



March 17, 2014

CASAC Ozone Review Panel
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Dear Panel Members:

We are writing to you on behalf of the American Lung Association to offer some thoughts on the recent court decision in *Mississippi v. EPA*, No. 08-1200, 2013 WL 6486930 (D.C. Cir. Dec. 11, 2013), as it relates to the manner in which CASAC advises EPA on NAAQS decisions. In that case, we argued on behalf of the Lung Association and others that EPA's 2008 ozone health standard was deficient because, among other things, the standard was less protective than recommended by CASAC. The Court upheld EPA's decision to depart from CASAC's advice, so the Court's explanation provides an important perspective for future CASAC recommendations.

During development of the 2008 ozone NAAQS, the CASAC Ozone Review Panel unanimously recommended a standard in the range of 0.060 to 0.070 ppm (8-hour average),¹ but EPA set the final standard at 0.075 ppm. The Court acknowledged this disparity, and noted that EPA was legally obligated to justify any departure from CASAC's recommendations. The Court further noted that, in this case, EPA's stated justification was that there was increasing uncertainty as to ozone's adverse effects at levels below 0.075 ppm, and that in the absence of a bright line clearly directing the choice of level, that choice was a public health policy judgment entrusted to the Administrator. The Court accepted EPA's justification, but only because it was "unable to determine" whether CASAC's recommendation was based on a scientific conclusion that adverse effects were likely to occur at 0.070 ppm. Specifically, the Court stated:

Had CASAC reached a scientific conclusion that adverse health effects were likely to occur at the 0.070 ppm level, EPA's failure to justify its uncertainty regarding the existence of adverse health effects at this level would be unacceptable

But we are unable to determine whether CASAC reached any such scientific conclusion. Although CASAC stated that "overwhelming scientific evidence" supported its recommendation that the standard be set no higher than 0.070 ppm, Mar. 2007 CASAC Letter, at 2, it never explained whether this proposal was based on its scientific judgment that adverse health effects would occur at that level or instead based on its more qualitative judgment that the range it proposed would be appropriately protective of human health with an adequate margin of safety. Indeed, although CASAC concluded that "there is no longer significant scientific uncertainty regarding [its] conclusion that the current 8-hr primary NAAQS must be lowered," given the "large body of data clearly demonstrat[ing] adverse human health effects at the current level," CASAC recognized that "[s]cientific uncertainty

¹ Letters from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee, to Stephen Johnson, Admin'r, EPA (Oct. 24, 2006 and Mar. 26, 2007).

does exist with regard to the lower level of ozone exposure that would be fully-protective of human health.” Oct. 2006 CASAC Letter, at 5.

....

[I]n order for EPA to explain adequately its reasons for disagreeing with CASAC, **CASAC itself must be precise about the basis for its recommendations.** Because in this case CASAC failed to specify whether the 0.070 ppm level it recommended as a maximum rested on a scientific conclusion about the existence of adverse health effects at that level, EPA’s invocation of scientific uncertainty and more general public health policy considerations satisfies its obligations under the statute.

Mississippi, 2013 WL 6486930, at *18-20 (emphasis added).

The takeaway from this decision is that CASAC should clearly segregate its scientific conclusions on matters such as the level of pollution that is likely to cause adverse effects from recommendations on matters such as the NAAQS level (or range of levels) requisite to provide an adequate margin of safety (which the Court views as involving a policy choice). The Court made clear that whether “adverse health effects [are] likely to occur” at a given level of pollution exposure is a scientific judgment. *Mississippi*, 2013 WL 6486930, at *19. More specifically, the Court’s decision (read together with prior court decisions) provides the following guideposts for future CASAC recommendations on any NAAQS:

1. It is particularly important that CASAC provide its scientific determination (to the extent possible given the evidence) of the lowest level of the pollutant at which adverse health effects are likely to occur, particularly for sensitive groups (such as the elderly, persons with COPD, and children with asthma). The Court has repeatedly recognized that “NAAQS must protect not only average healthy individuals, but also ‘sensitive citizens’ such as children....” *Coal. of Battery Recyclers Ass’n v. EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010); *Am. Lung Ass’n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998). CASAC should explain the basis for its scientific finding that adverse effects are likely at a given level, with reference to supporting scientific studies, data, and/or findings in the record.

2. Absolute certainty is not required for CASAC to offer its scientific judgment on the level at which adverse effects are likely. The Court stated that CASAC can “acknowledge[] uncertainty in the scientific evidence but explain[] that, based on its expert scientific judgment, it nonetheless believe[s] adverse health effects [a]re likely to occur” at a given level. *Mississippi*, 2013 WL 6486930, at *19. EPA would then need to have a reasoned scientific basis, not a policy one, for departing from CASAC’s judgment on that issue. *Id.*

3. The above discussion is not meant to suggest that CASAC should avoid offering its views on matters involving public policy, such as the ultimate NAAQS level (or a range of levels) requisite to provide an adequate margin of safety.² Indeed, while the Court held that EPA

² Although CASAC is free to recommend a range for the ultimate NAAQS level, governing case law requires that the upper end of the range must be below the lowest level at which adverse effects are likely to occur. Because the primary NAAQS must assure “the absence of adverse effects” on sensitive persons, EPA cannot lawfully set the NAAQS at a level where such adverse

has less of a burden to justify departing from such CASAC advice than from CASAC's scientific conclusions, it also held that EPA **can** base its decision on such advice if it so chooses. *Mississippi*, 2013 WL 6486930, at *6 (EPA "surely ... may rely on an explicit recommendation by the unanimous CASAC panel."). We mean to suggest only that CASAC should expressly state its scientific judgment, based on the evidence before it, about the lowest level at which adverse effects are likely and should carefully distinguish such scientific conclusions from advice involving public policy judgments.³

One final point: As noted above, the Court held that "[h]ad CASAC reached a scientific conclusion that adverse health effects were likely to occur at the 0.070 ppm level, EPA's failure to justify its uncertainty regarding the existence of adverse health effects at this level would be unacceptable." The Court also added a footnote to this sentence reading as follows:

This conclusion concerns only disagreements regarding the certainty of the science; of course, EPA could also have accepted CASAC's scientific conclusion and explained its view that any health effects at that level were not severe enough to be considered "adverse."

Mississippi, 2013 WL 6486930, at *18 n.6. In our view, the footnote language is nonbinding because it deals with a hypothetical - not an issue actually presented by the case: EPA did not in fact take the view that the health effects relied on by CASAC were non-adverse. But however one interprets the footnote, it will be valuable for CASAC to explain its reasons for finding that particular health effects (such as specific percentage decrements in lung function or shift in a population-level susceptibility for a health effect) qualify as "adverse," including any scientific grounds for such findings. For example, to the extent CASAC is relying on particular scientific criteria for gauging adversity of health effects, such as the American Thoracic Society guidelines, it would be helpful to clearly so state, and explain how such criteria apply to the particular effects under consideration. It would also be helpful for CASAC to elucidate the nature of the effects at issue and their importance for the physiology and function of the persons suffering them.

effects are likely to occur. *Coal. of Battery Recyclers*, 604 F.3d at 618 (primary NAAQS must protect "sensitive citizens," like children, the elderly, and people with respiratory illnesses, "and if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard") (internal quotation and alteration marks omitted); *Am. Lung*, 134 F.3d at 389. Also, recommendation of a range will be more effective if CASAC provides a reasoned explanation of both its scientific and policy grounds for selecting that range (including its grounds for selecting the top and bottom ends of the range).

³ By letters dated February 19, 2010, and March 30, 2011, CASAC provided additional advice to the Administrator on EPA's 2010 proposal to reconsider the 2008 ozone NAAQS. The *Mississippi* decision did not consider those letters because the 2010 reconsideration rulemaking was not at issue in the case. However, as with CASAC's letters in the 2008 review, the February 2010 and March 2011 letters do not appear to have clearly separated CASAC's policy judgment about an adequate margin of safety from its scientific judgment about the lowest level at which adverse effects are likely. The letters make general statements about the recommended range, but nowhere do they say that adverse effects are "likely" at any level within the range.

Thank you for your attention to this important matter.

Sincerely,

/s/ David S. Baron

David S. Baron

Counsel for American Lung Association