

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

CareToLive, a not for profit corporation
et al.,

Plaintiffs

Case No. 2:07 CV 729

vs.

Judge Frost

Andrew von Eschenbach, et al.,

Magistrate Judge King

Defendants.

**PLAINTIFF’S MEMORANDUM CONTRA
DEFENDANT’S MOTION FOR PROTECTIVE ORDER**

Defendants (hereinafter “FDA Defendants”), have requested a “protective order” in this matter. Despite the FDA Defendants knowledge that AIPC patients are dying each and every day in which the FDA Defendants delay taking actions to remedy the now undeniably known injustice, these FDA Defendants continue to act as an intentional hindrance to the due process rights of the patients. The FDA Defendants have not only established their intent to delay the progress of this litigation, they have overtly obstructed the further fact gathering of Plaintiffs, by contacting Plaintiff’s witnesses and instructing them not to talk to Plaintiffs or their counsel. This kind of request coming from the US Attorney’s office is threatening to the Plaintiff’s witnesses and has served to improperly chill the discovery rights of Plaintiff

Plaintiff has requested emergency injunctive relief and needs to take a few short depositions that will ensure that the evidence that is required to be efficiently presented to this court, is available to be presented at the time of that emergency hearing and later if a

trial is necessary. Plaintiff has tried to proceed in a manner that causes as little inconvenience to the FDA Defendants as possible. No damages or injury would result to the FDA Defendants if this court allows some limited discovery to proceed, because this case is going forward, whether it's now, later, in this court, or in another court, by these Plaintiffs, or others, it will proceed, and sooner or later the wrongdoing of the FDA Defendants will be proven in a court of law.

There can be but one simple way to end the *emergency* nature of the relief sought by Plaintiffs. FDA Defendant Andrew von Eschenbach can simply say: "We have decided to immediately reconsider the Provenge decision", with full due process protections in place. That simple statement would likely not only cause the Plaintiff to agree to a stay of discovery it would also cause the Plaintiff to withdraw its motion for emergency injunctive relief. For the FDA Defendants to argue that they cannot be inconvenienced by a short deposition at their own office or place of their choosing, when what we are talking about is the intentional and wrongful withholding by them of a safe treatment, proven to save lives, is incomprehensible. For the FDA Defendants to argue that they have 6 months (from July 27th 2007) to decide if they will reconsider Provenge, is indicative of their uncaring and arbitrary attitude toward the dying patients. What is more pressing on the FDA's agenda that is more important than this matter, that it makes them unable to admit their mistake and remedy it in a timely manner. Instead they have indicated their intent to use Title 21 to try to justify a six month delay in making a life or death decision on behalf of these dying men, despite the fact that their own client (FDA Commissioner von Eschenbach) has told them that he has *already made the decision* not to reconsider Provenge. To assert otherwise then as stated by their client, Defendant

Commissioner, is essentially a fraud on the court. In the Abigail Alliance case against the FDA, supra, the FDA attorneys stated they had 6 months to decide on a citizen's petition but then their client never ever did, and this unconstitutional FDA rule of protectionism is now known to work as merely a delaying tactic. The FDA typically waits the full six months and then never responds. Precedence has shown that it is an empty and inaccurate representation to the Courts. In this case such a representation is contrary to counsels own client's own individual assertion. In addition, what ever happens with the petition it does not decide all the legal issues herein.

A short deposition of a couple of key individuals will not only ensure that the Plaintiffs have all evidence necessary to present their case and pending motion in a timely way, but it may help resolve many of the factual and legal issues involved in this matter and thus simplify and efficiently advance the concept of judicial economy. Just a few depositions will so overwhelmingly prove the Plaintiffs case, that when added to the administrative record, would likely allow both the injunctive relief and the complaint to be decided in favor of the Plaintiffs upon a motion for summary judgment. Because of the alleged wrongdoing of individuals within the FDA the APA records must be and is permitted to be supplemented with evidence of the wrongful actions that directly affected the administrative record. In addition, as has been stated previously to this court, the due process denial is an ongoing violation and due to the fact, which the FDA now knows, that the decision was corrupted by doctors with undisclosed conflicts of interest, the refusal to take action to fix that mistake, is a continuing post decision constitutional violation. The other problem with the so called "administrative record" is the fact that the FDA has a history of doctoring and changing the record. Even the transcript of the

AC meeting has been revised and questions to Court Reporter Neal Gross's office have resulted in a refusal to answer for differences in the record (AC transcript) and that Plaintiff should "talk to the FDA". Add to that a consideration of the words of Senator Chuck Grassley in the e-mail press release attached hereto as "Exhibit A". This will allow the court to understand that the dysfunction at the FDA insures that a complete and accurate administrative record from this FDA, is unattainable and thus depositions are required.

The first two depositions that Plaintiffs have attempted to conduct are:

1. Maha Hussain, who can testify to the desires and requests of Richard Pazdur and that she provided help to him in his pre AC conceived plan to derail the agencies desired approval of Provenge. She also has the note handed her by Dr. Pazdur at a break in that meeting, providing her with information and suggestion on how to further attack Provenge at the advisory meeting. She also knows who helped write "The Cancer Letters" and who "leaked" them to the press in a conspiratorial effort to derail Provenge. She also discussed this conspiracy with Defendant Howard Scher and knows who requested that the letters be written, who wrote them and possibly how they were designed to be leaked from the FDA and the purpose for which they were to be leaked.
2. Dr. Andrew von Eschenbach, can testify as to the wrongful and unlawful actions of Defendant Richard Pazdur and confirm how Defendant Pazdur acted in his desperate attempt to derail the Provenge BLA and he can explain the political infighting at the FDA and he will even likely admit that he does not believe Provenge received a fair hearing and/or due process, because of the actions of

Defendant Pazdur. Although the US Attorney's office represents both Dr von Eschenbach and Dr. Pazdur, their interests are not the same in this matter. It is even believed that in his heart Dr. von Eschenbach wants to give this deposition to Plaintiffs but he is being guided by his concern for any hurt that may be caused to the FDA and he is persuaded by his government counsel, who also represents other persons with interest that are in conflict with his own (Scher and Pazdur).

The Plaintiffs will also seek to depose Defendant Richard Pazdur while in Rockville deposing Defendant von Eschenbach (Defendant Pazdur would not be considered a high government official as defined by case law). The deposition of Maha Hussain had been agreed to between her counsel and Plaintiff's counsel, and a date, time and place had also been agreed upon and said date was trying to be cleared, schedule wise, with the US Attorneys office, at the time the Defendant's motion was filed. Plaintiffs counsel and Ms. Hussain's counsel, have been dialoguing about this deposition for several months. Plaintiffs were in agreement to do it at Ms. Hussain's Attorney's office at the University of Michigan on September 27, 2007. A local US Attorney in Michigan could have easily sat in on the deposition then or on a future date and this practice is believed to be often done by US Attorneys with minimal inconvenience to their expansive nationwide offices.

In violation of Local and Federal Civil Rules no discussion occurred between the *US Attorney's Office* and Plaintiff's counsel in an extra judicial effort to resolve any issues regarding her deposition, rather counsel just filed this expansive "motion for protective order".

To limit the burden of an admittedly busy government official, Dr. von Eschenbach's deposition was noticed for Dr. von Eschenbach's very own office building in Rockville, Maryland to obtain information which he is personally aware of and personally involved in. The commissioner has personal knowledge pertaining to what essentially appeared to improper political pressure exerted upon him by Defendant Pazdur. General FDA counsel is also available there at the FDA offices so again there is very little inconvenience to the parties yet a few very brief depositions would enable this case to be quickly decided in favor of Plaintiffs on Summary Judgment (the issue or non-issue of deposing a high government official is addressed in Appendix One, attached hereto and incorporated by reference). The deposition could even be limited by this court to 1 and ½ hours. Hardly unduly burdensome, considering the circumstances and the high stakes for the dying patients.

It is important for this court to recognize that this case is not a simple complaint regarding general practices of the FDA rather it is an unprecedented legal action which contains supportable evidence of intentional wrong doing by several persons within the FDA who unlawfully conspired towards an illegal purpose. In that sense they are not government officials, but rather anti- government officials, as their actions threaten the very agency for which they work. The unlawful conduct that occurred within the FDA is known by Dr. von Eschenbach. In fact Dr. von Eschenbach will be one of the best witnesses that Plaintiff has in that he will actually testify against Defendant Pazdur. It is also important for the court to recognize that the legal claims against the FDA Defendants continue to mount in that each day is another due process violation and another day of death without hope for patients.

What offends the Plaintiffs sense of justice (besides the competing interests of Dr. von Eschenbach and Dr. Pazdur and their representation by one counsel, who is acting in the best interest of one to the exclusion of the other, as one will be a willing witness against the other) is the fact that the FDA Defendants through their counsel has stymied all attempts by Plaintiff to obtain discovery by advising others that they should not talk to or provide information to Plaintiff's counsel. It is believed that Defendants counsel has advised members of the "courageous 13" (the 13 experts who voted in favor of Provenge and who are now Plaintiff's witnesses) not to talk to or answer questions from Plaintiffs, and they have also told Proquest Investments not to provide requested documents to Plaintiffs. Attached hereto as "Exhibit B" is the letter from counsel for Proquest indicating that they had been provided information from counsel for FDA Defendants that this court said they did not have to respond to a subpoena, yet that is not accurately what this court indicated. Suspiciously, the US Attorney and the counsel for Proquest both say that this court said the subpoena was "invalid". This court did not say that, and the issue was never properly brought before the court. It is unclear why counsel for the FDA Defendants are trying to stop Plaintiffs from obtaining discoverable documents from Proquest Investments as the FDA is supposedly investigating the Scher Conflicts of Interest themselves, per an FDA spokesperson, (documents that the FDA is and/or should themselves be trying to obtain to find out the depth of Howard Scher's Conflicts of Interest). The interests of Defendant Scher are also in conflict with the FDA yet surprisingly the US Attorney represents them all. Justice is offended because Plaintiffs, some of whom will soon pass away, must sit and wait while the FDA tries to delay and stop this important case

from going forward, to the extent of obstructing the Plaintiffs gathering of information from its very own witnesses. Such intimidation by the US Attorneys of Plaintiffs witnesses is improper.

The Defendants proclaim that the court told them to file a protective motion. This is a bit misleading and slightly misstated. Counsel for Plaintiffs recollection is that Defendant's counsel asked the court to stay discovery, and the court responded that it would not do that, and then added that if there is a specific discovery request that the Defendants believe needs to be protected then they should file a request for the specific relief (protection), to the specific discovery requested and the court would then consider any protection that justice would require in each individual circumstance. While the Defendants have couched the title to their motion in terms of a protective order it seems that what they really seek is a stay of all discovery. Considering the massive amount of work (time) required by Plaintiff to assemble the remaining pieces required to clearly prove each assertion of the complaint (witnesses are spread all over the country) it serves merely to delay the pursuit of the Plaintiff's case. In addition, Defendants have not complied with Federal Rules of Civil Procedure 26(c) or Southern District of Ohio local rule 37.2 as they have not made extra judicial efforts to resolve any discovery dispute and they have not attached an affidavit that says that they did so (no certification). There have been no conversations between Plaintiffs and Defendants counsel other than Plaintiff said he would like to schedule a couple of depositions and he wanted to discuss times and locations and the Defendants only response was, no we will not agree to any depositions, no matter when, where and how they are scheduled and if you ask we

will file for a protective order. Date, time, location seemed irrelevant to the Defendants so they did not consider convenience issues or the fact that counsel for Maha Hussain had agreed to her deposition. Because the Defendants have not complied with the above stated federal and local rules of procedure the motion for protective order should be denied.

A court is given broad discretion regarding whether to issue a protective order under Rule 26(c). *Dove v. Atl. Capital Corp.*, 963 F.2d 15, 19 (2d Cir.1992)(grant and nature of protection is singularly within the district court's discretion); *Cruden v. Bank of New York*, 957 F.2d 961, 972 (2d Cir.1992)(order regarding sequence of discovery at discretion of trial judge). However, a court may issue a protective order only after the moving party demonstrates that good cause exists for the protection of the material. *In re Agent Orange Prod. Liab. Litig.*, 821 F.2d 139, 145 (2d Cir.1987). To establish good cause under Rule 26(c), courts require a “particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements.” *Havens v. Metro. Life Ins. Co. (In re Akron Beacon Journal)*, No. 94 Civ. 1402, 1995 WL 234710, at *10, 1995 U.S. Dist. LEXIS 5183, at *10 (S.D.N.Y. April 20, 1995)(quoting *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir.1986)) If the moving party establishes good cause for protection, “the court may balance the countervailing interests to determine whether to exercise discretion and grant the order.” *Rofail v. U.S.A.*, 227 F.R.D. 53, 55 (E.D.N.Y.2005) citing *Hasbrouck v. BankAmerica Housing Services*, 187 F.R.D. 453, 455 (N.D.N.Y.1999). As the moving party on this motion, the Defendants have the burden of demonstrating good cause for the issuance of the protective order delaying discovery.

In addition, the need for judicial expediency coupled with the fundamental purpose of discovery militate against a finding of good cause for the delay. Under Rule 26(c), “[o]pen discovery is the norm. Gamesmanship with information is discouraged and surprises are abhorred. Adherence to these principles assists the trier of fact and serves efficiency in the adjudication of disputes.” *Rofail* 227 F.R.D. at 58. Moreover, “[m]odern instruments of discovery ... [and] pretrial procedures make a trial less a game of blindman's bluff and more a fair contest with the basic issues and facts disclosed to the fullest practicable extent.” *Id.* citing *United States v. Procter & Gamble Co.*, 356 U.S. 677, 683, 78 S.Ct. 983, 2 L.Ed.2d 1077 (1958). Simple and non burdensome discovery such as is being pursued by Plaintiffs will ultimately help to preserve judicial resources in this matter and move this case towards a final resolution in an expeditious and efficient manner. There is a risk that if this case does not move forward that ultimately thousands of Plaintiffs could end up filing individual patient suits all across the country as well as within the States of the individual Defendants. Rather than the Defendants asking this court to avoid discovery and later asking to dismiss this case, the Defendants should welcome the chance to have the issues in the Plaintiff’s complaint fairly and promptly decided by this court.

Defendants argue that the discovery is not allowed because it is not relevant to their yet to be filed motion to dismiss. Not only is the information relevant to factual issues contained in the request for emergency injunctive relief itself, it is also relevant to facts that will be in dispute (pertaining to purely hypothetical argument of Defendants at this point) in the motion to dismiss, to be filed. This court has already

cut a break to the Defendants in that this court could have properly immediately proceeded with the emergency injunctive hearing, allowed discovery for that limited purpose and set it before the alleged dismissal motion, since they do not in fact currently exist. The added benefit of allowing Defendants to take their time, in what is an emergency situation, is one thing, but to completely stop the Plaintiffs from obtaining evidence in their case, made more difficult because of the obstruction by Defendants, that necessarily must be obtained from numerous states and court districts, would be going too far, particularly when some of the discovery is not the least bit burdensome to Defendants in any manner what so ever. Time is not a luxury the Plaintiffs have.

Further, the main issue likely to be raised in the Defendants motion to dismiss is that the Plaintiffs have not exhausted their administrative remedies under Title 21. One of the *many* counter arguments to this anticipated Defense is that the FDA already responded to the patient advocates request to reconsider the Provenge decision when Defendant von Eschenbach told them, after an extended meeting, that the FDA was not going to reconsider Provenge. What better and more final decision could there be than what the FDA commissioner has already himself stated. See *Abigail Alliance vs. FDA*, *Supra*, lower court decision (for reasons *other* than those issues discussed herein, that decision was overruled by the District Court three judge panel and then that three District Judge panel decision was over ruled by en banc decision and the lower court decision was then affirmed, and now is likely to be heard by the Supreme Court) which lower court case is attached hereto as “Exhibit C”. With facts similar, on those specific issues, to the facts herein relative to the motion to

dismiss, that attached decision goes over each and every assertion that will be made in Defendants anticipated motion to dismiss. In that case the court overruled all the arguments that Defendants have stated that they will make in their future motion to dismiss in a thoughtful and detailed decision. This court will likely perform a same or similar analysis when it denies the Defendants motion to dismiss completely or in part. The specific facts of this case make Plaintiff's arguments even stronger than those in the Abigail case, in many regards. The court in Abigail stated:

...the court holds that the challenged policy is a final agency action and further exhaustion of administrative remedies would be futile. *Ciba-Geigy*, 801 F.2d at 434. Thus, the suit is now ripe for review on its merits.

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

There is a factual issue to be presented as part of the motion to dismiss so a short deposition of Defendant von Eschenbach at his own office or other place he designates will be minimally inconvenient and is relevant to the facts as Plaintiff will set forth in the memorandum contra Defendants to be filed motion to dismiss. Facts relevant to the motion to dismiss can be obtained in this discovery and thus the evidence is in fact relevant to the courts jurisdictional decision itself. At this deposition and as relevant to the issue of exhaustion of administrative remedies, there will be testimony confirming what he told the patient advocates requesting reconsideration and whether he still means what he said to them, which is that the FDA has already decided that it is not going to reconsider Provenge, which then renders any argument that they need 6 months to decide it, moot. That simple statement obtained in a short deposition, will be indisputable evidence and decisive of

the administrative remedies issue without need to consider the many other arguments of Plaintiffs.

This takes us back to the beginning, wherein it was pointed out by Plaintiffs that the course of this litigation could be dramatically changed (whether at a deposition or otherwise) if the desired deponent Andrew von Eschenbach states that the FDA is going to immediately reconsider Provenge approval. He can state this in the deposition as easily as anywhere else or he can re confirm what he told the advocates, that the FDA is not going to reconsider. Either way the issue as to exhaustion of administrative remedies may become moot by a single short and unburdensome deposition itself.

Because the Plaintiffs have compelling evidence of improper behavior of these government officials, their depositions are clearly permitted by law. This is not an action that collaterally asserts some inappropriate action of FDA employees; this is an action that alleges intentional, unlawful conduct of government employees that has served to cause the premature death of tens of thousands of people. The allegations in the complaint go way beyond an arbitrary and capricious decision by the FDA as it alleges intentional unlawful conduct and abuse of power from the FDA employees as well as personal unjust enrichment for their own personal benefit and to assist their own pursuit of power, with complete disregard to the fact that the actions they were taking were unlawfully causing people to needlessly die. Defendants assert that merely alleging the wrong without proving it is not enough, yet they go out of their way on numerous occasions to interfere with and obstruct the attempts by Plaintiffs to gather additional evidence of the wrongful FDA actions. Time constraints now make

it necessary, in part due to the obstruction by Defendants, to go right to the heart of the matter, which is at the FDA.

Surprisingly the Defendants counsel has even objected to written questions being sent to potential Plaintiff's expert witnesses ("courageous 13") in order to obtain affidavits and avoid the necessity of taking their depositions. Plaintiff's counsel has gone out of his way to obtain answers in a manner that is the least inconvenient and the least burdensome to everyone involved.

Plaintiffs will overcome the arguments that are to be set forth in Defendants motion to dismiss and under the circumstance of this case some of the Defendants claims are callous and shockingly insensitive to the patients.

Even if this court ruled that the Plaintiffs have not exhausted the administrative remedies, then the actions for intentional misconduct by the individual Defendants outside the scope of their employment would still proceed and the FDA would be brought back into the matter in January after the 180 days have run, so the discovery will be required either way in this case. Such an event would only occur if, and it's a big if, that this court finds that

1. Title 21 is constitutional as applied to terminal patients that will die before the 6 month period is up.
2. The petition has not been established to be a futile act.
3. That the effective date of the petition did not start running when the many Plaintiffs and advocates requested the same relief from the FDA previously.

4. That the petition is required in spite of the fact that it concerns only one small issue of the complaint and would not be relevant to questions of law and other questions of fact that this court must make irrespective of the FDA's decision regarding the petition.
5. That Defendant von Eschenbach's response to the advocates request that the FDA would not reconsider the Provenge decision combined with the non-responsiveness to the thousands of citizen requests, to be indicative of the fact that all other further actions of Plaintiff will be futile.

It is unlikely that the court would make the above findings in an *emergency case such as this one*, meaning there will be no need to refile or amend the case in January. It is a crying shame the FDA itself cannot recognize the emergency nature of the relief sought in the petition itself and take action to remedy the injustice without orders of this court.

The Plaintiff has already set forth some of the proof of the allegations of misconduct by government officials in its motion for injunctive relief. That Defendant Howard Scher has substantial undisclosed conflicts of interest that served to deny due process of law to the Plaintiffs cannot be denied or meaningfully contested by the FDA Defendants (that he has an undisclosed conflict by virtue of being on the board of directors for Proquest Investments can be easily seen by simply logging on the Proquest web site and selecting "board of directors"). Point in fact is that it is the FDA (and thus Scher's counsel themselves) should be filing a third party complaint *against* Defendant Scher for fraud against the agency. To do otherwise essentially hints that the FDA knew about the undisclosed Conflicts of Interest (COI) of Defendant Howard Scher, rather than

that they were duped by him, possibly indicating that it is they themselves who have defrauded the American people and in particular the AIPC patients, rather than Howard Scher. The interests of the FDA and Howard Scher are in conflict. A few simple and short depositions would quickly and efficiently provide the additional proof required for the Plaintiff to prevail on summary judgment in this matter. As the conflicts of interest among the Provenge reviewers have become more apparent, the FDA is left holding the bag for a bad decision. But in the current environment the FDA won't acknowledge a known mistake. At least not until they are placed under oath at a short non intrusive deposition

The whole trend in disclosure is that governmental agencies should not do their business behind closed doors. Courts are open to the public so that the public understands that the judicial process is fair and unbiased. Certainly, no class of plaintiffs deserve their day in court more than those who might die needlessly from the denial by the FDA of a safe and effective therapy for reasons other than the science. The good that can come out of discovery is that those making the decisions behind closed doors may have to explain themselves on the public record, much as judges explain their decisions. The FDA has not explained why they reached the decision they did and that silence is deafening. Discovery in itself supports a vital role in good governance, even if (and however unlikely) it eventually proves that the FDA decision was a sound one, properly and fairly decided.

Finally, it remains unclear what exactly the relief sought by the Defendants even is. Are they seeking protection on behalf of the witness Maha Hussain from being deposed and Proquest from being served subpoenas for documents, and Plaintiffs own

expert witnesses from being spoken to, or are they seeking to protect Defendant von Eschenbach from deposition, or are they seeking to stay all discovery of any kind, from any person?

WHEREFORE the Defendants over expansive motion for a protective order over all forms of discovery and over some needed depositions, particularly the short deposition of Defendant von Eschenbach at his own office, which is required in part as one of the facts in dispute relative to the motion to dismiss, must be allowed to proceed and the Defendants motion should be denied.

RESPECTFULLY SUBMITTED,

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CERTIFICATE OF SERVICE

This motion was e-filed with the court and it is understood that the clerk will serve all parties of record by e-mail transmission this 23rd day of September 2007.

S/Kerry M. Donahue

Kerry M. Donahue

APPENDIX ONE

Defendants have set forth some marginally relevant issues concerning one of the proposed discovery methods which would be the deposition of Andrew von Eschenbach. Because it is generally not applicable under the specific facts of this case it is being discussed in an appendix should the court properly choose to ignore this entire issue. This matter also demonstrates the importance of meaningful conversation prior to the filing of a motion for protective order as details and alternatives could have been discussed by the parties and an alternative such as written deposition, interrogatories, agreed to response times, affidavits and such could have been discussed and arranged.

The reason these argument have no merit herein is that this is not a case that involves some slight involvement from the agency. This is a complaint against the agency that sets forth conduct that could be regarded as completely unlawful, some actions that were taken beyond the scope of employment. Andrew von Eschenbach knows what improper and unlawful actions were taken by Defendant Pazdur in conspiracy with others and knows that the actions of Pazdur's division of the FDA were unlawful. He is uniquely situated to be aware of the unlawful conduct and the extent to which it occurred and to hear the threats made by Defendant Pazdur. This is not the kind of case where the analysis suggested by Defendants is appropriate. That said, should this court decide otherwise, the following is submitted:

Where high ranking government officials lack personal knowledge of events they are granted limited immunity from being deposed in order to insure they have time to dedicate to the performance of their governmental functions." *Marisol A.*, 1998 WL

132810, at *3 (citing *Warzon v. Drew*, 155 F.R.D. 183, 185 (E.D.Wis.1994)). *Gil v. County of Suffolk* 2007 WL 2071701, *1 (E.D.N.Y.) (E.D.N.Y.,2007).

As a result of this undue burden, courts have offered special protections to high-ranking government officials. “There is substantial case law standing for the proposition that high-ranking government officials are generally not subject to depositions unless they have some personal knowledge about the matter and the party seeking the deposition makes a showing that the information cannot be obtained elsewhere.” *Alexander*, 186 F.R.D. at 4 (citations omitted). Courts have carved out this special rule for high-ranking government officials because, if they did not, “we would find that heads of government departments and members of the President's Cabinet would be spending their time giving depositions and would have no opportunity to perform their functions.” *Capitol Vending Corp.*, 36 F.R.D. at 46.

When moving for a protective order to limit discovery, the movant must establish good cause “by demonstrating the specific evidence of the harm that would result.” *Jennings v. Family Mgmt.*, 201 F.R.D. 272, 275 (D.D.C.2001). The burden is on the movant to establish that a protective order should be granted. *Fonville v. District of Columbia*, No. CIV. A.02-2353, 2005 WL 1244816, at *1 (D.D.C. May 25, 2005). Furthermore, a party seeking a protective order prohibiting deposition testimony must establish a specific need for protection, as opposed to simply making conclusory or speculative statements. *Alexander*, 186 F.R.D. at 75 (citations omitted).^{FN1} FN1. Good cause exists under Fed.R.Civ.P. 26(c) when justice requires the protection of a person from annoyance, embarrassment, oppression, or undue burden or expense. Alliance

for *Global Justice v. District of Columbia* 2005 WL 1799553, *1
(D.D.C.) (D.D.C.,2005).

This matter is an emergency, therefore a quick deposition is the fastest and most efficient way to deal with this in a timely and efficient manner, and obviates the need for the Commissioner to be subpoenaed to court for the hearing or trial. That it is to be done at the Commissioner's own office and could be limited to 1 ½ hours means limited interruption of his schedule and minimal inconvenience and burden. Because this is an emergency there is a particularized need for a quick and efficient way to obtain the testimony.

It is rare to quash a deposition altogether, particularly where the deponent indisputably possesses relevant information. *See Sanstrom v. Rosa*, No. 93 Civ. 7146, 1996 WL 469589, at *5 (S.D.N.Y. Aug. 16, 1996); *Martin v. Valley National Bank of Arizona*, 140 F.R.D. 291, 314 (S.D.N.Y.1991). Nevertheless, “the burden a deposition would place on a high ranking government official must be given special scrutiny.” *Marisol A. v. Giuliani*, No. 95 Civ. 10533, 1998 WL 132810, at *2 (S.D.N.Y. March 23, 1998); *accord Lederman v. Giuliani*, No. 98 Civ.2024, 2002 WL 31357810, at *1 (S.D.N.Y. Oct. 17, 2002). This scrutiny is exercised using a two-part analysis. A high level government official may be deposed if it is established that “(1) the deposition is necessary in order to obtain relevant information that cannot be obtained from any other source and (2) the deposition would not significantly interfere with the ability of the official to perform his governmental duties.” *Marisol A.*, 1998 WL 132810, at *2; *accord Murray v. County of Suffolk*, 212 F.R.D. 108, 109 (E.D. .N.Y.2002); *Lederman*, 2002 WL 31357810, at *1. Furthermore, “[t]he first prong of this test has been strictly imposed to

the extent that if a person does not have unique, personal knowledge, that is not obtainable elsewhere, then the deposition should not be permitted.” *Lederman*, 2002 WL 31357810, at *1 (citing *Marisol A.*, 1998 WL 132810, at *3). *Schiller v. City of New York* 2006 WL 2708464, *2 (S.D.N.Y.) (S.D.N.Y.,2006).

Clearly a brief deposition at his office would not significantly interfere with the ability of this official to perform his governmental duties and clearly, only the Commissioner knows what threats, improper conduct and other actions by Defendant Pazdur and his division of OOD occurred that placed him in the middle of agency infighting over power and control of immunotherapies for the treatment of cancer, and what actions were threatened that persuaded him to make a decision based on the long term viability of the FDA, rather than on the issue of these patient’s right to life.

EXHIBIT A

EXHIBIT B

EXHIBIT C