures to act.

It is unnecessary for the Court to consider the constitutional issue at this point in the proceedings and the Court should not decide constitutional issues unless it is absolutely necessary for a determination at each stage of the proceedings. See, *e.g., NLRB v. Catholic Bishop of Chicago,* 440 U.S. 490, 502, 99 S.Ct. 1313, 59 L.Ed.2d 533 (1979) (refusing to engage in extended analysis in the process of applying the avoidance canon "as we would were we considering the constitutional issue"); see also Vermeule, Saving Constructions, 85 Geo. L.J.1945, 1960-1961 (1997) (providing examples of cases where the Court construed a statute narrowly to avoid a constitutional question ultimately resolved in favor of the broader reading). Indeed, one of the canon's chief justifications is

that it allows courts to *avoid* the decision of constitutional questions. Clark v. Martinez 543 U.S. 371, *381, 125 S.Ct. 716, **724 (U.S.,2005). A court should not decide a constitutional issue unless it is absolutely compelled to do so. If another basis for decision exists, the constitutional question should be avoided. "[I]f a case can be decided on either of two grounds, one involving a constitutional question, the other a question of statutory construction or general law, the Court will decide only the latter." *Ashwander v. Tenn. Valley Auth.,* 297 U.S. 288, 347, 56 S.Ct. 466, 80 L.Ed. 688 (1936) (Brandeis, J., concurring); *see *622 also Three Affiliated Tribes of Fort Berthold Reservation v. Wold Eng'g, P.C.,* 467 U.S. 138, 157, 104 S.Ct. 2267, 81 L.Ed.2d 113 (1984) ("It is a fundamental rule of judicial restraint ... that this Court will not reach constitutional questions in advance of the necessity of deciding them."); *Spector Motor Service, Inc. v. McLaughlin,* 323 U.S. 101, 104, 65 S.Ct. 152, 89 L.Ed. 101 (1944) ("If there is one doctrine more deeply rooted than any other in the process of constitutional adjudication, it is that we ought not to pass on questions of constitutionality ... unless such adjudication is unavoidable."); *Blair v. United States,* 250 U.S. 273, 279, 39 S.Ct. 468, 63 L.Ed. 979 (1919) ("Considerations of propriety, as well as long-established practice, demand that we refrain from passing upon the constitutionality of an act of Congress unless obliged to do so in the proper performance of our judicial function, when the question is raised by a party whose interests entitle him to raise it."); *Gulf Oil Co. v. Bernard,* 452 U.S. 89, 99, 101 S.Ct. 2193, 68 L.Ed.2d 693 (1981) ("[P]rior to reaching any constitutional questions, federal courts must consider nonconstitutional grounds for decision."); *Dept. of Commerce v. United States House of Representatives,* 525 U.S. 316, 119 S.Ct. 765, 142 L.Ed.2d 797 (1999). In re Basch 341 B.R. 615, *621 -622 (Bkrtcy.W.D.Mich.,2006).

While Plaintiffs agree that the Abigail Alliance case is in many ways procedurally similar to this case it is not similar when it comes to the constitutional issue. The Abigail Alliance sought a judicial determination that terminal patients had a right to access investigational treatments once they had passed phase one testing. Plaintiffs' herein complaint is about the lack of procedural and substantial due process afforded them due to the actions and unlawful conduct of the FDA, Scher and Pazdur. The more narrowly defined constitutional issue herein is more a question of *right to survive* or, specifically; *whether there is a fundamental right of late stage cancer patients in consultation with their doctors, who have no reasonable alternative treatments available and when their only alternative to treatment is death without hope do that have a right to access to a treatment that has been substantially proven to be effective and which has been demonstrated to be safe or at least have a right to proper procedural due process if it is to be denied by action taken by the FDA.* The fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.' *Mathews v. Eldridge,* 424 U.S. 319, 333, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). Its not meaningful if the public AC hearing is merely a sham and the "real meeting" occurs behind closed doors in ignorance that this is The United States of America where operating in secrecy in a non democratic manner is frowned upon. To determine what process is due, the Court utilizes the *Mathews* balancing test and looks at three factors: (1) the private interest that will be affected by the official action; (2) the risk of an erroneous deprivation of such interest through the procedures used, and the probable value of additional or substitute procedural safeguards; and (3) the Government's interest. *Id.* at 335, 96 S.Ct. 893.

The actions of the individuals herein rise to the level of constitutional malice and were at a minimum with wanton and willful disregard to the rights of dying cancer patients at least some of which were done outside the scope of their employment. That there was a duty to the health and welfare of the pubic cannot be denied. Indeed the FDA under McClellan broadened the scope of the FDA's duty when he changed the FDA motto to include "protecting and advancing America's health".

The Defendants are both accomplished medical school graduates. They both have suggested through their counsel that they did not have fair warning that their conduct would not violate anyone's rights. Theirs is a very bold statement. They were well aware that if they took actions that resulted in a safe and effective therapy from not getting to terminal cancer patients who needed it, that they have done something seriously wrong. The decision to take the "due" out of due process was a deliberate wrongdoing and more then just run of the mill negligent conduct. Seeing that the agency is sworn to protect the public, each employee of he FDA *should* be sworn in at the start of employment to so protect the health and welfare of the public. None the less there is an implied contract that they have to perform their jobs with the utmost honesty and integrity to best serve the American public, putting their own personal financial and political agendas aside. FDA employees, being a part of our government and paid for with tax payer money, must be held accountable for their actions even more so than employees in the private sector because of the power they wield, by virtue of being part of government. Both Scher and Pazdur violated the public trust. With or without such an oath these Doctors have a fundamental duty to cancer patients not to cause them harm. If as believed and alleged these doctors worked to derail Provenge knowing that Provenge met the Congressional

standard of safety and substantial evidence of efficacy, then they have caused injury to every suffering AIPC patient and their families.

When Howard Scher disseminated his insincere (to put it nicely) letter to the FDA and to the public, Provenge advocates contacted Dr. James Marincola one of the Courageous 13 on the AC panel who refused to be bullied by Pazdur and Scher, asking that he respond and do as Scher did (who lobbied for non approval). His response was as follows:

> Dear All
>
> Thank you for your supportive words about my participation at the FDA advisory board. As you may well infer from my comments I share several of your opinions. However, *I strongly believe that my role as member of the advisory board is to express my opinion during the meeting but I believe it would be ill advised to influence the FDA decision on my part beyond that point;* if it is true (which I doubt) that some other members of the board contact(ed) the FDA afterwards is beyond my control but my personal opinion is that my credibility as a member of the board will be better preserved if I give my impartial opinion at the time of the meeting and let the FDA do their work afterwards. I believe that I should not be part of this activity if I did not believe in the integrity of the process.
>
> At the personal level I do share many of your concerns but this is beyond my role as an advisor to the FDA.
>
> Thanks again for your support and you may be sure that independently of my role as an advisor to the FDA I will continue to fight for the improvement of the strategies for the treatment of cancer
>
> Francesco M Marincola, MD
>
> Chief Infectious Disease and Immunogenetics Section,
>
> Department of Transfusion Medicine,
>
> Clinical Center, NIH,
> 10 Center Dr. Bldg 10, Room1C711, Bethesda MD, 20892

Dr. Marincola refused to exceed the scope of his authority, unlike Dr. Pazdur and Dr. Scher.

EQUAL PROTECTION AND SECTION 1985 AND 1986 CLAIMS

The discrimination against the patient Plaintiffs is both age and gender based. The conspiratorial action of Pazdur, Scher, and others affects elderly men. AIPC patients are on average 70 years old with 19 months to live from diagnosis. They are often very sick and have been ravaged by the disease by the time it gets to APIC stage. They often have already lost much of their family support and the advocacy groups are not as powerful and far reaching as other advocacy groups. They often tend to be somewhat sheltered and depressed. Pazdur and Scher knew that this was a group that they might be able to get away with treating differently and could avoid excessive scrutiny denying them a needed treatment. It didn't hurt that the main prostate cancer group (PCF) would be apparently supportive of their action because PCF was invested in Provenge's competition and would benefit via their investment vehicle (Proquest) by at least slowing down the approval process when it came to Provenge. The best way to make money investing in biotechs is to have an FDA insider like Howard Scher as a paid doctor advising you. This combination of circumstances enabled the Defendants to make their power play and think that it would escape the scrutiny that resulted. The FDA has historically been discriminatory against men. There have been numerous treatments (believed to be 64) approved for late stage breast cancer (women) (a very good thing) in the past 45 years yet there has only been one (taxotere) treatment for late stage prostate cancer patients (men). Just in the past few weeks the FDA approved Ixempra for the treatment of patients with metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine or whose

cancer is taxane resistant and for whom further anthracycline therapy is contraindicated. Ixempra's applicant was Bristol Myers Squibb (BMS) (whose Senior Director of Oncology Licensing spoke out against approval of Provenge, between the AC meeting and the FDA decision, soon after the Scher leaked letter appeared). BMS is one of the big pharmaceutical companies that help to fund the FDA.

The Equal Protection Clause provides that no state shall "deny to any person within its jurisdiction the equal protection of the laws." U.S. CONST. amend. XIV, § 1. "To state a claim under the Equal Protection Clause, a section 1983 (1985, 1986) plaintiff must allege that a state actor intentionally discriminated against the plaintiff because of membership in a protected class' or burdened a fundamental right." *Midkiff v. Adams County Reg'l Water Dist.*, 409 F.3d 758, 770 (6th Cir.2005) (quoting *Purisch v. Tennessee Tech. Univ.*, 76 F.3d 1414, 1424 (6th Cir.1996)). "[W]here no suspect class or fundamental right is implicated, this Court must apply rational basis review." *Id.* (citation omitted). Under rational basis review, "the governmental policy at issue will be afforded a strong presumption of validity and must be upheld as long as there is a rational relationship between the disparity of treatment and some legitimate government purpose." *Id.* (internal citations and quotations omitted). To prevail on a claim under rational basis review, Plaintiff must "negate all possible rational justifications" for the disparity of treatment.

The doctrine of intra intra-corporate immunity does not apply here. (Reply Def. Gray to Pl.'s Resp. to Renewed Mot. Summ. J. at 11.) Under this doctrine, a corporation cannot conspire with its agents or employees for purposes of a civil conspiracy claim. *Doherty*, 728 F.2d at 339 (citing *Nelson Radio & Supply Co. v. Motorola, Inc.*, 200 F.2d

911 (5th Cir.1952)). “There is no conspiracy if the conspiratorial conduct challenged is essentially a single act by a single corporation acting exclusively through its own directors, officers, and employees, each acting within the scope of his employment.” *Herrmann v. Moore,* 576 F.2d 453, 459 (2d Cir.1978), *quoted in Doherty,* 728 F.2d at 339. Defendants claims that because all Defendants were acting on behalf of the Government that there could be no conspiracy. The argument is without merit. As stated by that court “Defendants could not have acted within the scope of their employment by retaliating against Plaintiff for exercising her First Amendment rights”. *See Bloch v. Ribar,* 156 F.3d 673, 682 (6th Cir.1998); *Duran v. City of Douglas,* 904 F.2d 1372, 1378 (9th Cir.1990). The intra-corporate immunity doctrine does not bar claims at the summary judgment phase where there is a question as to whether defendants were acting outside the scope of their employment if they committed acts of intentional discrimination. *See Reese v. City of Southfield,* 162 F.3d 1162, 1998 WL 552841 at 6 (6th Cir.1998) (table opinion). Ross v. City of Memphis 394 F.Supp.2d 1024, *1040 - 1041 (W.D.Tenn.,2005).

ABIGAIL ALLIANCE

In the Abigail case, the Washington DC District Court, the three Judge Court of Appeals, and the en banc Court of Appeals had no issue with the court's jurisdiction or with Abigail Alliance having due process rights. The en banc court just did not agree with its prior three judge panel on the specifically phrased question as to whether the Abigail Alliance had failed to state a claim in accordance with Federal Rule of Civil Procedure 12(b)(6). The present case presents a related but much stronger factual platform on which

this Court could decide that the way to remedy the harm to the plaintiff group is to decide a more general constitutional question of right to life, or right to survive.

The Supreme Court has not yet ruled on the specific question presented in the Abigail Alliance case but still might do so. A decision reached by this court could provide a stronger parallel action to a possible Abigail presentation before the Supreme Court.

In addition plaintiffs do not challenge (other then through the "new drug" definition) the FDA's general right to take regulatory action; rather they challenge the ability of the FDA to deny substantial and procedural due process by arbitrarily and capriciously not approving an immunotherapy that was (even by a summary judgment standard) substantially proven to be effective and definitely proven to be safe as mandated for approval by congress and that such action is taken secretively and behind closed doors presenting a false face on the general public who does not have insiders in the FDA. It matters little what the agency guidelines are but matters greatly that they have elected not to follow the mandates of congress. In this regards, even if FDA's often modified guidelines are wrongly decided to trump the will of congress the assertion by Defendants that the decision to reject Provenge approval was a predictable, normal course of business given FDA guidance and Congressional mandates is without merit as the FDA routinely does not follow its own guidance but does not routinely disregard Congressional mandate. The *exact* extent of the both the deviation from both FDA guidance and Congressional mandates cannot be determined unless this case proceeds. However, we do know the following:

1. Provenge had a statistically significant survival advantage.

2. FDA guidance for prostate cancer endpoints state only survival is suitable as an appropriate endpoint for prostate cancer trials.
3. Yet, the FDA did not approve Provenge.

The FDA's reason has not been provided and cannot be known for certain unless this case proceeds. *Interpreting* Defendants comments, however, it appears the FDA did not approve Provenge because survival was a "secondary" endpoint in the clinical trials. However, a few short months after the rejection of Provenge, the FDA was poised to reject a second drug for prostate cancer called satraplatin. This drug met its primary endpoint with a high degree of statistical significance. Under the direction of defendant Pazdur, however, the FDA said they would not approve satraplatin because it had not met its secondary endpoint of survival. This is essentially the exact opposite of what the FDA *implied* was their reason for rejecting Provenge.

Even a basic of other decisions to approve or reject drugs, particularly oncology drugs, demonstrates the FDA capriciously applies their stated rules and guidances. Some drugs were approved with only a few dozen patients. Some drugs were approved without statistically significant results on primary endpoints. Some drugs were approved with "supportive" data far inferior to that possessed by Provenge.

Without admitting the applicability of the case law cited in Defendant's response, the Courts have generally allowed government agencies some degree of latitude to make regulatory decisions according to established policies and procedures. Rarely if ever has a Court upheld the right of a government agency to make completely capricious decisions marred by significant conflicts of interest without any recourse in the judicial system by affected parties.

Title 21 section 10 is rendered meaningless if patients do not have a right to a judicial review of the FDA process when it by all public appearances has acted capriciously. Arguably Title 21 section 10 itself suggest that the *public has a right to bring suit after 180 days.* Where are citizens to bring these suits referenced under Citizen Petitions if not in their own Federal Courts? Are patient's heretofore apparent processes for *redress of their grievances* just illusory, or in other words that upon actual suit after 180 days they would be told the court has no jurisdiction effectively rendering even Title 21 section 10 functionally meaningless.

The Defendants cannot be allowed to simultaneously hide behind a facade of rules, guidance, and regulations when in the courtroom while acting without regard to the same rules, guidance, and regulation during decision-making processes that affect the lives of US citizens. At a minimum the court must allow some discovery to proceed.

OTHER LEGAL CLAIMS

Defendant Scher accepted the responsibility to act in the best interest of the public and in this instance dieing cancer patients. He did not and instead acted in his own best interest instead. By accepting this role and then rendering it (intentionally and with wanton and willfully disregard to patients rights), he took the job from another competent expert who would have acted assumed his role on the AC and acted in the public best interest instead of his own. If he had not wrongfully assumed this *role then another would have*. This "other" then would have acted properly and thus provided even more evidence of efficacy of Provenge making approval on or before the May 15th PDUFA date. In other words the non conflicted expert actually working to in the AIPC patient's

best interest would likely have done as all the other “Courageous 13” non conflcited experts did.

Plaintiff assert a cause of action under both Restatement of Torts (Second) section 324:

> § 324A. Liability To Third Person For Negligent Performance Of Undertaking
>
> One who undertakes, gratuitously or for consideration, to render services to another *which he should recognize as necessary for the protection of a third person* or his things, is subject to liability to the third person for *physical harm* resulting from *his failure to exercise reasonable care to protect his undertaking*, if
>
> (a) his failure to exercise reasonable care *increases the risk of such harm, or*
> (b) he has undertaken to perform a duty owed by the other to the third person, or
> (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.
> (emphasis added)
>
> REST 2d TORTS § 324A

The FDA relied on the false conflicts waiver submitted by Scher and invited Scher onto the Advisory Committee. His acceptance and attainment of the position under false pretenses meant that another more qualified and able expert did not sit in his place. It meant that he was going to be one of the individuals who was to protect the patients health and welfare. Liability To Third Person For Negligent Performance Of Undertaking under § 324 is more appropriate herein then is Restatement (Second) of Torts § 323. Section 324A is applicable when a third party (whose protection is contingent upon the voluntary undertaking) is injured as a result of the actor's negligent performance of a voluntary undertaking. See Solis v. Lincoln Elec. Co. 2006 WL 1305068, *4 (N.D.Ohio) (N.D.Ohio,2006). The patients would have been the admitted beneficiaries of

the approval of Provenge which was more likely to have occurred if an expert concerned with their best interest and not his own was placed in position number 17.

Plaintiffs were also denied the right to be rescued as Dendreon and some employees of the FDA were trying to do provide them aid in the form of Provenge. The Plaintiffs were arbitrarily deprived of their rights to private rescue pursuant to the [defendants'] custom, policy, ordinance, regulation, or decision preventing private rescue efforts. *Beck v. Haik* 377 F.3d 624, *633 -634 (C.A.6 (Mich.),2004)

Plaintiffs claim this case is similar to *Beck v. Haik,* No. 99-1050, 2000 WL 1597942 (6th Cir. Oct.17, 2000), which held that allegations that law enforcement officers prevented rescue efforts by qualified civilian divers but failed to provide meaningful alternative rescue services were sufficient to give rise to a due process violation. Defendants site to Abigail Alliance but fail to cite this important language from that Washington DC case:

> The Restatement of Torts, published in 1934, generalized this point of law: "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." RESTATEMENT OF TORTS § 326; *see also id.* § 327 (negligence); RESTATEMENT (SECOND) OF TORTS §§ 326, 327; W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS 382 (5th ed.1984). This common law rule is firmly grounded.[FN4] By interposing itself *719 between a terminally ill patient and her only means of prolonging her life, the FDA's policy runs counter to the common law's historical prohibition on interfering with rescue.
>
> FN4. *See, e.g., Beck v. Haik,* 377 F.3d 624, 633-34 (6th Cir.2004) (discussing appropriate jury instruction for claim of interference with rescue); *Ross v. United States,* 910 F.2d 1422 (7th Cir.1990) (holding that a deputy sheriff committed a constitutional tort by interfering with efforts to rescue a drowning boy); *United States v. Lawter,* 219 F.2d 559, 562 (5th Cir.1955) (holding that the government is liable when it prevents others from attempting a rescue and takes no action itself); *Sneider v. Hyatt Corp.,* 390 F.Supp. 976, 980 & n. 2 (N.D.Ga.1975) (noting that "deliberate interference with rescue efforts by third parties is a traditional basis for imposing liability"); *Soldano v. O'Daniels,* 141 Cal.App.3d 443, 190 Cal.Rptr. 310, 313, 316-18 (Ct.App.1983) (applying Restatement); *Thomas v. Williams,* 105 Ga.App. 321, 124 S.E.2d 409, 414 (1962) (sustaining cause of action for

interference with rescue where defendant prevented rescue of inmate from jail cell during fire); *Riggs v. Colis,* 107 Idaho 1028, 695 P.2d 413, 415 (1985) (applying Restatement); *Byrne v. Long Island State Park Comm'n,* 66 Misc.2d 1070, 323 N.Y.S.2d 442 (Sup.Ct.1971); *see also Commonwealth v. Marcelli,* 14 Mass.App.Ct. 567, 441 N.E.2d 270, 271 (1982) (criminal liability); CAL.PENAL CODE § 148.2(1) (same).

The common law protection, of course, is for rescues that are reasonably necessary. In an effort to distinguish this historical protection, the court relies upon the fact that the new investigational drugs "have not been shown to be safe, let alone effective at (or 'necessary' for) prolonging life." Op. at 708. But this confuses what is necessary with what is sufficient. This is not a case about elective medical treatments. Without access, Alliance members will die. No doubt the deceased members of the Alliance who were denied access to experimental drugs that were subsequently approved by the FDA would have been surprised to learn that these drugs, under the court's analysis, were unnecessary to the preservation of their lives. *See* Br. of Appellants at 31 n. 15; Reply Br. of Appellants at 23. *See generally Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach,* 469 F.3d 129 (D.C.Cir.2006) (" *Abigail Alliance II* "). Thus, the court's apparent understanding of the meaning of "necessity" is manifestly flawed. *See* Op. at 708-09 n. 15. By the court's reasoning, it is not "necessary" for the driver of a car that is hurtling toward a cliff to press the brake because we "cannot know until after" he has done so whether the car will stop in time. Alliance members, like the endangered driver, will perish without remedial steps. The question presented in this case is not whether investigational drugs are necessary to a terminally ill patient who has exhausted conventional treatment options-they are-but who will make the subsequent decision about using these medications, the patient with her doctor or the government. Moreover, as Prosser and Keeton have explained, "[t]he principle [that one may not prevent aid by others] has been carried even to the length of holding that there is liability for interfering with the possibility of such aid." KEETON ET AL., *supra,* at 382.

Throughout its discussion of self-defense and interference with rescue, the court recognizes that common law rights are not unlimited but fails to acknowledge that the evolved limitations on hallowed rights do not undercut the core concerns that animate them-here, the special importance of life and attempts to preserve it. That the ultimate protection of such varying attempts to save life is cabined by precedents discussing "necessity" speaks not to the absence of an underlying right to attempt to protect life but rather to the recognition of competing governmental interests that in various circumstances justify the deprivation of or a limitation upon the right. Whether similar countervailing interests exist in this case is a question bearing on the resolution of strict scrutiny analysis, not on whether it should apply.

Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach 495 F.3d 695, *718 -719 (C.A.D.C.,2007).

Although Plaintiff reiterates the similarities procedurally of the Abigail Alliance case, this court is reminded of the factual specificities of this case, which make its arguments stronger and narrower. Plaintiffs do not necessarily seek access to experimental treatments rather it seeks due process and accountability by a public agency that decided to do one thing publicly and another thing privately. In this case Plaintiffs call for the FDA to follow congressional mandates and to approve a therapy that has been demonstrated to b safe and effective, for which the evidence is so overwhelmingly in favor or Provenge that Plaintiff believes it can prove, after a small amount of discovery, its case, even on summary judgment. This court is also reminded that eventually all the nine therapies and drugs advocated for by the Abigail Alliance were *later* approved by the FDA and are saving life's still today. The Abigail Alliance now advocates for Provenge.

Diversity of citizenship and over $50,000.00 in damages is also actionable and a basis for jurisdiction by the investor portion of CTL membership, as to Defendant Scher who used his insider position and undisclosed conflicts for financial gain to the detriment of investors that did not have the information provided to a select few in the financial community, by Defendant Scher.

The potential John Doe Plaintiffs are thankfully still with us and still have the chance to obtain Provenge to extend and improve their quality of life and so can not be substituted now by amendment otherwise. The FDA still has the power to see that these potential Plaintiffs obtain Provenge now despite their refusal to date to make this matter a priority for the agency and thus making it so they never have to be individual Plaintiffs. These potential Plaintiffs (more specifically their families) do not need to be from the

Southern District of Ohio. That they are from Ohio is only important because it establishes the state law to be applied to the action for wrongful death, which amendment and permission to substitute will be sought form this court at the appropriate time. Plaintiffs sincerely hope that the FDA sees the light and takes action now, or that this court compels such action on the basis of law, equity or fundamental fairness, so that such action would not ever be necessary. The Pubic also seeks public accountability and a stated rationale from the FDA.

WHEREFORE the Plaintiffs motion to dismiss filed by the individual Defendants should be denied.

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 24th day of October, 2007.

S/Kerry M. Donahue

Kerry M. Donahue