

ORAL ARGUMENT NOT YET SCHEDULED

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

COMPETITIVE ENTERPRISE
INSTITUTE, ANTHONY
KREUCHER, WALTER M.
KREUCHER, JAMES LEEDY,
and MARC SCRIBNER,

Petitioners,

v.

NATIONAL HIGHWAY TRAFFIC
SAFETY ADMINISTRATION;
JAMES C. OWENS, in his official
capacity as Acting Administrator,
National Highway Traffic Safety
Administration; ENVIRONMENTAL
PROTECTION AGENCY; ANDREW
R. WHEELER, in his official
capacity as Administrator of the
Environmental Protection Agency

Respondents.

No. 20-1145 and
consolidated cases

**PETITIONERS' REPLY IN SUPPORT OF THEIR
MOTION TO COMPLETE THE RECORD**

Devin Watkins
Sam Kazman
COMPETITIVE ENTERPRISE INSTITUTE
1310 L Street NW, 7th Floor
Washington, DC 20005
202-331-2278
Devin.watkins@cei.org
Sam.kazman@cei.org
Attorneys for Petitioners in 20-1145

ARGUMENT

Defendants have conceded that the certified index submitted to this court was incomplete. Def. Opp. p. 4 (“the agencies agree that the December 2019 final ISA is part of the administrative records for the SAFE II rulemaking.”). This undercuts the presumption of regularity normally enjoyed by agency compilations of their rulemaking records. In order to succeed in their motion to include two reports of the Clean Air Scientific Advisory Committee (CASAC) in the record, movants must “put forth concrete evidence and identify reasonable, non-speculative grounds for [its] belief that the documents [at issue] were considered by the agency and not included in the record.” *Oceana, Inc. v. Ross*, 290 F. Supp. 3d 73, 78-79 (D.D.C. 2018). Movants merely need to make a “substantial showing” to satisfy this burden. *Cty. of San Miguel v. Kempthorne*, 587 F. Supp. 2d 64, 72 (D.D.C. 2008).

Defendants concede that the letter in Exhibit C of movants’ motion shows that the EPA Administrator considered the CASAC reports, although they claim it was only in “in the context of the particulate matter NAAQS review.” Def. Opp. p. 4. The agencies say, in essence, that the EPA Administrator personally sent a letter to CASAC noting their objections to the EPA’s lack of a “sufficiently comprehensive, systematic assessment of the available science”, but that when it

came to the SAFE rulemaking, which involved, in part, this same issue, he completely ignored those errors.

“It is a widely accepted principle of administrative law that the courts base their review of an agency’s actions on the materials that were before the agency at the time its decision was made.” *IMS, P.C. v. Alvarez*, 129 F.3d 618, 623 (D.C. Cir. 1997). “The agency may not ... skew the ‘record’ for review in its favor by excluding from that ‘record’ information in its own files which has great pertinence to the proceeding in question.” *Env’tl. Def. Fund, Inc. v. Blum*, 458 F. Supp. 650, 661 (D.D.C. 1978); see also *Blue Ocean Institute v. Gutierrez*, 503 F.Supp.2d 366, 369 (D.D.C.2007) (Agencies “may not skew the record by excluding unfavorable information but must produce the full record that was before the agency at the time the decision was made.”). Instead, “a complete administrative record should include all materials that ‘might have influenced the agency’s decision,’ and not merely those on which the agency relied in its final decision.” *Amfac Resorts, L.L.C. v. U.S. Dep’t of the Interior*, 143 F. Supp. 2d 7, 12 (D.D.C. 2001). “[A] party seeking to supplement the record must establish that the additional information was known to the agency when it made its decision, the information directly relates to the decision, and it contains information adverse to the agency’s decision.” *San Miguel*, 587 F. Supp. 2d at 72 (citing *San Luis Obispo*

Mothers for Peace v. Nuclear Regulatory Comm'n, 751 F.2d 1287, 1327 (D.C.Cir.1984), *aff'd* 789 F.2d 26 (1986)).

The CASAC reports were submitted to EPA and were considered by its staff. This by itself, of course, does not make those reports part of the SAFE record. Instead the question is whether the specific agency decisionmaker for the SAFE Rule directly or indirectly considered these reports. *Pac. Shores Subdivision, California Water Dist. v. U.S. Army Corps of Engineers*, 448 F. Supp. 2d 1, 6–7 (D.D.C. 2006). This is especially true when the reports directly relate to the decision and contain information adverse to the agency's decision. *County of San Miguel v. Kempthorne*, 587 F.Supp.2d 64, 72 (D.D.C.2008) (“a party seeking to supplement the record must establish that the additional information was known to the agency when it made its decision, the information directly relates to the decision, and it contains information adverse to the agency's decision”).

The agencies do not dispute that Administrator Wheeler, who personally dealt with the CASAC reports, was a primary agency decisionmaker for the SAFE Rule. *See Pac. Shores*, 448 F. Supp. 2d at 6–7 (“it is not enough for [movants] to state that the documents were before the entire [agency], but rather it must instead prove that the documents were before the [agency] decisionmaker(s).”). His personal consideration of those reports is demonstrated by his statement that he instructed EPA to “incorporate the CASAC’s comments and recommendations, to

the extent possible,” in its final Integrated Science Assessment for Particulate Matter (ISA). See Petitioners’ Motion to Complete, Exhibit C. p. 3; EPA, ISA (Dec. 2019), p. ES-3. For this reason, the CASAC reports clearly “might have influenced the agency’s decision.” See *Amfac Resorts, L.L.C. v. U.S. Dep’t of the Interior*, 143 F. Supp. 2d 7, 12 (D.D.C. 2001). In fact, “might have” is an understatement in this case.

The agencies claim that, under petitioners’ approach, all of the comments submitted in the NAAQS rulemaking would be part of the SAFE rulemaking. This is incorrect. As shown directly below, CASAC was unique in its impact on the ISA, and the ISA’s importance to the SAFE rulemaking was conceded by EPA when it agreed to make that document part of the SAFE record. Def. Opp. p. 7-8.

The ISA itself makes clear both CASAC’s special statutory status and the importance of its comments:

Section 109(d)(2) of the Clean Air Act, describes the appointment of an independent scientific review committee and their role in reviewing the documents developed by U.S. EPA that provide the air quality criteria defined in Section 108(a)(2), herein the draft PM ISA. This independent review function has been performed by [CASAC]. The U.S. EPA released the External Review Draft of the PM ISA on October 23, 2018 (83 FR 53471), which was reviewed in a public meeting of the CASAC to discuss the ISA and provide an independent scientific peer review of the document (83 FR 55529). The CASAC review of the External Review Draft of the PM ISA resulted in a final letter to the Administrator detailing their review, which was released on April 11, 2019.

The Administrator responded to the CASAC's letter on the External Review Draft of the PM ISA on July 25, 2019,³⁴ and indicated the Agency will "incorporate the CASAC's comments and recommendations, to the extent possible, and create a final PM ISA so that it may be available to inform a proposed decision on any necessary revisions of the NAAQS in early 2020." The U.S. EPA focused on addressing comments presented in the main body of the CASAC letter (i.e., the cover letter and consensus responses to charge questions), and to the extent possible, addressed individual CASAC member comments as well as public comments on the draft PM ISA. The consensus CASAC comments on the draft PM Policy Assessment (December 16, 2019) stated "...the Draft PM ISA, does not provide a ... comprehensive, systematic review of relevant scientific literature; inadequate evidence and rationale for altered causal determinations; and a need for clearer discussion of causality and causal biological mechanisms and pathways." To address these comments in the Final PM ISA, the EPA: (1) added text to the Preface and developed a new Appendix to more clearly articulate the process of ISA development; (2) revised the causality determination for long-term UFP exposure and nervous system effects to suggestive of, but not sufficient to infer, a causal relationship; and (3) added additional text to the Preface (Section P.3.2.1) as well as text in the health effects chapters to clarify the discussion of biological plausibility and its role in forming causality determinations.

EPA, ISA p. ES-3 (footnote omitted).

The agencies conceded that the 2019 ISA is a part of both the SAFE rulemaking and the NAAQS rulemaking. Def. Opp. p. 4. This similarly shows that the fact that the CASAC reports are part of the NAAQS record does not somehow bar them from being part of the SAFE record as well. These are closely inter-related actions, as shown by the 73 mentions of NAAQS in the final SAFE rule. Moreover, these documents could have influenced the decision in the SAFE proceeding. See *Amfac Resorts, L.L.C. v. U.S. Dep't of the Interior*, 143 F. Supp.

2d 7, 12 (D.D.C. 2001) (the “complete administrative record should include all materials that ‘might have influenced the agency’s decision’”).

The only case the agencies cite to support their arguments is *Linemaster Switch Corp. v. U.S. E.P.A.*, 938 F.2d 1299, 1305 (D.C. Cir. 1991). In *Linemasater*, petitioners challenged their properties addition to the National Priorities List (locations posing the greatest risk to human health and the environment). Linemaster had submitted arsenic data on the properties to EPA, but “Linemaster failed to submit the data to the proper division of EPA or even to flag it as relevant to the NPL listing process.” *Id.* The Hazardous Site Evaluation Division of EPA, the primary decisionmaker in that case, had no knowledge of the arsenic data’s existence. It was for that reason that the court held that this data could not be considered as being before the primary agency decisionmaker. This obviously was not true of Administrator Wheeler and the CASAC reports.

The agencies claim that *Styrene Information & Research Center, Inc. v. Sebelius*, 851 F. Supp. 2d 57 (D.D.C. 2012), is not relevant to this motion because in that case the “the administrative record contain[ed] several references to omitted subgroup reports.” *Id.* at 64. But the court merely used those references to show that they “suggest that the Expert Panel substantively considered scientific information and advice contained in the subgroup reports, and was aware of the Expert Panel’s reliance on this information and advice.” *Id.* The evidence here is

far more direct that the Administrator “substantively considered scientific information and advice contained in the [CASAC] reports, and was aware of the [] reliance on this information and advice.” See *Styrene*, 851 F. Supp. 2d at 64. Furthermore, *Styrene* held that those documents should be included as they “were an integral part of the Expert Panel’s peer review process and influenced the Expert Panel’s recommendation, upon which the [agency] based its listing determination.” *Id.* The same circumstances as in *Styrene* exist here: the CASAC reports were an “integral part of the [] peer review process” and uniquely influenced the 2019 ISA that the agency relied on promulgating the SAFE rule.

CONCLUSION

For the foregoing reasons, the court should order that the administrative record be completed by including the 2019 ISA on Particulate Matter, the CASAC report of April 11, 2019, and the CASAC report of December 16, 2019.

Dated: September 25, 2020

Respectfully submitted,

/s/ Devin Watkins

Devin Watkins

Sam Kazman

COMPETITIVE ENTERPRISE INSTITUTE

1310 L Street NW, 7th Floor

Washington, DC 20005

Phone: 202-331-2278

devin.watkins@cei.org

sam.kazman@cei.org

Attorneys for Petitioners in 20-1145

CERTIFICATE OF COMPLIANCE

Counsel certifies as follows:

1. The above document complies with the type-volume requirement of Fed. R. App. P. 27(d)(2)(A) because this reply contains 1729 words, as determined by the word-count function of Microsoft Word 2016, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).
2. The above document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this reply has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font.

Dated: September 25, 2020

Respectfully submitted,

/s/ Devin Watkins

Devin Watkins

Sam Kazman

COMPETITIVE ENTERPRISE INSTITUTE

1310 L Street NW, 7th Floor

Washington, DC 20005

Phone: 202-331-2278

devin.watkins@cei.org

sam.kazman@cei.org

Attorneys for Petitioners in 20-1145

CERTIFICATE OF SERVICE

I hereby certify that on September 25, 2020, a copy of the reply was electronically filed and served by operation of the Court's CM/ECF system to all parties other than the following which and was served via First Class Mail on September 25, 2020 to:

William F. Cooper
State of Hawaii Department of the Attorney General
425 Queen Street
Honolulu, HI 96813

Dated: September 25, 2020

Respectfully submitted,

/s/ Devin Watkins

Devin Watkins

Sam Kazman

COMPETITIVE ENTERPRISE INSTITUTE

1310 L Street NW, 7th Floor

Washington, DC 20005

Phone: 202-331-2278

devin.watkins@cei.org

sam.kazman@cei.org

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