IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

STYRENE INFORMATION AND RESEARCH CENTER, INC., *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 1:11-cv-01079-RBW**
KATHLEEN SEBELIUS, *et al.*,	)	
Defendants.	)	

PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO COMPLETE THE ADMINISTRATIVE RECORD AND TO COMPEL DISCOVERY

In their Opposition to Plaintiffs' Motion to Complete the Record ("Opposition") (Doc. No. 29), Defendants misstate the controlling law and obfuscate important facts about the completeness of the Administrative Record ("Record") on which this case will be decided. Defendants can recite all the statistics they like about the volume of the record, the number of years of research that went into the decision to list styrene, the rounds of public comments, and the impressive qualifications of the individuals who served on the various boards. But none of that changes the fact that the Record is missing important documents that were before the agency when it made the decision to list styrene in the Report on Carcinogens ("RoC"). Plaintiffs are entitled to have those documents included in the Record under the controlling law.

Through their Motion to Complete the Administrative Record ("Motion") (Doc. No. 27), Plaintiffs seek the following classes of documents: (1) documents relating to the work performed by the various subgroups of the Expert Panel, (2) independent analyses conducted by the National Toxicology Program ("NTP") or others of data from the studies reported in the

Styrene Background Document, (3) documents relating to the Agency for Toxic Substances and Disease Registry's ("ATSDR") Cancer Policy Chart and the Portier Letter, and (4) documents relating to the work performed by consultants on the Styrene Background Document. Plaintiffs are withdrawing their request for the documents from the consultants on the Background Document.

Defendants argue that Plaintiffs must show bad faith to receive these missing documents, but that standard applies only to discovery sought beyond the Record. The standard for obtaining documents that should have been included in the Record in the first place is much lower, and Plaintiffs satisfy it here. The government is presumed to have properly designated the Record, but that presumption is rebuttable by a showing that the Record does not contain documents that should have been included. Plaintiffs have made this showing, and they are entitled to the missing documents.

A. Plaintiffs Complied With Local Rule 7(m)

Defendants' argument that Plaintiffs failed to comply with LCvR 7(m) is meritless. Opposition at 1. On the morning of September 22, 2011, Plaintiffs' counsel wrote an e-mail to Defendants' counsel seeking a meeting to confer about the missing documents. Sept. 22, 2011, e-mail from Robert Sheffield to Eric Beckenhauer, attached hereto as Exhibit A. E-mail communications between counsel have been common because it has been difficult to reach Defendants' counsel by telephone. However, government counsel had not responded by the time Plaintiffs filed their Motion four days later, on the afternoon of September 26. Surely Plaintiffs were not foreclosed from filing their Motion by counsel's lack of responsiveness. In any event, as Defendants' own exhibit to their Opposition shows, their position all along has been that

Plaintiffs are not entitled to anything more than the Record produced on August 26, 2011. Defendants' objections to Plaintiffs' discovery request left no doubt about this position. *See* Sept. 8, 2011, letter from Eric Beckenhauer to Robert Sheffield, attached hereto as Exhibit B. To the extent the Court finds an e-mail to be an insufficient attempt to confer under LCvR 7(m), such error was clearly harmless.

B. Defendants Disingenuously Misstate the Controlling Law

Defendants are wrong in their assertion that Plaintiffs must show bad faith to obtain a complete Record. The bad faith standard applies only when a plaintiff in a record-review case seeks to take discovery or gather evidence beyond that which is, or properly should be, in the administrative record.

The two principal cases Defendants rely on—*Commercial Drapery Contractors, Inc. v. United States*, 133 F.3d 1 (D.C. Cir. 1998), and *Coal. on Sensible Transp., Inc. v. Dole*, 826 F.2d 60 (D.C. Cir. 1987)—demonstrate this very point. Both cases involved attempts to "supplement" the record through discovery rather than through requests to "complete" the record through the inclusion of agency documents. For instance, in *Commercial Drapery*, the General Services Administration ("GSA") suspended Commercial Drapery Contractors ("Commercial") and canceled its existing contracts. Commercial sued the GSA and, before the district court, sought discovery and submissions of affidavits in support of its position and further argued that the administrative record should be supplemented by certain missing documents. *Commercial Drapery Contractors, Inc. v. United States*, 967 F.Supp. 1, 4-6 (D.D.C. 1997). The district court denied Commercial discovery and refused to consider its affidavits in granting summary judgment to the GSA. The district court also noted that the documents alleged to be missing had

later been included in the administrative record, mooting that argument. *Id.* at 5. On appeal, the D.C. Circuit affirmed the district court's actions, finding that Commercial was not entitled to "discovery of the agency's decisionmaking process" without a showing of bad faith. *Commercial Drapery*, 133 F.3d at 144. Similarly, the court in *Sustainable Transportation* was addressing a request for "unlimited discovery" when it held that such discovery required a showing of bad faith. 826 F.2d at 72.

Defendants' position here is untenable; they would require a plaintiff who successfully demonstrates that the record is incomplete also to prove that it is incomplete because of an improper motive by the agency. This is simply not the law. *Marcum v. Salazar*, 751 F.Supp.2d 74, 78 (D.D.C. 2010) (holding that "[i]f an agency did not include materials that were part of its record, *whether by design or accident*, then supplementation is appropriate.") (emphasis added); *Calloway v. Harvey*, 590 F.Supp.2d 29, 37 (D.D.C. 2008) (Walton, J.)

Aside from the document requests related to the Portier Letter, Plaintiffs do not seek information beyond what was considered during the process employed by the NTP in making its recommendation to the Secretary and by the Secretary in approving that recommendation. As noted in Plaintiffs' Motion, cases from this and other circuits unambiguously require such information be included in the Record; a properly-compiled administrative record includes all materials "that 'might have influenced an agency's decision,' and not merely those on which the agency relied in its final decision." *Amfac Resorts, L.L.C. v. United States Dep't of the Interior*, 143 F.Supp.2d 7, 12 (D.D.C. 2001) (quoting *Bethlehem Steel v. EPA*, 638 F.2d 994, 1000 (7th Cir. 1980)). *See also Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993) ("The complete administrative record consists of all documents and materials directly or indirectly

considered by the agency."); *Fund for Animals v. Williams*, 391 F.Supp.2d 191, 197 (D.D.C. 2005) ("Nor may the agency exclude information on the grounds that it did not rely on the excluded information in its final decision."). *See also* Memorandum in Support of Plaintiffs' Motion to Complete the Record ("Memo in Support") (Doc. No. 27-1) at 5-6 (citing additional cases). The law in this and other circuits entitles a plaintiff to the complete record if the party shows that the record is incomplete and that documents have been withheld. *Natural Res. Def. Council v. Train*, 519 F.2d 287 (D.C. Cir. 1975); *Portland Audubon Soc'y v. Endangered Species Comm.*, 984 F.2d 1534 (9th Cir. 1993); *Nat'l Ass'n of Chain Drug Stores v. U.S. Dep't of Health and Human Servs.*, 631 F.Supp.2d 23 (D.D.C. 2009).

C. Defendants Have Withheld Non-Privileged Documents That Belong in the Record

Plaintiffs seek the following documents through their Motion: (1) documents relating to the work performed by the various subgroups of the Expert Panel, (2) independent analyses conducted by the NTP or others of data from the studies reported in the Styrene Background Document, (3) documents relating to the ATSDR Cancer Policy Chart and the Portier Letter, and (4) documents relating to the work performed by consultants on the Styrene Background Document.

Defendants argue that three of these categories of documents are protected by the deliberative-process privilege and that all four categories do not belong in the Record or are already there.

Plaintiffs concede that documents relating to the work performed by consultants on the Styrene Background Document are privileged. But Plaintiffs are entitled to the three other classes of documents.

1. Plaintiffs are entitled to documents relating to the work performed by the various subcommittees of the Expert Panel

Defendants argue that documents relating to the work of the Expert Panel's subgroups are not part of the Record because the agency never looked at them in the decision-making process. Opposition at 10. Defendants accordingly believe that only the final report of the Expert Panel needs to be included in the Record. *Id.* This cramped interpretation of what documents belong in the Record finds no support in the law.

The law in this and other circuits requires a properly-compiled administrative record to include all materials "that might have influenced an agency's decision, and not merely those on which the agency relied in its final decision." *Amfac Resorts*, 143 F.Supp.2d at 12 (internal quotations omitted). Nor must a document "literally pass before the eyes of the final agency decision maker to be considered part of the administrative record." *Miami Nation of Indians of Indiana v. Babbitt*, 979 F.Supp. 771, 777 (N.D. Ind. 1996).

Under this accepted standard, there is no doubt that the work of the Expert Panel's subgroups belong in the Record. The Expert Panel was convened to "peer review" the Background Document. Opposition at 10. The Expert Panel review was part of the NTP process announced in the Federal Register and was, in part, the agency's process for considering public comments on the NTP Draft Background Report on Styrene. Report on Carcinogens Review Process for the 12th Report on Carcinogens, 72 Fed. Reg. 18999 (Apr. 16, 2007).

To do its work, the Expert Panel divided itself into subgroups based on areas of expertise, and each subgroup drafted a section of the peer review report. *Id.* One group reviewed the animal studies set out in the Draft Background Report on Styrene, another considered the human studies, and a third looked at the mechanistic studies. *See* Expert Panel Peer Review Comments

on the Draft Background Document – Cancer Studies in Experimental Animals, attached hereto as Exhibit F; Expert Panel Peer Review Comments on the Draft Background Document – Human Cancer Studies, attached hereto as Exhibit G; Expert Panel Peer Review Comments on the Draft Background Document – Other Relevant Data, attached hereto as Exhibit H. No single member of the Expert Panel reviewed or opined on the entire Background Document. In this light, the subgroup reports take on a greater role in shaping the scope of the peer review as well as the import of the "vote" of the Expert Panel because that vote appears to be merely the approval of the work of each subgroup. Further, the report from one such group was attached to the Expert Panel's Report in the Record, and the NTP had possession of all of the subgroup reports. *See* Record at 1120, Ex. 2 to Memo in Support. Finally, Defendants cite the unanimous vote of the Expert Panel to list styrene without providing any breakdown on the opinions of the individual members about the various alternative bases set out for listing. Given the importance of the Expert Panel, its role in the notice and public comment process of the NTP's process, and the fact that its draft reports were maintained by the NTP, those reports were at least indirectly considered by Defendants in the decision to list styrene and must be included in the Record.

The need to include these reports in the record is made stronger by Defendants' representation in their Opposition, at 10, that certain subgroup drafts were rejected by the full Expert Panel. Plaintiffs are entitled to see the contrary evidence not included in the final Expert Panel Report and the reasons why non-experts in a particular area voted to reject the report of a subgroup of experts in that same area.[1] *See Fund for Animals v. Williams*, 391 F.Supp.2d 191,

[1] Defendants do not argue that any of the Expert Panel's documents are privileged. But Plaintiffs nonetheless note that as an independent, non-governmental body, the deliberative processes of the Expert Panel are not protected by the deliberative-process privilege. Defendants

198 (D.D.C. 2005) (holding that supplementation of the record is appropriate to include adverse documents that are related to the ultimate decision).

It is true that the Secretary probably never looked at the drafts of the Expert Panel's subgroups, as Defendants assert. But that is not the standard. The drafts and other documents evincing the back-and-forth that led to the final peer review document surely "might have influenced" first the NTP and the Secretary—indeed, they no doubt did. *Amfac, supra*. The documents must be included in the Record.

2. Plaintiffs are entitled to independent analyses of data from the studies reported in the Styrene Background Document

The Record indicates that during its peer review of the Background Document, the Expert Panel apparently received supplemental information from the contractor to assist their review. *See* Record at 1123, Ex. 3 to Memo in Support ("During the styrene review the contractor provided trend tests for several sites, which the Panel much appreciates."). Defendants respond merely by citing what Plaintiffs already knew: that the Expert Panel received certain analyses performed by the NTP or others to assist it in its peer review. Opposition at 12. Defendants assert that all analyses received by the Expert Panel were either not incorporated into the Final Background Document "or were excluded from the Expert Panel's final recommendations to the NTP, and thus were not considered by the agency in reaching a listing determination, and are not properly part of the record." Opposition at 13. For the reasons stated in Section 1, above, in

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also waived any claim of privilege over Expert Panel documents by producing them under FOIA. *See* Oct. 20, 2008, letter from Kim L. Minneman, Freedom of Information Coordinator, Department of Health and Human Services, to Jean-Cyril Walker, Keller and Heckman LLP, attached hereto as Exhibit C; *see also* Exhs. F-H.

reference to Expert Panel documents, Plaintiffs are entitled to see the independent analyses excluded by the Expert Panel the reasons for such exclusions.

3. Plaintiffs are entitled to documents relating to the ATSDR Cancer Policy Chart and the Portier Letter

Plaintiffs sought these documents through a request to Defendants because they anticipated the documents would not be included in the Record. Plaintiffs were correct. But because these documents belonged in the Record all along, this dispute is not controlled by the bad faith standard required for extra-record discovery.

Defendants have included in the Record a letter from Dr. Christopher Portier, the director of the ATSDR, a sister agency to the NTP. Record at 2301a, attached hereto as Exhibit D. The letter serves two purposes: it purports to interpret the ATSDR's November 2010 Toxicology Profile on Styrene and the NTP's listing classifications, and it opines that the conclusions reached by the ATSDR through its notice and comment process were not inconsistent with the NTP's conclusions. Dr. Portier's letter is an attempt to rebut arguments made to counsel for the Department of Health and Human Services that the NTP recommendation conflicted with the ATSDR's conclusion.

The Record includes only Dr. Portier's Letter. Defendants claim that everything related to the genesis and meaning of that letter is privileged. This is incorrect; nothing behind the letter is privileged. The deliberative-process privilege protects only pre-decisional and deliberative documents. *Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980). The Portier letter is neither. The letter was authored by the head of the ATSDR on May 6, 2011—five months after release of the ATSDR's Toxicological Profile for Styrene. The letter was not "generated before the adoption of" the Toxicological Profile for Styrene, or anything

else by the ATSDR, and thus is not pre-decisional to the ATSDR report it purports to interpret. *Id.* To say that documents related to the Portier Letter—documents of the ATSDR that relate in no way to the development of the RoC—are protectable as pre-decisional to the RoC would make every government document pre-decisional to something and render meaningless the pre-decisional requirement.

Nor do the requested materials "reflect[] the give-and-take of the consultative process" and therefore are not deliberative. *Id.* The letter was not generated in the ordinary course of the development of the RoC. Rather, it was a collusive document written as a defensive response to a letter from Plaintiffs' counsel pointing out the irreconcilable conflict between the carcinogenicity standards of the ATSDR and the NTP. *See* Dec. 20, 2011, letter from Peter L de la Cruz, Keller and Heckman LLP, to Mark B. Childress, Acting General Counsel, Department of Health and Human Services at 5-6, attached hereto as Exhibit E. The Portier Letter does not indicate that it was requested by the Secretary to assist her in her decisionmaking, and the only apparent purpose of the letter is to provide Defendants with a defense to the claim of inconsistency. The letter and the documents related to it had no bearing on the consultative process of the RoC's development and therefore are outside the scope of the privilege.

Defendants have not claimed that the Portier Letter is privileged. Therefore, Plaintiffs are entitled to see all documents referring or relating to it, including documents evincing the genesis of the letter, correspondence leading to the final letter, drafts of the letter, and documents showing the basis for Dr. Portier's conclusions.

Defendants also put the Portier Letter and the ATSDR's Cancer Policy chart in issue in its Opposition to Plaintiffs' Motion for Preliminary Injunction (Doc. No. 12) at 28-29.

Defendants cannot on the one hand argue the merits of these documents while on the other hand claim that they are privileged and inaccessible.

D. Conclusion

For the foregoing reasons, the Court should order Defendants to include the following documents in the Record: (1) all documents relating to the work performed by the various subgroups of the Expert Panel, (2) all independent analyses conducted by the NTP or others of data from the studies reported in the Styrene Background Document, and (3) all non-privileged documents relating to the ATSDR Cancer Policy Chart and the Portier Letter as identified in Plaintiffs' document requests.

Dated: October 28, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 28, 2011, a copy of the foregoing was filed with the Court's CM/ECF software and served via the same on Defendants' counsel of record.

/s/ Robert A. Sheffield
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