SUMMARY MEMORANDUM AND OPINION; NOT INTENDED FOR PUBLICATION IN THE OFFICIAL REPORTERS

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IVY SPORTS MEDICINE, LLC, Plaintiff, v. **KATHLEEN SEBELIUS, et al.,** Defendants.	Civil Action No. 11-cv-1006 (RLW)

MEMORANDUM OPINION[1]

Plaintiff Ivy Sports Medicine, LLC ("Ivy") has moved this Court for an Order requiring the U.S. Food and Drug Administration and other Defendants in this action (collectively "FDA") to supplement the administrative record with certain materials purportedly missing. For purposes of this ruling, the Court will assume the reader is familiar with the factual assertions and arguments made by the parties, and will not recite them here. Before the Court is Ivy's Motion for Supplementation of Administrative Record to Include Materials Omitted by Agency (Dkt. No. 36). For the reasons set forth below, the Motion is granted in part and denied in part.

[1] This unpublished memorandum opinion is intended solely to inform the parties and any reviewing court of the basis for the instant ruling, or alternatively, to assist in any potential future analysis of the *res judicata*, law of the case, or preclusive effect of the ruling. The Court has designated this opinion as "not intended for publication," but this Court cannot prevent or prohibit the publication of this opinion in the various and sundry electronic and legal databases (as it is a public document), and this Court cannot prevent or prohibit the citation of this opinion by counsel. Cf. Fed. R. App. P. 32.1. Nonetheless, as stated in the operational handbook adopted by our Court of Appeals, "counsel are reminded that the Court's decision to issue an unpublished disposition means that the Court sees no precedential value in that disposition." D.C. Circuit Handbook of Practice and Internal Procedures 43 (2011).

WHAT CONSTITUTES THE ADMINISTRATIVE RECORD

When reviewing agency action, the APA requires a court to review "the whole record or those parts of it cited by a party." 5 U.S.C. § 706. Although FDA regulations define the administrative record as the material "on which the Commissioner relies to support the action," 21 C.F.R. § 10.3, the Supreme Court and this Circuit indicate the record should not be so narrowly construed. Instead, a court must review "the full administrative record that was before the [FDA] at the time [it] made its decision." American Bioscience, Inc. v. Thompson, 243 F.3d 579, 582 (D.C. Cir. 2001) (alteration in original) (citing Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420 (1971)). A fair review by this court requires it to have "neither more nor less information than did the agency when it made its decision." Walter O. Boswell Mem'l Hosp. v. Heckler, 749 F.2d 788, 792 (D.C. Cir. 1984). Thus information considered, even if not relied upon, may need to be included in the record. See Fund for Animals v. Williams, 391 F. Supp. 2d 191, 196-97 (D.D.C. 2005) (citing cases) (Urbina, J.).

STANDARD FOR SUPPLEMENTING ADMINISTRATIVE RECORD

There is a strong presumption that the agency properly compiled the administrative record. "Supplementation of the administrative record is the exception, not the rule." Pacific Shores Subdivision, Cal. Water Dist. v. U.S. Army Corps of Eng'rs, 448 F. Supp. 2d 1, 5 (D.D.C. 2006) (Facciola, Mag. J.). "Therefore, absent clear evidence to the contrary, an agency is entitled to a strong presumption of regularity, that it properly designated the administrative record." WildEarth Guardians v. Salazar, 670 F. Supp. 2d 1, 5 (D.D.C. 2009) (citations omitted) (Kollar-Kotelly, J.). "Were courts cavalierly to supplement the record, they would be tempted to second-guess agency decisions in the belief that they were better informed than the administrators empowered by Congress and appointed by the President." Amfac Resorts, LLC v.

U.S. Dep't of the Interior, 143 F. Supp. 2d 7, 11 (D.D.C. 2001) (Lamberth, C.J.) (quoting San Luis Obispo Mothers for Peace v. NRC, 751 F.2d 1287, 1325-26 (D.C. Cir. 1986) (en banc)).

In addition, a motion to supplement the record should not merely guess about who has seen the documents at issue. A party moving to supplement the administrative record "must do more than imply that the documents at issue were in the [agency's] possession"; they "must prove that the documents were before the actual decisionmakers involved in the determination." Sara Lee Corp. v. Am. Bakers Ass'n, 252 F.R.D. 31, 34 (D.D.C. 2008) (Facciola, Mag. J.).

INTERVIEW NOTES

Plaintiff requests an Order to supplement the record with notes from interviews of twenty-two current and former FDA employees conducted for a September 2009 Preliminary Review. FDA set up the review "to determine whether changes should be made to the agency's policies, processes, procedures, or practices to better protect the integrity of FDA's decisionmaking." (Apr. 29, 2009 Memorandum from Dr. Joshua Sharfstein, FDA003519.) While noting the "final findings and recommendations" would likely be made public, FDA stated the review should be conducted "[w]ith appropriate concerns for privacy." (Id.) Two attorneys conducted the interviews, and it appears they are the only two people who have seen the notes taken during them. (Dkt. No. 35 Exs. A & B.)

Plaintiff's motion to supplement the record with notes from the interviews fails to meet the "heavy burden" required of a party moving to supplement the record. WildEarth, 670 F. Supp. 2d at 6. First, Ivy's argument in this litigation is that FDA acted without legal authority when it rescinded the Substantial Equivalence Order on March 30, 2011. The interview notes taken as part of the review in 2009 were not before the agency as part of that decision, and therefore need not be made part of the administrative record. The record "should not

include materials that were not considered by agency decisionmakers." Pacific Shores, 448 F. Supp. 2d at 4 (citations omitted).

Second, the interviews were part of an internal deliberative process and therefore the FDA is entitled to withhold the notes under the deliberative process privilege. To invoke the deliberative process privilege, the communication must be both "predicisional" and "a direct part of the deliberative-process in that it makes recommendations or expresses opinions on legal or policy matters." Judicial Watch v. Dep't of Army, 466 F. Supp. 2d 112, 120 (D.D.C. 2006) (Urbina, J.). FDA efforts to determine whether any changes are necessary to the Agency's oversight and decisionmaking satisfy this test. "[D]eliberative intra-agency memoranda and other such records are ordinarily privileged, and need not be included in the record." Amfac, 143 F. Supp. 2d at 13 (citing cases). And while certain references to the interviews in the Preliminary Review waive the privilege for the information made public, with respect to the deliberative process privilege "courts have said that release of a document only waives these privileges for the document or information specifically released, and not for related materials." In re Sealed Case, 121 F.3d 729, 741 (D.C. Cir. 1997).

510(k) SUBMISSIONS

Ivy also requests an Order to supplement the record with seven 510(k) submissions of predicate meshes it identified in its premarket notification submission. The FDA states it "likely . . . consulted specific parts of" these (and other) 510(k) submissions in order to compare them to Ivy's Collagen Scaffold device. (Dkt. No. 35 at 10.)

Ivy has the better argument with respect to the limited 510(k) submissions requested. FDA consulted these documents when considering whether to rescind Ivy's clearance. The Agency admits it relied on certain information from underlying predicates'

510(k) submissions, but claims "supplementing the record with additional materials containing the same information is unnecessary." (Id.) But not all of the additional material would be "the same."

The government's other arguments similarly fail to persuade. FDA's offer of including summaries of these applications as extra-record material is insufficient. (Id. at 9.) FDA has made no argument, and there is no indication, that it merely reviewed the summaries. Thus Ivy is entitled to the information before the Agency. See American Bioscience, 243 F.3d at 582. And finally, FDA's claims of significant burden are unavailing. FDA's reference to the size of the record in Pacific Shores, a case involving a different agency's actions under a different statute, has little relevance here. Ivy is entitled to have the seven 510(k) submissions it identified as part of the administrative record, and FDA should work expeditiously to complete the necessary redactions.

CONCLUSION

For the foregoing reasons, Ivy's Motion for Supplementation of Administrative Record to Include Materials Omitted by Agency is granted in part and denied in part. An Order accompanies this Memorandum.

Date: October 24, 2012

Digitally signed by Judge Robert L. Wilkins
DN: cn=Judge Robert L. Wilkins, o=U.S. District Court, ou=Chambers of Honorable Robert L. Wilkins, email=RW@dc.uscourt.gov, c=US
Date: 2012.10.24 16:15:00 -04'00'

ROBERT L. WILKINS
United States District Judge