

**IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION**

No. 3:22-cv-184

ROBERT L. APTER, M.D., FACEP; MARY
TALLEY BOWDEN, M.D.; and PAUL E.
MARIK, MBBCh, M.MED, FCCM, FCCP,

Plaintiffs,

v.

DEPARTMENT OF HEALTH AND HUMAN
SERVICES; XAVIER BECERRA, in his
official capacity as Secretary of Health and
Human Services; FOOD AND DRUG
ADMINISTRATION; and ROBERT M.
CALIFF, M.D., MACC, in his official capacity
as Commissioner of Food and Drugs,

Defendants.

JOINT DISCOVERY/CASE MANAGEMENT PLAN

1. State where and when the conference among the parties required by Rule 26(f) of the Federal Rules of Civil Procedure was held, and identify the counsel who attended for each party, including name, address, bar number, phone and fax numbers, and email addresses. Note: The Rule 26(f) conference must be held in person or by phone, not simply over email.

The conference was held via telephone on August 25, 2022.

Counsel for Plaintiffs were: R. Trent McCotter (So. Dist. No. 3712529, DC Bar No. 1011329; 801 17th St. NW, #350; Washington, DC 20006; P: (202) 706-5488; F: (202) 955-0621; mccotter@boydengrayassociates.com) and Jared M. Kelson (*pro hac vice*, DC Bar No. 241393; 801 17th St. NW, #350; Washington, DC 20006; P: (202) 706-5488; F: (202) 955-0621; kelson@boydengrayassociates.com).

Counsel for Defendants were: Isaac Belfer (*pro hac vice*, DC Bar No. 1014909; P.O. Box 386, Washington, DC 20044-0386; P: (202) 305-7134; F: (202) 514-8742;

Isaac.C.Belfer@usdoj.gov) and Oliver McDonald (*pro hac vice*, NY Bar No. 5416789; P.O. Box 386, Washington, DC 20044-0386; P: (202) 305-0168; F: (202) 514-8742; Oliver.J.McDonald@usdoj.gov).

2. List the cases related to this one that are pending in any state or federal court with the case number and court, and state how they are related.

None known.

3. Briefly describe what this case is about.

Plaintiffs allege Defendant federal agencies engaged in unlawful action by interfering with the practice of medicine, the regulation of which federal law reserves for the States, and that Plaintiffs were injured as a result of Defendants' actions.

4. Specify the allegation of federal jurisdiction.

Plaintiffs allege this Court has jurisdiction under 5 U.S.C. §§ 701–706, and 28 U.S.C. §§ 1331, 1346, 1361, 2201, under the U.S. Constitution, and pursuant to the Court's equitable powers.

5. Name the parties who disagree with the plaintiff's jurisdictional allegations and state their reasons.

Defendants contend that the Court lacks subject matter jurisdiction because Plaintiffs have failed to show standing and have failed to identify an applicable waiver of sovereign immunity. Defendants contend that Plaintiffs have not shown standing because, *inter alia*, their allegations of injury are insufficient to the extent they do not allege personal, concrete injuries to Plaintiffs; their alleged injuries are not fairly traceable to the FDA statements cited in the Amended Complaint, which were purely informational; and their alleged injuries are not likely to be redressed by the requested relief because even if the Court vacated the cited statements, that would not likely cause the independent third parties that allegedly injured Plaintiffs to change their decisions. *See Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016); *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). Defendants further contend that the Administrative Procedure Act ("APA") does not provide a waiver of sovereign immunity because Plaintiffs have not shown that the FDA statements cited in the Amended Complaint are "agency action" or "final agency action." *See Alabama-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484 (5th Cir. 2014). Defendants filed a motion to dismiss on August 26, 2022, ECF No. 25, which sets out their arguments in greater detail.

6. List anticipated additional parties that should be included, when they can be added, and by whom they are wanted.

None anticipated.

7. List anticipated interventions.

None anticipated.

8. Describe class-action issues.

None.

9. State whether each party represents that it has made the initial disclosures required by Rule 26(a)(1). If not, describe the arrangements that have been made to complete the disclosures.

The parties have not made initial disclosures because this case is exempt from initial disclosures under Rule 26(a)(1)(B)(i).

10. Describe the proposed agreed discovery plan, including:

a. discovery is needed on the following subjects:

b. the date experts for plaintiff (or party with the burden of proof on an issue) will be designated and their reports provided to opposing party:

c. the date experts for defendant will be designated and their reports provided to opposing party:

d. the date discovery can reasonably be completed:

This case arises from agency action that would normally be reviewed based on an administrative record. The parties disagree about the potential for discovery after production of the administrative record (see next entry).

11. If the parties are not agreed on a part of the discovery plan, describe the separate views and proposals of each party.

Plaintiffs' position: Once the administrative record is submitted, Plaintiffs would be entitled to seek discovery if the administrative record appears to be incomplete. *See, e.g., City of Dallas, Tex. v. Hall*, No. 3:07-cv-60, 2007 WL 3257188, at *5 (N.D. Tex. Oct. 29, 2007) (“[C]ourts have held that plaintiffs are entitled to an opportunity to determine whether any other documents that are properly part of the administrative record have been withheld. Courts have also permitted litigants to supplement the administrative record with additional material that explains the administrative officials’ basis for their actions” because “in these circumstances, the only way a non-agency party can demonstrate to a court the need for extra-record judicial review is to first obtain discovery from the agency.”).

Because the potential for discovery in an Administrative Procedure Act case can be determined only *after* the administrative record is completed and submitted, Plaintiffs believe the Court should order Defendants to prepare and submit the administrative record promptly.

Moreover, even though Judge Brown is aware this case arises under the APA, he declined to cancel this conference (*compare* ECF No. 24, *with* ECF No. 23-1). This confirms the propriety of keeping this case moving quickly, which will be aided by requiring Defendants to submit the administrative record promptly.

Defendants’ position: Discovery is inappropriate in this case. If the Court does not grant Defendants’ motion to dismiss, then this case—like any other case arising under the APA—should be resolved on cross-motions for summary judgment based on a certified administrative record.¹ With limited exceptions that have not been shown to be relevant here, review of agency action under the APA is restricted to the “administrative record that was before [the agency] at the time [it] made [its] decision,” *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977); *see* 5 U.S.C. § 706, and “not some new record made initially in the reviewing court,” *Camp v. Pitts*, 411 U.S. 138, 142 (1973). “Supplementation of the administrative record is not allowed unless the moving party demonstrates ‘unusual circumstances justifying a departure’ from the general presumption that review is limited to the record compiled by the agency.” *Medina Cnty. Envtl. Action Ass’n v. Surface Transp. Bd.*, 602 F.3d 687, 706 (5th Cir. 2010) (quoting *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008)). At this point in the litigation, where no administrative record has been prepared, it would be premature to consider whether to supplement the administrative record.

Furthermore, for two reasons, Defendants should not be required to prepare and serve an administrative record unless and until the Court denies their motion to dismiss. First, it would be premature to require Defendants to prepare an administrative record when they have filed a motion to dismiss for lack of subject matter jurisdiction and failure to state a claim. ECF No. 25; *see Carder v. Cont’l Airlines, Inc.*, 595 F. App’x 293, 300 (5th Cir. 2014) (“[A] trial court may properly exercise its discretion to stay discovery pending a decision on a dispositive motion.” (quoting *Corwin v. Marney, Orton Invs.*, 843 F.2d 194, 200 (5th Cir. 1988)) (internal quotation marks omitted)). Requiring Defendants to prepare an administrative record and permitting motions to supplement the administrative record while Defendants’ motion to dismiss is pending “would be wasteful” of the Court’s and the parties’ resources in the event the Court grants Defendants’ motion to dismiss.

¹ The Amended Complaint asserts a nonstatutory cause of action (Count I), APA causes of action (Counts II–IV), and a declaratory judgment cause of action based on Counts I–IV (Count V). All of those causes of action should be resolved using the normal procedure for APA cases.

Corwin, 843 F.2d at 200; *accord Sapp v. Mem'l Hermann Healthcare Sys.*, 406 F. App'x 866, 870 (5th Cir. 2010). By contrast, deferring preparation of the administrative record until after the Court resolves Defendants' motion to dismiss would "conserve the parties' and the court's resources, and manage the case efficiently." *Brown v. DFS Servs., LLC*, 434 F. App'x 347, 352 (5th Cir. 2011).

Second, how the Court resolves Defendants' pending motion to dismiss may affect the scope of the administrative record. The administrative record "consists of all documents and materials directly or indirectly considered by the agency" in making the decisions at issue. *Rocky Mountain Peace & Just. Ctr. v. U.S. Fish & Wildlife Serv.*, 40 F.4th 1133, 1160 (10th Cir. 2022) (quotations omitted). Even if the Court does not grant Defendants' motion to dismiss in full, its decision may affect which of the FDA statements cited in the Amended Complaint are at issue. For example, if the Court finds that Plaintiffs have standing to challenge only some of the cited statements or that only some of those statements are "final agency action," the Court's decision would be relevant to determining which documents and materials should be included in the administrative record. Thus, Defendants should not be required to prepare an administrative record while their motion to dismiss remains pending.

Notably, Plaintiffs did not request a preliminary injunction, and the Amended Complaint does not indicate any urgent need for relief. Thus, there is no reason to expedite preparation of an administrative record while Defendants' motion to dismiss for lack of subject matter jurisdiction and failure to state a claim is pending. If the Court denies Defendants' motion to dismiss, the parties should submit a proposed summary judgment briefing schedule that includes deadlines for production of the administrative record and for briefing on cross-motions for summary judgment. After the administrative record is produced, Defendants can confer with Plaintiffs if Plaintiffs have any concerns about the administrative record.

12. Specify the discovery beyond initial disclosures that has been undertaken to date.

None.

13. Describe the possibilities for a prompt settlement or resolution of the case that were discussed in your Rule 26(f) meeting.

At the Rule 26(f) conference, the parties discussed possibilities for resolving this case outside of litigation. Those discussions are continuing.

14. Describe what each party has done or agreed to do to bring about a prompt resolution of this dispute.

On August 2, 2022, pursuant to Rule 6 of the Rules of Practice of the Galveston Division of the U.S. District Court for the Southern District of Texas, Defendants' counsel sent Plaintiffs' counsel a letter stating the bases for Defendants' intended motion to dismiss and informing Plaintiffs of their right to amend their Complaint within 14 days. On August 4, 2022, the parties met and conferred regarding Defendants' intended motion to dismiss. On August 8, 2022, Plaintiffs filed their Amended Complaint, ECF No. 12, and on August 26, 2022, Defendants filed their Motion to Dismiss the Amended Complaint, ECF No. 25.

On August 18, 2022, the parties filed a Joint Unopposed Motion for a Briefing Schedule for Defendants' Motion to Dismiss, ECF No. 23, which the Court granted on August 19, 2022, ECF No. 24. And on August 25, 2022, the parties held a Rule 26(f) conference via telephone, during which the parties discussed possibilities for resolving this case outside of litigation.

The parties have agreed to work cooperatively with each other, and both sides desire to resolve this case efficiently.

15. From the attorneys' discussion with their client(s), state the alternative dispute resolution techniques that are reasonably suitable.

The parties believe that this case turns on legal issues, and they anticipate that it will be resolved either on Defendants' motion to dismiss or on cross-motions for summary judgment. As such, the parties agree that alternative dispute resolution is not suitable to this case.

16. With the consent of all parties, United States Magistrate Judge Andrew Edison may preside and hear jury and nonjury trials. Indicate the parties' joint position on a trial before Magistrate Judge Edison.

The parties do not consent.

17. State whether a jury demand has been made and if it was made on time.

There is no jury demand.

18. Specify the number of hours it will take to try this case (including jury selection, presentation of evidence, counsel's opening statements and argument, and charging the jury).

Trial is not necessary because this case arises from agency action that would be reviewed based on an administrative record and, according to Plaintiffs, discovery if necessary. The parties anticipate that this case will be resolved either on Defendants' motion to dismiss or on cross-motions for summary judgment.

19. List pending motions that could be ruled on at the initial pretrial conference.

None.

20. List other motions pending.

On August 26, 2022, Defendants filed their Motion to Dismiss the Amended Complaint. ECF No. 25. The briefing on that motion is ongoing, pursuant to the schedule set by Judge Brown. See ECF No. 24.

21. Indicate other matters peculiar to this case, including but not limited to traditional and electronic discovery issues, that deserve the special attention of the court at the conference.

As noted above, Plaintiffs contend that Defendants should promptly prepare and file an administrative record pursuant to the APA, 5 U.S.C. § 706. Defendants contend that, for the reasons stated above, they should not be required to prepare an administrative record unless the Court denies their motion to dismiss, in which case the parties will file a proposed schedule for serving the administrative record and briefing cross-motions for summary judgment.

22. Certify that all parties have filed Disclosure of Interested Parties as directed in the Order for Conference and Disclosure of Interested Parties, listing the date of filing for original and any amendments. DO NOT STATE THAT THE DISCLOSURE OF INTERESTED PARTIES WILL BE FILED IN THE FUTURE.

Plaintiffs filed their Disclosure of Interested Parties on June 4, 2022 (two days after filing the complaint). Plaintiffs simultaneously served a copy of their disclosure on the United States Attorney's Office.

Defendants have not filed a Disclosure of Interested Parties. See Fed. R. Civ. P. 7.1.

/s/ R. Trent McCotter
Counsel for Plaintiffs

September 2, 2022
Date

/s/ Isaac C. Belfer
Counsel for Defendants

September 2, 2022
Date