

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

CARETOLIVE, etc.	:	
	:	
Plaintiff,	:	Case No. C2-07-729
	:	
v.	:	JUDGE FROST
	:	
ANDREW VON ESCHENBACH, etc.	:	Magistrate Judge King
et al.	:	
	:	
Defendants.	:	

DEFENDANTS’ MOTION FOR PROTECTIVE ORDER

Now come Defendants, by and through their counsel, and move the Court, pursuant to Rule 26 (c), Federal Rules of Civil Procedure, for a Protective Order which stays discovery by the Plaintiff<sup>1</sup> at least until such time as the Court rules on the motions to dismiss to be filed by Defendants.<sup>2</sup> The Court’s attention is directed to the accompanying memorandum of law.

Respectfully submitted,

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<sup>1</sup> On September 5, 2007, Plaintiff, as ordered by the Court, filed an Amended Complaint. The Amended Complaint purports to add a “John Doe” as an additional Plaintiff. Since the Amended Complaint does not comply with Federal Rule of Civil Procedure 10(a), and Plaintiff did not seek leave of Court to add an anonymous party, Defendants will refer to Plaintiff CareToLive solely.

<sup>2</sup> The parties agreed during the August 29, 2007 informal conference that all Defendants shall have until October 5, 2007 to respond to the Amended Complaint. By filing this motion for protective order, Defendants do not waive any and all available defenses.

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MEMORANDUM IN SUPPORT OF MOTION

INTRODUCTION

Rule 26(c), Federal Rules of Civil Procedure, requires that a party certify “that the movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute without court action.” See also S.D. Ohio Civ. R. 37.2 (2007) (requiring certification of moving party’s extrajudicial efforts to resolve disputes before filing motion for protective order). At the Rule 65 informal conference held on August 29, 2007, counsel for Defendants asked counsel for Plaintiff to agree to stay discovery. Counsel for Plaintiff refused to agree to a stay. The Court then opined that Defendants could file a protective motion.

On August 30, 2007, in response to a voice mail message from counsel for Plaintiff (that acknowledged the dispute over discovery), counsel for Defendants sent a letter confirming the position that under any legal theory presented by Plaintiff, and based on the numerous jurisdictional issues raised in the August 29<sup>th</sup> conference, discovery should not proceed. The government believes it has complied with Rule 26(c) in that its arguments raised in the conference were made in good faith and for the purpose of saving both parties time and expense.

On September 12, 2007, Counsel for Plaintiff filed a notice of deposition for Defendant Von Eschenbach (Doc. 24). In addition, he has tendered the following since the commencement of this action:

- 1) Multiple subpoenas to the publishers of “The Cancer Letter.” These subpoenas are the subject of Case No. 1:07-mc-316 in the United States District Court for the District of Columbia. Plaintiff seeks to enforce subpoenas issued by the Clerk of this Court in the D.C. District Court. Communications to the publishers also threatened to add them as parties to this action and bring them to all hearings.

2) A subpoena issued to the President of Proquest Investments in New Jersey. Once again, the subpoena was issued by this Court. In the informal conference held on August 29, 2007, the Court opined that the subpoena is “invalid.”

3) A letter to FDA Advisory Committee member Dr. Maha Hussain. In this letter, a copy of which is attached as Exhibit A, counsel for Plaintiff seeks information from Dr. Hussain with the request to “confidentially discuss this matter...(y)our cooperation would be appreciated by us and make us more inclined NOT to name you as a Defendant in the future. If you do not want to meet with us...it is our intention to formally depose you and following that deposition we could decide it would be appropriate to add you to the complaint.

4) Letters to FDA Advisory Committee members, a copy of which is attached as Exhibit B, consisting of 46 questions concerning the Advisory Committee meeting of March 29, 2007, represented by counsel for Plaintiff as being less intrusive than “depositions and attendance at court hearings.”

5) In the same email sent by counsel for Plaintiff to the undersigned on September 12, 2007, the following is included: “Also I have arranged for the Deposition of (Dr.) Maha Hussain to occur...on September 27, 2007...” (A copy is attached as Exhibit C).

I. PLAINTIFF IS NOT ENTITLED TO DISCOVERY

A. Any discovery should be deferred pending a decision on the dispositive motion.

“When...the determination of a preliminary question may dispose of the entire suit, applications for discovery may properly be deferred until the determination of such questions.”

O’Brien v. Avco Corp., 309 F. Supp. 703, 705 (S.D.N.Y. 1969). Discovery is especially inappropriate when the material sought is not relevant to the issues in the case as, for example, when the questions involved are legal, not factual. In Groves v. United States, 533 F.2d 1376, 1380 (5<sup>th</sup> Cir. 1976), the Court agreed with the government’s proposition that “[t]he sole issue to be decided is one of law...discovery was properly denied because the materials sought were not relevant...”.

At the Local Rule 65 informal conference held on August 29, 2007, Defendants pointed out the numerous jurisdictional questions presented in this case. The filing of Plaintiff's Amended Complaint on September 5, 2007 has not altered these questions. Plaintiff's action cannot survive a motion to Dismiss and/or Summary Judgment for the following reasons.<sup>3</sup>

First, there is no final agency action in this case. "Final agency action" is a jurisdictional prerequisite to review of the merits of Plaintiff's claims against the government: "A preliminary, procedural, or intermediate agency action or ruling (is) not directly reviewable," and may be examined by a federal court only through "review of the final agency action." 5 U.S.C. §704, Air Brake Systems v. Mineta, 357 F.3d 632, 638 (6th Cir. 2004). For agency action to be final, the action must be one by which "'rights or obligations have been determined,' or from which legal consequences will flow." Bennett v. Singer, 520 U.S. 154, 177-78 (1997).

Here, Plaintiff complains that the FDA did not grant immediate approval to Dendreon Corporation's application for Provenge, but instead issued a "complete response" letter. By definition, such a letter is an intermediate, not final, decision, which indicates that there are deficiencies remaining in the application. The Complete Response Letter summarizes the deficiencies and describes the actions necessary to place the application in a condition for approval. See, CBER, Manual of Standard Operating Procedures and Policies, SOPP 8405 ("Complete Review and Issuance of Action Letters"), ver. 4 (Sept. 20, 2004, available at <http://www.fda.gov/cber/regsopp/8405.htm>). Following the issuance of the FDA letter, Dendreon immediately issued a press release stating that it intends to work with the FDA and continue the

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<sup>3</sup> Defendants do not intend to exhaustively argue each of the following points. The arguments will be fully presented in the forthcoming dispositive motion.

application process: “We are committed to working closely with the FDA to resolve these questions in a timely and efficient manner.” It issued a second press release on May 31, 2007 stating that the FDA indicated it will accept interim or final results from Dendreon’s latest testing. Dendreon understood the complete response letter to be of a merely interlocutory nature.

Second, Plaintiff has failed to exhaust its administrative remedies. Prior to filing the instant lawsuit, Plaintiff filed with the FDA a Citizen Petition seeking reconsideration of the FDA’s May 8, 2007 decision not to grant immediate approval. See Exhibit B to Plaintiff’s Original Complaint (Doc. 1), and [www.caretolive.com](http://www.caretolive.com). In doing so, Plaintiff has created an administrative process that is not yet complete. The FDA has 180 days to act on the petition. FDA’s regulations require that the administrative process be complete “before any legal action is filed in a court complaining of the (FDA’s administrative) action or failure to act.” 21 C.F.R. § 10.45(b). This regulation is an exhaustion rule, the purpose of which is to “allow an administrative agency to perform functions within its special competence - to make a factual record, (and) to apply its expertise...” Shawnee Coal Co. v. Andrus, 661 F.2d 1083, 1092 (6th Cir. 1981). Plaintiff is still actively seeking comments in support of its Citizen Petition. See [www.caretolive.com](http://www.caretolive.com).

Third, in addition to the APA prohibitions present, the individually named defendants must have the opportunity to raise any and all defenses available including, but not limited to personal jurisdiction and qualified immunity, in their first responsive pleading or motion, which the parties agreed is due by October 5, 2007. The First Amended Complaint alleges that Defendant Dr. Pazdur is a resident of Maryland and Defendant Dr. Scher resides in New Jersey. First Amended Complaint at p. 33. To the extent that the individual capacity claims, which now

seek monetary damages in the Amended Complaint, allege a constitutional tort, such action must be brought in the appropriate court.<sup>4</sup> Moreover, the defendants must have the opportunity to raise qualified immunity in their first responsive pleading or motion, which is “an immunity from suit rather than a mere defense to liability.” Saucier v. Katz, 533 U.S. 194, 202 (2001); see also Behrens v. Pellitier, 516 U.S. 299, 308 (1996). If a defendant raises qualified immunity in a motion to dismiss or pre-discovery motion for summary judgment, then discovery should not be allowed until the threshold immunity question is resolved. The district court should resolve the qualified immunity question before permitting discovery, Crawford-El v. Britton, 523 U.S. 574, 598 (1998); see also Harlow v. Fitzgerald, 457 U.S. 800, 818 (1982). Even if the plaintiff’s action survived such a motion by the individual capacity defendants, the district court would need to tailor discovery specifically to the defendant’s qualified immunity. Anderson v. Creighton, 483 U.S. 635, 640 n.6 (1987).

B. Even if this action proceeds, the case against the government is governed by the APA.

It is well settled that the focal point for judicial review of final agency action is the administrative record already in existence, not some new record made initially in the reviewing court.<sup>5</sup> “The task of the reviewing court is to apply the appropriate APA standard of review ... to the agency decision based on the record the agency presents to the reviewing court.” Florida

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<sup>4</sup> The same analysis applies to Plaintiff’s newly presented cause of action under 42 U.S.C. §§ 1985 & 1986, and to the extent Plaintiff asserts any state law tort claims for which Dr. Pazdur and Dr. Scher were not within the scope of their employment. Assuming these individuals were within the scope of their employment and are so certified by the U.S. Attorney, the United States is the only proper party pursuant to the Federal Tort Claims Act. See 28 U.S.C. § 2679(a)–(d).

<sup>5</sup> In this instance, in fact, because plaintiff has not yet exhausted its administrative remedies, no administrative record has yet been compiled.

Power & Light Co. v. Lorion, 470 U.S. 729, 743-44 (1985). The APA does not provide for review of extra-record evidence, such as any information generated through interrogatories or depositions. Rather, it operates as a bar to discovery by requiring the court to look no further for evidence than the administrative record on which the agency based its decision. See IMS, P.C. v. Alvarez, 129 F.3d 618, 623 (D.C. Cir. 1997) (“If a court is to review an agency’s action fairly, it should have before it neither more nor less information than did the agency when it made the decision”). Id. (citing Walter O. Boswell Mem’l Hosp. V. Heckler, 749 F.2d 788, 792 (D.C. Cir. 1984)). The reviewing court “is not entitled to conduct a de novo inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry.” Pueblo of Sandia v. Babbit, 231 F.3d 878, 881 (D.C. Cir. 2000) (quoting Florida Power & Light, 470 U.S. at 744). The Federal Rules of Civil Procedure recognize this settled point of law. Fed. R. Civ. P. 26(a)(1)(E)(I) (providing that “action for review on an administrative record” is “exempt from initial disclosures under Rule 26(a)(1)”). See also Fed. R. Civ. P. 26(f) (requiring parties to conduct a discovery conference and discuss discovery scheduling “[e]xcept in categories of proceedings exempted from disclosure under Rule 26(a)(1)(E)”).

Because a court’s review of an agency’s decision is confined to the administrative record, in the administrative law context courts uniformly have held that discovery typically is not permitted. Common Sense Salmon Recovery v. Evans, 217 F.Supp.2d 17, 20 (D.D.C. 2002). See NTEU v. Seidman, 786 F.Supp. 1041, 1046 (D.D.C. 1992) (plaintiff may not take discovery to create a new administrative record for the purpose of second guessing the agency).

Even if an agency record does not support the agency’s action or shows that the agency did not consider all the relevant factors, or if the reviewing court cannot evaluate the challenged

agency action on the basis of the record before it, the proper course for a court, except in rare circumstances, is to remand to the agency for additional investigation or explanation. If a plaintiff successfully contends that an agency decision is flawed because it failed to take certain evidence into account or failed to consider all relevant factors, then the proper remedy is to remand to the agency for further investigation and explanation, not for the district court to re-weigh the matter itself. See, e.g., Florida Power & Light Co., 470 U.S. at 744 (holding that proper course is generally to remand for additional investigation or investigation “if the record before the agency does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it”); Chevron USA Production Co. v. U.S. Dep’t of Interior, 254 F. Supp. 2d 107, 109 (D.D.C. 2003) (“If it is determined that the agency did not consider all relevant factors, the court must remand to the agency for additional investigation or explanation.”); Wuliger v. Office of Comptroller of Currency, 394 F. Supp. 2d 1009, 1013 (N.D. Ohio 2005) (“Where the agency determination cannot be sustained, the court must remand for further consideration.”).

Here, the initial issue in this case is whether the court has jurisdiction over plaintiff’s claims. But if the Court even reaches the merits, the issue would be whether, based on the administrative record and not some new record generated in this litigation, whether the agency acted arbitrarily, capriciously, or otherwise not in accordance with law, based on a review of the record that was before the agency, not some new record generated in litigation. As the objective of discovery is the eventual production of relevant evidence, discovery beyond the

administrative record is impermissible – it cannot lead to the disclosure of admissible evidence as required by Fed. R. Civ. P. 26(b)(1).

C. Plaintiff's intent to depose high level agency officials is inappropriate.

Counsel for plaintiff has stated – and by today's filing, has now demonstrated – his clear intention to depose numerous individuals, starting with Defendant FDA Commissioner von Eschenbach. However, the planned depositions are objectionable because they are designed to probe inappropriately into the mental processes of high level government officials. In addition, they are unduly burdensome given these individuals' significant responsibilities with regard to protecting public health.

The proposed depositions would allow plaintiff to delve impermissibly into the mental processes of agency personnel and into deliberative and predecisional matters properly outside the administrative record. The Supreme Court has held that such inquiries are almost always prohibited. See e.g., Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 420 (1971) (“[S]uch inquiry into the mental processes of administrative decision makers is usually to be avoided.”); United States v. Morgan, 313 U.S. 409, 422 (1941) (it is “not the function of the court to probe the mental processes” of high ranking agency officials) (quoting Morgan v. United States, 304 U.S. 1, 18 (1938)). This form of prying into the government decision making process has been compared to cross examination of judges on their decisions. Morgan, 313 U.S. at 422. (“Just as a judge cannot be subjected to such a scrutiny...so the integrity of the administrative process must be equally respected.”).

“Judicial review of agency action should be based on an agency’s stated justifications, not the predecisional process that led up to the final, articulated decision.” Ad Hoc Metals Coalition v. Whitman, 227 F. Supp. 2d 134, 143 (D.D.C. 2002).

The deposition of any government official about the decision making process itself encroaches upon the deliberative process privilege. The likelihood that plaintiff’s discovery will generate yet another round of discovery disputes over the deliberative process and other privileges counsels a strict adherence to the limits on discovery imposed by the APA.

Even “[a]llegations that a high government official acted improperly are insufficient to justify the subpoena of that official unless the party seeking discovery provides compelling evidence of improper behavior and can show that he is entitled to relief as a result.” In re United States, 197 F.3d 310, 314 (8th Cir. 1999). See also United States v. Litton Industries, Inc., 462 F. 2d 14, 18 (9th Cir. 1972) (rejecting an attempt to seek discovery into the mental processes of SEC commissioners accused of prejudice and bias in a pending decisional administrative setting).

“[T]op executive department officials should not, absent extraordinary circumstances, be called to testify regarding their reasons for taking official actions.” Simplex Time-Recorder Co. v. Secretary of Labor, 766 F.2d 575, 586 (D.C. Cir. 1985); In re United States, 985 F.2d 510, 512 (11<sup>th</sup> Cir. 1993) (per curiam) (“the practice of calling high officials as witnesses should be discouraged”); In re Office of Inspector General, 933 F.2d 276, 278 (5<sup>th</sup> Cir. 1991) (“exceptional circumstances must exist before the involuntary depositions of high agency officials are permitted”).

In addition, high-ranking officials would be inhibited from effectively carrying out their duties if required to give testimony in numerous civil actions against their agencies. Community Fed. Sav. & Loan Assn. v. Fed. Home Loan Bank Board, 96 F.R.D. 619, 621 (D.D.C. 1983). As the Eleventh Circuit explained, these concerns apply with particular force to the FDA Commissioner:

The reason for requiring exigency before allowing the testimony of high officials is obvious. High ranking government officials have greater duties and time constraints than other witnesses. In this case, the government notes that Commissioner Kessler is responsible for the regulation of all drugs, foods, cosmetics, and medical devices as well as overseeing the enforcement of statutes and regulations governing the distribution and sales of these items. Thus, his time is very valuable. This concern about a high official's time constraints is particularly relevant to selective prosecution claims. If the Commissioner was asked to testify in every case which the FDA prosecuted, his time would be monopolized by preparing and testifying in such cases. In order to protect officials from the constant distraction of testifying in lawsuits, courts have required that defendants show a special need or situation compelling such testimony.

In re United States, 985 F.2d at 512 (citation and footnote omitted).

Before plaintiff can take the depositions of high government officials such as Commissioner von Eschenbach, it must, at minimum, be required to provide evidence demonstrating and proving (1) that it has an extraordinary need for these particular depositions, and (2) that the precise information it seeks from these individuals is available from no other source. Until such time, this Court should enter a protective order pursuant to Rule 26(c).

D. Plaintiff's repeated efforts to take premature discovery further require a protective order.

As shown above, plaintiff's aggressive efforts at seeking discovery require entering a protective order pursuant to Rule 26(c). In addition, because these repeated efforts are also improperly premature, plaintiff violates a separate provision of Rule 26, namely, Rule 26(d), as well as Rule 30(a)(2)(C). Rule 26(d) provides, "Except in categories of proceedings exempted from initial disclosure under Rule 26(a)(1)(E), or when authorized under these rules or by order or agreement of the parties, a party may not seek discovery from any source before the parties have conferred as required by Rule 26(f) [i.e., the conference at which the parties are required to develop a joint discovery plan and schedule]." Fed. R. Civ. P. 26(d). As discussed above, the primary relief plaintiff seeks is review of FDA action, available only through the APA and thus exempted from initial disclosure requirements under Rule 26(a)(1)(E). But to the extent that CareToLive maintains that any of its causes of action authorize it to seek *any* discovery, it may seek such discovery *only* subject to the timing requirements of Rule 26(d). Under this Court's scheduling order, the parties' Rule 26(f) conference is not required until November 9, 2007. See Doc. 21 (pre-trial order filed 9/5/07, requiring parties to file Rule 26(f) report at least 7 days before November 21, 2007); Fed. R. Civ. P. 6(a) (computation of time less than 11 days). Until this conference has occurred, Rule 26(d) prohibits CareToLive from seeking discovery from *any* source, absent leave of Court (or as allowed by another rule, or by agreement of the parties).

Significantly, plaintiff has not sought leave of Court to take premature discovery before the time allowed by Rule 26(d). Even if plaintiff had properly sought such leave, it could be granted only on a showing of good cause. Whitfield v. Hochsheid, No. C-1-02-218, 2002 WL 1560267, at \*1 (S.D. Ohio July 2, 2002) (Hogan, M.J.) (citing Yokohama Tire Corp. v. Dealers

Tire Supply, Inc., 202 F.R.D. 612, 614 (D. Ariz. 2001)). CareToLive has made no effort to demonstrate the required good cause.

In addition, Rule 30(a)(2)(C) provides that “[a] party *must* obtain leave of court . . . if . . . a party seeks to take a deposition before the time specified in Rule 26(d) unless the notice contains a certification, with supporting facts, that the person to be examined is expected to leave the United States and be unavailable for examination in this country unless deposed before that time.” Fed. R. Civ. P. 30(a)(2)(C) (emphasis added). CareToLive here did not even *request* leave of Court, much less obtain it, before it noticed the current depositions. Nor has CareToLive made any suggestion that Dr. Pazdur, Dr. Hussain, or any other potential witness “is expected to leave the United States and be unavailable for examination in this country unless deposed before [November 9, 2007].”

Even if CareToLive had filed the required Rule 30(a)(2) motion, it would still have the burden of showing good cause to take premature depositions before the Rule 26(f) discovery conference. Qwest Commc’n Int’l, Inc. v. WorldQuest Networks, Inc., 213 F.R.D. 418, 419 (D. Colo. 2003) (“a party seeking expedited discovery in advance of a Rule 26(f) conference has the burden of showing good cause for the requested departure from usual discovery procedures.”); Yokohama Tire Corp., 202 F.R.D. at 614. Because plaintiff has improperly noticed multiple depositions before the time allowed by Rule 26(d) and 30(a)(2)(C), there is further reason for this Court to enter an order prohibiting plaintiff from seeking any discovery at least until such time as the Court rules on the motions to dismiss to be filed by Defendants.

## II. CONCLUSION

Before an APA plaintiff may conduct discovery on the theory that the record is incomplete, it must make a “substantial showing that the record is incomplete...or a strong showing of bad faith or improper behavior by the [agency].” TOMAC v. Norton, 193 F. Supp. 2d 182, 194-95 (D.D.C. 2002).

Plaintiff has made manifest its continuing agenda: to conduct a far-flung fishing expedition in which it hopes to obtain volumes of material extraneous to the administrative record, and to propound discovery requests which are inappropriate, irrelevant, and unduly burdensome. Plaintiff determined early on in this case that it wanted to propound discovery as if this were *not* an APA record review case. But as will be shown in the Defendants’ upcoming motions to dismiss, the APA provides the only feasible waiver of sovereign immunity which might allow plaintiff’s case to go forward.

Until the court has ruled on the prospective dispositive motions, no discovery should be permitted. Plaintiff will not be prejudiced if its discovery is postponed until resolution of dispositive motions. A stay of discovery would result in a more orderly and efficient approach to the lawsuit. If the dispositive motion is granted there will, of course, be no need for discovery at all in this case. If the dispositive motion is denied, the court may review the administrative record and avoid the unnecessary burden presented by Plaintiff’s present requests for broad ranging discovery.

Simply alleging that the agency is wrong or even that it has acted illegally or unconstitutionally does not equate to a showing that the agency has acted in bad faith. If it did, the rule limiting challenges to agency decision making to review of the record before the agency would have no force, since Plaintiff could circumvent the rule simply by setting forth naked

allegations that the agency did not rely on the relevant factors. As it is generally understood, bad faith “means more than an erroneous determination of law or fact.” Matter of National Hospital & Institutional Builders Co., 658 F. 2d 39, 44 (2nd Cir. 1981).

Plaintiff’s attempted discovery should be denied or, at a minimum, be stayed pending resolution of Defendant’s dispositive motion.

Respectfully submitted,  
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CERTIFICATE OF SERVICE

I hereby certify that the foregoing Motion for Protective Order was filed on the 12th day of September, 2007, using the Court's CM/ECF system, which will serve all counsel of record electronically.

s/Mark T. D'Alessandro

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