

**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 SUPPLEMENTAL MEMORANDUM
IN SUPPORT OF MEMORANDUM IN OPPOSITION
DEFENDANT'S MOTION TO DISMISS AND AS SUPPLEMENT TO
MOTION FOR INJUNCTIVE RELIEF

This court in its recent order regarding discovery indicated that thus far the court has seen no evidence that this matter is the rare circumstance wherein the administrative record in an APA action might be supplemented through some discovery. While Plaintiffs believe, for reasons set forth in other memorandum pending before this court, that the case is much more than just an APA case, if the Court does decide to proceed only on an APA claim then Plaintiff's believe it prudent and appropriate to bring several matter in that regards to the attention of the court and to otherwise brief that specific issue as it is at least like no other APA case ever presented. In addition, the Plaintiffs have new evidence that what constitutes *the record* in this matter is entirely unclear and unlikely ever to be agreed upon by the parties, and thus the issue itself requires discovery. If the court decides not to allow Plaintiffs

to proceed on its numerous causes of action and orders that they may proceed only on the APA and FOIA claims, the issue of what the administrative record will consist of, and whether it can or cannot be supplemented is of utmost importance.

First, this is not a run of the mill case that can be easily quantified and categorized. It is an unprecedented action that will take serious and understandably careful scrutiny and analysis by this Court in order to properly evaluate. Consider that never in the history of the FDA has the FDA *over ruled* its own self empanelled advisory committee of experts who found that a treatment for a terminal stage group of cancer patients with no viable alternative treatments should be allowed to be prescribed by doctors to their patients. Never in the history of the FDA has two committee members with extreme conflicts of interest worked in conspiracy with one another to attack a product *after* the AC hearing was over. Never in the history of the FDA (that we know of) did an individual within the agency, with his own agenda, purport to influence and control the decision of another branch of the agency and conspire with AC members to sabotage a BLA. This individual's (Dr. Pazdur's) actions would *not be a part of the administrative record* and he would have been careful not to take unlawful and inappropriate action on the record. To explain to this court the extent of the actions that occurred to intimidate and otherwise persuade the CBER to reach the decision to issue a non –approval letter, the court must look outside the record.

More importantly is the fact that there is already evidence that the FDA “record” is inaccurate and discovery must be allowed to determine the correct record, present these inaccuracies and find out the reasons why the FDA or others may have altered the records that have been to date made public (specifically the transcript of the AC hearing). Just the fact the agency considered evidence they should not have, takes the case outside the APA

record.

Because of the change and confusion over the question of whether “substantial evidence of efficacy” was provided by the applicant, the answers by several of the experts were confusing and unclear. This is one of the reasons the court must look outside the record for explanation. Some experts purported to answer the first question and not the second, some answered both and others remained unclear and/or seemed not entirely clear what they answered.

The AC hearing was on March 29th. On April 4th the FDA came out with an audio mp3 of it. It was in six parts. Part six contains the voting. Dr. Scher’s safety vote is completely left out of this audio tape.

This recording has the times the last 7 panelists voted:

Samuels at 3:23

Terry at 3:32

Taylor at 3:53

Woo at 4:09

Marincola at 4:16

Scher should have been here! He is not. Nor do we hear Mule acknowledge him.

Mule acknowledged everybody else prior to the vote. The link to the FDA PDF transcript on the FDA's site: <http://www.fda.gov/ohrms/dockets/ac/07/transcripts/2007-4291T1.pdf> (and is attached to Plf’s mot inj rel.).

The transcript was created on April 13, 2007 (the same day Scher's letter to the FDA came out in the press which was also 8 days after Dr. Scher’s letter had been distributed to the decision makers at the FDA). The transcript, just as the heard on the mp3, leaves out

Scher's safety vote. According to some at the AC hearing and according to the vote calculation by Celia Witten at the end, Scher must have voted Yes that Provenge is safe, even though his vote and any comments he may have made relative to safety are not in the transcript.

The Court Reporter was contacted by Plaintiffs' and ask why this testimony was not in the transcript and he stated "talk to the FDA".

Scher's safety vote and comments are missing:

The voting for question #1 starts on page 365. Following it through you see the court reporter and the audio leaves out Scher. He should have been before Tomford and after Marincola on page 368.

This is a gap. In addition, although it is announced that the vote was 17-0 on safety the record does not indicated that Howard Scher ever voted. People at the meeting say he was called on and voted but it is not in the transcript and not in the mp3 and thus not a part of the "record". Nor are any comments that he may have made.

Further in Scher's letters to the FDA, attached hereto as "Exhibit A" which Plaintiffs received today (11/09/07) he actually argues the safety issue contrary to the way he allegedly voted at the AC hearing. Whether his letter was contrary to his comments is unknown since his comments and vote have disappeared from or never were in the administrative record. On Exhibit A Scher seems to take issue with the safety profile that he purportedly had no issue with just a few days earlier before he was counseled by others, including Alison Maritn at NCI. Why did Dr. Scher have a change of heart, or did he. Since the record is devoid of this information the court must allow Plaintiff to go outside the record to establish this. What other parts of the record are missing? This activity alone is enough for this court to allow

Plaintiffs to do discovery and seek answers outside the record, but there is more.

Because of the rare and never before occurrence of a rephrasing of the efficacy question during the panel hearing the answer from several panelists was not clear.

DR. ALEXANDER: Is the evidence
9 enough to be conclusive to the standard that
10 we need for approving something? That's up
11 to the FDA to decide. And from my
12 standpoint, as designing clinical trials
13 where I am trying to say that it uses
14 definitive evidence that something is
15 conclusive based on a secondary, or not even
16 a secondary endpoint is, you know, is
17 statistically not a valid thing. And that's
18 what -- if we're going to design the study
19 to answer a question, we have to design the
20 best study possible, and that study is
21 ongoing. So that's where I would say, you
22 know, *is there substantial evidence that the*
Page 380
drug has efficacy? Yes. I would say this
2 qualifies as substantial evidence, but is
3 not enough for me that if I was in the seat
4 of saying yea or nay that I would say yea.

5 I would say nay.

6 DR. MULÉ: Okay. Dr.

7 Chamberlain?

8 DR. CHAMBERLAIN: I vote yes,

9 there is substantial evidence.

10 DR. MULÉ: Dr. Kwak?

11 DR. KWAK: Yes, substantial

12 evidence.

13 DR. MULÉ: Dr. Calos?

14 DR. CALOS: Yes, I think there's

15 substantial evidence.

The other doctors above answered the proper question but Dr. Alexander apparently chose to answer a question not before him and as to the proper question he actually voted “yes”. These inconsistencies in the record need to be inquired into. The question had been altered but some, including Dr. Scher expected a different question, and chose to answer a different question. The proper congressionally mandated standard is: has the applicant *demonstrated substantial evidence of efficacy*. The question was first asked: did the applicant *establish* efficacy which is a higher standard than that set forth by congress before Dr. Witted discovered the mistake and fixed it. Still several members were unclear on what they were answering and the transcript indicates that they were unclear. Thus the record is unclear on the issue. While some were unclear others with their own agendas used the opportunity (that they knew was coming because Dr. Pazdur, who had no business even being there, had tipped them off) to answer the first incorrect question and thus never

actually answered the second corrected question on the record (Dr. Pazdur was also seen handing notes to Dr. Hussain during the meeting and it is not expected that the FDA will include those notes in the record either). This is Dr. Scher's on the record testimony with regards to the efficacy question:

DR. MULE: Dr. Scher?

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

Dr. Scher said he believed that there is sufficient evidence. That means his vote should have been counted as a yes, which is different then the position he took in 'Exhibit A'. But then since Dr. Mule was justifiably confused by the answer he was asked again.

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

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

established, I say no (audience laughs on mp3).

Again for the second time Dr. Scher seems to answer the efficacy question by saying: “yes”.

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

DR. SCHER: I will say no.

So Dr. Scher *seemingly twice answered the question as to whether there was substantial evidence of efficacy as “yes”*. And then chose to answer the wrong question and never did actually vote on the proper question making the voting records, and thus THE record, inaccurate (as well as being incomplete).

Was Dr. Scher confused? A review of Exhibit A page four (4) and the e-mail he sent trying to influence CBER head Jesse Goodman *after* the AC meeting attached hereto as “Exhibit B”, indicated that maybe this esteemed doctor and expert in prostate cancer research does not understand the congressional standard for BLA approval and did not understand the question. Exhibit B states:

"I noticed an error in the letter on page 4 of my letter with regard to the change in the question which I will correct in the hard copy that is being forwarded".

He said the question was changed to:

“do the data show significant benefits”.

That would be a new third version of the AC question and entirely inaccurate once again.

This court should also anticipate further administrative record errors as this case proceeds. Attached hereto is an *incomplete response* to an FOIA request the Plaintiffs today received (Exhibit A, Exhibit B and Exhibit C). Of all the participants only the FDA’s Jesse

Goodman was forth coming to the FOIA employee seeking information. Mr. Goodman provided all his copies of the letters he received as a post AC lobbying by the two conflicted AC panelists plus the letter from Dr. Pazdur's cohort (Dr. Fleming). Although the letters were cc'd to others including Dr. Pazdur, he did not provide his records to the FOIA employee. He either did not ever receive his copies, or he has them and chose to violate the FOIA request, or in violation of this court status conference order of August 29th, he destroyed them. Point being is that the FDA is unlikely to be any more forthcoming with regards to production of the record in this matter in the future. In addition Exhibits A, B and C are evidence that these "leaked letters" *were in fact considered* by the decision makers at the FDA (See Dr. Goodman e-mails to Dr. Scher) and thus all versions and other correspondence and e-mail that went with them must be part of the record. Prior to this time the FDA counsel has been *suggesting* to this court that there were no such letters ever received by the FDA. This court should also consider that this new evidence just obtained by Plaintiffs (the letter) from Dr. Scher came on his Sloan Kettering letterhead. Clearly what was considered and not considered by the decision makers at the FDA and what is and is not part of the record or at least whether some matters were appropriately or not appropriately considered, must be looked into. If the letters (Exhibit A, B and C) by friends of Dr. Pazdur and conflicted AC panelists should not have been considered but were considered anyways, as confirmed previously by Patricia Harley and now Jesse Goodman then it is now all germane to this matter. In other words the first question that the "leaked letters" were considered being now irrefutably answered, the second questions becomes where is the related evidence requested and should it have been properly considered. First it must all be produced, something that Dr. Pazdur by his refusal to turn them over to FOIA employees has

shown no inclination towards doing.

Finally, why were the letter even sent to Dr. Pazdur. Pazdur is head of OOD and his division had absolutely no authority to be involved in the CBER decision. That the letters were sent to him are indicative of his involvement where he had no business being involved. Where will the APA record indicate his involvement when he would have carefully not taken any unlawful action on that record.

As a general rule, judicial review of agency actions is limited to the administrative record, but evidence outside the record may be considered when necessary to determine whether the agency has considered all relevant factors and has *explained its decision*, when supplementing the record is necessary to explain technical terms or complex subject matter, or *when the agency has swept stubborn problems or serious criticism under the rug*. Northwest Ecosystem Alliance v. Rey 380 F.Supp.2d 1175 (W.D.Wash.,2005)

Evidence outside the record may be considered when “necessary to determine whether the agency has considered all relevant factors and has explained its decision, ... when supplementing the record is necessary to explain technical terms or complex subject matter,” *id.* at 1030, or when the agency has “*swept stubborn problems or serious criticism under the rug.*” *National Audubon Soc. v. U.S. Forest Serv.*, 46 F.3d 1437, 1447 (9th Cir.1993) (quotation and citation omitted).

The reasons for supplementation will vary; they might include *gaps in the administrative transcript* owing to mechanical failure, unavailability of a witness, *an improper exclusion of evidence by the administrative agency*, and evidence concerning *relevant events occurring subsequent to the administrative hearing*. K.C. v. Board of Educ. for Montgomery County Public Schools 2007 WL 1521054, *3 (D.Md.) (D.Md.,2007).

While the general rule is that the court must look to the agency record, there are recognized exceptions. The courts have held that consideration of after-the-fact affidavits or testimony is sometimes necessary for background purposes, to help determine whether the agency record is complete as to the issues being raised, or to help determine whether the agency considered all of the required factors. Also, after-the-fact evidence can be considered to help understand the agency decision when the agency record is inadequate, but only in the rare instances when remand for creation or supplementation of the record is not the preferred option. *See generally Florida Power & Light Co. v. Lorion*, 470 U.S. at 743-744, 105 S.Ct. 1598; *Camp v. Pitts*, 411 U.S. 138, 142-143, 93 S.Ct. 1241, 36 L.Ed.2d 106 (1973); *Esch v. Yeutter*, 876 F.2d 976, 992 n. 166 (D.C.Cir.1989); *Friends of the Earth v. Hintz*, 800 F.2d 822, 828-829 (9th Cir.1986); *Asarco, Inc. v. U.S. E.P.A.*, 616 F.2d 1153, 1158-61 (9th Cir.1980). *In re Guardianship and Conservatorship of Blunt* 358 F.Supp.2d 882, *893 (D.N.D.,2005). A remand in this case would not be likely to produce a more reasoned record as to date the agency has been unable and unwilling to announce reasons for its decision and has a history of not providing full records plus the existing records are ambiguous. In addition time is of the essence in this matter and the terminal patients lack time for the Court to have to suffer the inevitable gamesmanship from the agency.

The Eleventh Circuit has not opined upon the circumstances under which supplementation of the record would be permissible under the arbitrary and capricious standard of review; it has, however, been among the more liberal courts in permitting supplementation of the record upon *denovo review*. *In Moon v. Am. Home Assurance Co.*, 888 F.2d 86, 89 (11th Cir.1989), the court reasoned that, prior to ERISA, parties would have been able to submit additional evidence to the court for review in a denial of benefits claim.

As a result, restricting parties to the administrative record would “afford less protection to employees and their beneficiaries than they enjoyed before ERISA was enacted,” a conclusion that, according to the court, would run counter to the Supreme Court's holding in *Firestone*, which was based in part on preserving pre-ERISA levels of protection for employees. *Id* Other Circuits have held that while judicial review is generally restricted to the record before the administrator, exceptions may exist in which supplementation is appropriate. In *Vescera v. Unum Provident Corp.*, 2006 U.S. Dist, LEXIS 76147 (D.Vt.2006), the court declined to permit the plaintiff to supplement the administrative record. The court noted, however, that circumstances could exist to warrant a contrary decision: “While there certainly exist circumstances in which supplementing the record may be proper, the Court finds *Vescera* has failed to demonstrate the existence of additional factors that would constitute ‘good cause’ in this case.” There are too many irregularities in this matter for the record to fully explain to the court how far a field the process went in this matter. The Court should not evaluate this case as a typical APA case as it is not a typical APA case in any manner what so ever.

In *Sanzone* the court reasoned:

.....must therefore determine whether good cause exists to permit *Sanzone* to supplement the record in this case.

In this case, *Sanzone* seeks to supplement the record with an affidavit from her treating physician; this affidavit was not before the administrator when the decision was made denying *Sanzone* disability benefits. Normally, this would be precisely the type of document which would not be permitted into the record for judicial review. The circumstances of this case, however, are unusual.

When *Sanzone* applied for disability benefits, her claim was initially denied. Following the denial, *Sanzone*, through counsel, requested the complete file relating to her treatment and care from her treating physician, Dr. Jarolem. Dr. Jarolem's notes and recommendations all concurred that *Sanzone* was permanently disabled.

Upon the initiation of this lawsuit, Sanzone received through discovery from Hartford a letter signed by Dr. Jarolem. This letter was written by Hartford, and sent to Dr. Jarolem for his signature. The letter details the results of surveillance on Sanzone, in which she was seen walking, driving, carrying items, etc. It also includes information gleaned from interviews with Sanzone, and a neurologist's report. At the end of the letter is a paragraph which states:

Based on the findings of our investigation, the documented inconsistencies between this claimant's reported limitations and observed activities, and the medical documentation provided in our file, it is our belief that Ms. Sanzone is not precluded from performing full-time, unrestricted SEDENTARY work (as defined by the Dictionary of Occupational Titles, see attached definitions). If you agree with the above abilities, please sign the following statement.

Below that paragraph was a signature and date line, which was signed and dated by Dr. Jarolem.

Based on *the inconsistency* between Dr. Jarolem's agreement with Hartford as to Sanzone's ability to work, and his opinion thirty days earlier that Sanzone was disabled, counsel for Sanzone contacted Dr. Jarolem to find an explanation for the discrepancy. As noted in Dr. Jarolem's affidavit, Dr. Jarolem disagrees with the findings of the Hartford letter, In his affidavit, Dr. Jarolem states;

Attached hereto is a copy of the letter from the Hartford dated October 13, 2005. This letter is not in the patient's file nor do I have an independent recollection of signing same. If this letter was in fact signed by me, it was done in error and does not reflect the opinions I have with regard to this patient, Lucyanne Sanzone's disability. Furthermore, I specifically disagree with the statement that Ms. Sanzone is not precluded from performing full-time unrestricted sedentary work. To the contrary, Ms. Sanzone is precluded from performing full-time unrestricted sedentary work as a result of her medical condition and my findings.

The letter from Hartford, signed by Dr. Jarolem, was part of the administrative record which the administrator relied upon in denying Sanzone's disability benefits. Because Dr. Jarolem was Sanzone's treating physician, his agreement that Sanzone was not disabled could have weighed heavily in the administrator's decision to deny benefits. However, because Dr. Jarolem signed that letter inadvertently, and disavows agreement with its findings, the administrator's decision in this case may have been based upon erroneous information.

*4 Hartford cites numerous cases in which courts have rejected plaintiffs' attempts to supplement the administrative record with affidavits from doctor that refute the opinions that were before the administrator: *Richards v. Hartford Life & Accident Ins. Co.*, 153 Fed.Appx. 694, 697 (11th Cir.2005); *Orndorf v. Paul Revere Life Ins. Co.*, 404 F.3d 510, 519 (7th Cir.2005); *Lopes v. Met. Life Ins. Co.*, 332 F.3d 1, 5 (1st Cir.2003). However, none of these cases involve the affidavit of a physician which

refutes his own, earlier, and acknowledged mistaken, opinion.

I consider the very real possibility that the administrator's decision was based upon a mistaken opinion as good cause to permit Sanzone to supplement the record with Dr. Jarolem's affidavit in this case.

In light of the foregoing, I find that good cause has been shown to supplement the record with the affidavit of Dr. Jarolem. I further find that there is no need to review the deposition transcript proffered by Hartford.

Sanzone v. Hartford Life and Acc. Ins. Co. L 3101664, *2 -4 (S.D.Fla.,2007)
(emphasis added)

In the Eighth Circuit, “[w]hen there is a contemporaneous administrative record and no need for additional explanation of the agency decision, there must be a strong showing of bad faith or improper behavior before the reviewing court may permit discovery and evidentiary supplementation of the administrative record.” *Id.* (internal quotations omitted). In fact, except in rare circumstances, the proper remedy for correcting an inadequate administrative record is to remand the record to the agency for supplementation. *See Newton County*, 141 F.3d at. In some cases the matter should be returned to the agency to develop the record but this is an extra ordinary case where irreparable injury will occur by any delay and this Court has discretion to avoid that injustice. This case involves a treatment for terminal cancer patients with no viable treatment alternatives. This Court and Plaintiff do not have the luxury to await an agency that can’t respond to terminal patients petition to reconsider over the course of four plus months. This court has the discretion and authority to consider the administrative record supplemented, “if necessary, by affidavits, depositions, or other proof of an explanatory nature.” *Ind. Meat Packers Ass'n v. Butz*, 526 F.2d 228, 239 (8th Cir.1975). Agency action” includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act. The Administrative Procedure Act,

codified at 5 U.S.C. § 701, *et. seq.*, provides a waiver of sovereign immunity for challenges to administrative action that seek non-monetary relief.

In, *Muwekma Ohlone Tribe v. Kempthorne* 452 F.Supp.2d 105, *114 (D.D.C.,2006)
5 U.S.C.A. § 551

An agency action challenged pursuant to the APA “must be set aside if the action was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law or if the action failed to meet statutory, procedural, or constitutional requirements.” *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 414, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971) (quoting 5 U.S.C. § 706(2)) (internal quotation marks omitted). “The scope of review under the ‘arbitrary and capricious standard’ is narrow and a court is not to substitute its judgment for that of the agency.” *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983). “To survive review under [this standard], an agency must ‘examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.’ ” *Tripoli Rocketry Ass'n v. Bureau of Alcohol, Tobacco, Firearms, and Explosives*, 437 F.3d 75, 81 (D.C.Cir.2006) (citations omitted). That is, “an agency action must be supported by reasoned decisionmaking,” *id.* at 77 (quoting *Allentown Mack Sales & Serv. v. NLRB*, 522 U.S. 359, 374, 118 S.Ct. 818, 139 L.Ed.2d 797 (1998)) (internal quotation marks omitted), and “[w]here the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [a court] must undo its action,” *Petroleum Commc'ns v. FCC*, 22 F.3d 1164, 1172 (D.C.Cir.1994) (citation omitted). *See also Bowman Transp. v. Arkansas-Best Freight Sys.*, 419 U.S. 281, 285, 95 S.Ct. 438, 42 L.Ed.2d 447 (1974) (stating that courts “may not supply a reasoned basis for the agency's action that the agency itself has not given,” but that they “will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned”). *Muwekma Ohlone Tribe v. Kempthorne* 452 F.Supp.2d 105, *114 (D.D.C.,2006) (emphasis added)

Based on historical evidence that the agency is unlikely to provide a full and accurate record, the rare and historical nature of the events that occurred in this matter, the gaps in the record, and the ambiguities and inaccuracies contained therein, this Court should allow the

record to be supplemented and some discovery to take place so the Court can fully and fairly review the course of events that resulted in a safe and effective cancer treatment being further denied to terminal patients and the doctors that wish to prescribe it to them. Without some discovery there is no way the court could ever be sure it has the complete record in the matter as it appears that the agency will consider evidence from employees with agendas in other divisions and post AC meeting diatribes by Conflicted AC members. The Court further must determine the propriety of even considering post AC letters from conflicted AC members with their own agendas. As AC members they should have voiced any concerns ON THE RECORD at the AC hearing where 15 others were present to challenge and or at least discuss (due process) what they had to say rather than in an unassailable way by using their contacts and access to FDA decision makers in a an intentional post AC conspiracy to sabotage of Provenge.

Respectfully submitted,

S/Kerry M. Donahue

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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 9th day of November, 2007.

S/Kerry M. Donahue

Kerry M. Donahue