

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

NATIONAL ASSOCIATION OF CHAIN
DRUG STORES *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH &
HUMAN SERVICES, *et al.*,

Defendants.

Civil Action No. 07-02017 (RCL)

MEMORANDUM OPINION

Before the Court is plaintiffs’ Motion [63] to Compel Production of Documents and a Privilege Log. Upon consideration of the motion, the opposition, and reply thereto, the Court will grant in part and deny in part plaintiffs’ motion. The Court will grant plaintiffs’ motion to compel defendants to produce comments and any other documents added to the record of the Average Manufacturer Price (“AMP”) Rule during the official regulatory comment period between July 17, 2007 and January 2, 2008, and will deny plaintiffs’ motion to compel defendants to produce a privilege log of any materials withheld from the administrative record based on the deliberative process privilege.

I. BACKGROUND

Plaintiffs have brought this lawsuit to challenge the July 2007 AMP Rule as well as the March 2008 and October 2008 revisions to the AMP Rule. (*See* Second Am. Compl. [66].) On July 17, 2007, the Centers for Medicare and Medicaid Services (“CMS”) of the U.S. Department

of Health & Human Services (“HHS”) issued a rule (“AMP Rule”) implementing the Medicaid-related provisions of the Deficit Reduction Act of 2005 (“DRA”) and defining the term “average manufacturer price.” *See* 72 Fed. Reg. 39142. When they issued the AMP Rule, defendants left open the record and invited the public to submit comments on the AMP Rule until January 2, 2008. Defendants explicitly stated that they would consider the comments submitted prior to the end of the comment period. *See, e.g., id.* (“To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 2, 2008.”) Following the comment period, defendants promulgated a revision to the AMP Rule regarding the definition of “multiple source drug” (“MSD”). *See* 73 Fed. Reg. 13785 (Mar. 14, 2008). Defendants once again sought comments and then further revised the MSD definition in October 2008. *See* 73 Fed. Reg. 58491 (Oct. 7, 2008).

The Court has ordered defendants to produce the administrative record related to the AMP Rule. (*See* Scheduling Order [49], June 24, 2008, *amended* Aug. 6, 2008.) Defendants filed a portion of the administrative record on May 30, 2008, then filed a supplement to the administrative record on September 30, 2008. Defendants filed a second supplement to the administrative record on October 6, 2008.

Plaintiffs have asked defendants to produce the comments and other documents added to the administrative record during the official comment period between July 17, 2007 and January 2, 2008. (Mot. to Compel [63] 2.) Defendants claim that the comments and other documents from July 17, 2007 and January 2, 2008 are not part of the administrative record in this case and therefore need not be produced. (*Id.*) Defendants also contend that the deliberative process privilege protects certain unidentified documents which are not part of the administrative record and have refused to provide a privilege log or otherwise identify those documents. (*Id.*)

Plaintiffs have thus requested that defendants produce a privilege log detailing all of the materials withheld on the basis of this privilege. (*Id.*)

II. ANALYSIS

A. Defendants must produce documents added to the record from July 17, 2007 to January 2, 2008

The public comments and documents added to the administrative record between July 17, 2007 and January 2, 2008 are part of the administrative record and therefore must be produced. The Administrative Procedures Act, 5 U.S.C. § 706, directs a court reviewing an agency decision to “review ‘the whole record or those parts of it cited by a party.’” *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008) (quoting 5 U.S.C. § 706 (1966)); *Pac. Shores Subdiv., Cal. Water Dist. v. United States Army Corps of Engineers*, 448 F. Supp. 2d 1, 4 (D.D.C. 2006) (Facciola, J.). Judicial review of administrative action “should normally be based on the full administrative record that was before a decision maker at the time the challenged action was taken.” *Cnty. for Creative Non-Violence v. Lujan*, 908 F.2d 992, 998 (D.C. Cir. 1990). The administrative record consists of all documents and materials gathered by an agency when creating or revising a rule. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419 (1971). The “whole record” has been interpreted to include documents and materials directly and indirectly considered by the agency. *Pac. Shores*, 448 F. Supp. 2d at 4.

An informal rulemaking record consists of the following materials: (1) the notice of proposed rulemaking; (2) comments submitted by interested persons; (3) hearing transcripts, if any; (4) other factual information considered by the agency; (5) reports of advisory committees, if any; and (6) the agency’s statement of basis and purpose. *See Home Box Office, Inc. v. Fed.*

Comm’n Comm’n, 567 F.2d 9, 57 note 130 (D.C. Cir. 1977) (citing Recommendation 74-4 of the Administrative Conference of the United States); *see also Rodway v. United States Dep’t of Agric.*, 514 F.2d 809, 817 (D.C. Cir. 1975) (“The whole record of an informal rule-making case is comprised of comments received, hearings held, if any, and the basis and purpose statement.”).

Defendants assert that, because the AMP Rule was issued on July 17, 2007, any comments and other documents generated after that date are not part of the administrative record in this case because the comments and documents were not before the agency at the time the challenged action was taken. (Defs.’ Opp’n [67] 12.) However, defendants’ argument ignores the fact that plaintiffs have also challenged the March 14, 2008 revision to the AMP Rule, which occurred after the close of the comment period on January 2, 2008. Defendants’ argument also neglects to consider that the defendants themselves invited the public to submit comments for the specific purpose of helping the defendants consider issues and develop policies related to the AMP Rule. Defendants point out that they did not base their revisions to the AMP Rule on the public comments submitted during the comment period between July 17, 2007 and January 2, 2008. (Defs.’ Opp’n at 12.) However, the fact that defendants ignored the comments does not mean that the comments should be excluded from the record. *See Fund for Animals v. Williams*, 391 F. Supp. 2d 191, 199 (D.D.C. 2005) (Urbina, J.) (agency cannot exclude documents from administrative record “simply by claiming that the documents were not ‘directly or indirectly considered’ by the agency”). As the public comments at issue were generated during the official comment period established by the defendants, and those records were generated prior to defendants’ decision to revise the AMP Rule in March 2008, the documents that plaintiffs request are in fact part of the administrative record and defendants therefore must produce the documents.

B. Defendants do not need to produce a privilege log describing documents withheld from the administrative record

As they are not part of the administrative record to begin with, defendants' pre-decisional, deliberative documents do not need to be logged as withheld from the administrative record. In this Court, there is a well-established presumption that an agency has properly designated the administrative record absent clear evidence to the contrary. *See Blue Ocean Inst. v. Gutierrez*, 503 F. Supp. 2d 366, 369 (D.D.C. 2007) (Facciola, J.); *Fund for Animals*, 391 F. Supp. 2d at 197. "The Agency decision and the Administrative Record are clothed with a presumption of regularity until proven otherwise by the Plaintiff." *Oceana, Inc. v. Guitterez*, 2009 WL 1491516, 4 (D.D.C.) (Kay, J.). Furthermore, internal deliberative materials are not part of the administrative record. "Deliberative intra-agency memoranda and other such records are ordinarily privileged, and need not be included in the record." *Amfac Resorts, L.L.C. v. U.S. Dep't of the Interior*, 143 F. Supp. 2d 7, 13 (D.D.C. 2001) (Lamberth, J.). Deliberative documents are excluded from the record because, when a party challenges agency action as arbitrary and capricious, the reasonableness of the agency's action "is judged in accordance with its stated reasons." *In re Subpoena Duces Tecum Served on Office of Comptroller of Currency*, 156 F.3d 1279, 1279 (D.C. Cir. 1998). "[T]he actual subjective motivation of agency decisionmakers is immaterial as a matter of law – unless there is a showing of bad faith or improper behavior." *Id.* As pre-decisional, deliberative documents are immaterial to the court's decision, they are not designated part of the administrative record that forms the basis of the court's decision.

Since deliberative documents are not part of the administrative record, an agency that withholds these privileged documents is not required to produce a privilege log to describe the

documents that have been withheld. In *Blue Ocean*, the Court found that agencies need not file privilege logs of deliberative documents absent a “clear command from the court of appeals, particularly in light of the unequivocal statement by that court that such materials are not a part of the administrative record when an agency decision is challenged as arbitrary and capricious.” 503 F. Supp. 2d at 372. This was reaffirmed in *Oceana* when the Court ruled in favor of the contention that “excluding deliberative documents from the administrative record does not necessitate the preparation of a privilege log.” 2009 WL 1491516 at note 5. Another judge in this District also recently denied, in an unpublished order, a similar request for a privilege log in a record review case. See Order, *Greater Yellowstone Coal. v. Kempthorne*, No. 07-211 (May 23, 2008) (Sullivan, J.). Here, the internal deliberative materials that plaintiffs seek from defendants are no more a part of the administrative record than were the materials in *Blue Ocean*, *Oceana*, or *Greater Yellowstone Coalition*. Defendants need not, therefore, file a privilege log pertaining to the withheld documents.

Plaintiffs claim to seek a privilege log so that they can participate in the process of determining what documents are and are not part of the administrative record. (See Mem. of P. & A. in Supp. of Pls.’ Mot. to Compel [63] 5) (“The Court and the Plaintiffs have no way to determine whether the deliberative process privilege protects the documents that the Defendants claim should be withheld from the administrative record.”) However, the argument that a plaintiff and the Court should be permitted to participate in an agency’s record compilation as a matter of course contravenes “the standard presumption that the agency properly designated the Administrative Record.” *Amfac Resorts*, 143 F. Supp. 2d at 12 (quotations omitted). To overcome the assumption that the agency properly designated the record, a party must make a “significant showing” that the agency has acted in bad faith. *Id.* Plaintiffs here have not alleged

any bad faith on the part of defendants, and absent such an allegation and showing, defendants' determination as to which materials are and are not part of the administrative record is conclusive.

The documents plaintiffs request from defendants amount to internal deliberative material, which has been designated to be outside of the administrative record. Since the agency is entitled to a presumption that it has properly designated the documents, and no bad faith or improper motive has been alleged or proven, defendants are not required to provide plaintiffs with a privilege log detailing the documents.

III. CONCLUSION & ORDER

For the foregoing reasons, it is hereby

ORDERED that the motion [63] is GRANTED IN PART and DENIED IN PART. With respect to the motion to compel defendants to produce comments and any other documents added to the record of the AMP Rule during the official regulatory comment period between July 17, 2007 and January 2, 2008, the motion is GRANTED. With respect to the motion to compel defendants to produce a privilege log of any materials withheld from the administrative record based on the deliberative process privilege, the motion is DENIED.

SO ORDERED.

Signed by Royce C. Lamberth, United States District Judge, June 23, 2009.