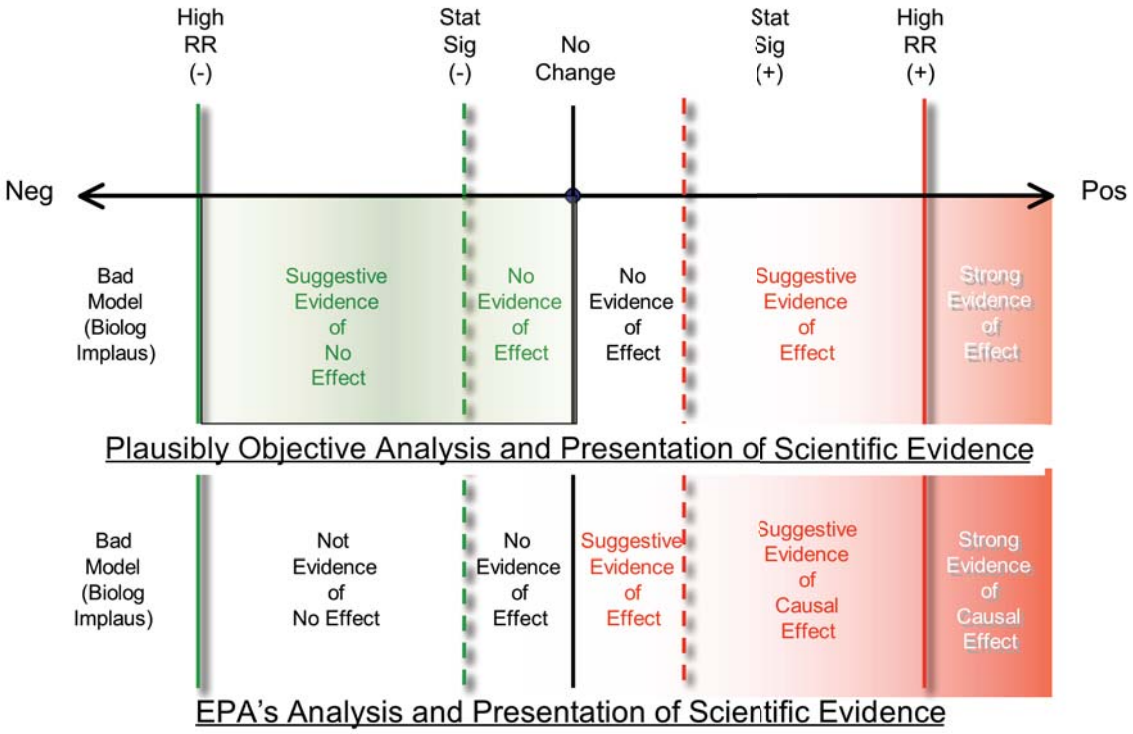
Figure B: Signal Strength and Statistical Significance in EPA's Ozone Risk Assessment



D. EPA's Risk Assessment Is Biased as a Matter of Policy

In our RFC, we said EPA's risk assessment lacked objectivity as a matter of policy, rooted in the Agency's narrow mission and implied by the policy views of its career staff (National Association of Manufacturers 2007, pp. 39-40). We noted that this policy is a matter of public record. We cited as our authority a recent EPA Staff Paper on Risk Assessment Principles and Methods that celebrates the staff's practice of producing purposefully biased risk assessments (U.S. Environmental Protection Agency Office of the Science Advisor 2004a). In this Report, EPA staff gave a *pro forma* commitment "to provide the best possible scientific characterization of risks based on a rigorous analysis of available information and knowledge" (p. 3, emphasis in original), and endorsed the information quality principle of "objectivity" (pp. 9-10). The Report makes clear, however, that these commitments are subordinate to the greater goal that its risk

assessments be biased in favor of erring on the side of overestimating human health risk, not estimating it objectively:

> EPA's risk assessments are conducted in support of its mission to protect public health and the environment. Given the uncertainty, variability, and data gaps encountered when conducting any risk assessment, a key objective for EPA's risk assessments is that they avoid both underestimation of risk and gross overestimation of risk (p. 11, emphasis added).

"In other words," the staff continued, "EPA seeks to adequately protect public and environmental health by ensuring that risk is not likely to be underestimated."

This staff policy explicitly leads to bias that the staff justify on account of the existence of uncertainty and variability:

> Since uncertainty and variability are present in risk assessments, EPA usually incorporates a "high-end" hazard and/or exposure level in order to ensure an adequate margin of safety for most of the potentially exposed, susceptible population, or ecosystem (U.S. Environmental Protection Agency Office of the Science Advisor 2004b, p. 16, emphasis added).

The Clean Air Act delegates to the Administrator, not to his technical staff, the authority to decide what constitutes an "adequate margin of safety." By embedding an "adequate margin of safety" into its risk assessments, EPA staff assures that whatever margin of safety the Administrator chooses, it will be over and above the margin of safety that his staff have already included in its risk assessment and characterization.

In our RFC, we said EPA's ozone risk assessment was faithful to the EPA Staff Paper on Risk Assessment Principles and Methods, and the staff's commitment "op avoid both underestimation of risk and gross overestimation of risk." In its Response to Comments, EPA does not actually deny that its risk assessment adheres to these principles. Rather, EPA simply waves the talisman of the CASAC peer review – and gives a self-serving exposition of the panel's views, at that (U.S. Environmental Protection Agency 2008e, p. 85). EPA notes that CASAC graciously called its risk characterization "well done, balanced and reasonably communicated," but EPA fails to mention any of the important caveats CASAC included in the same paragraph of the same letter:

- "Although a number of issues are raised, their impacts on the estimates have not been thoroughly explored."
- "Additional sensitivity analyses seem warranted."

- "Although the 3 parameter logistic (3PL) model emulates the pattern seen in the five "data points," these points are aggregates of the original data, and may give a misleadingly optimistic picture of the quality of the fit."
- "More importantly, although the problem of model uncertainty is noted it has not been addressed even though methods exist for doing so."
- "Even if only the linear and logistic models were included in the analysis, the error bands around the estimated response probabilities would likely increase to better reflect that uncertainty."
- "In addition, a suggestion to deal with the uncertainties surrounding estimation of PRB, particularly as related to Table 5.5 (for lung function) and Table 5.11 (mortality), would be to change the form of the analyses to assess the impact of the concentration change in the expected number of health effects relative to the current standard. The key advantage of estimating the effect of concentration change is that it does not depend on the choice of the PRB."[111]

As we have noted elsewhere, EPA never asked CASAC to review its scientific work products to ensure that they were objective. The information quality principles that the EPA Staff Paper on EPA Risk Assessment Principles and Practices says the staff is committed to uphold are missing entirely from the panel's Charge, which asks them instead to evaluate its scientific and technical work for "reasonableness." "Objectivity" can be refuted by the application of methods that scientists such as CASAC panel members know well. On the other hand, "reasonableness" is purely a matter of judgment and opinion, and as such, it can never be refuted. Thus, the goal of EPA staff has been to persuade CASAC that their effort has been reasonable, not that the output of that effort is objective.

[111] See Henderson (Henderson 2006c, p. 12). All comments cited here – including the praise cited by EPA – were on the second draft Staff Paper published in August 2006 (U.S. Environmental Protection Agency 2006f). CASAC's review of the final draft Staff Paper apparently was so abbreviated by time constraints that it did not examine the extent to which EPA staff had responded to its concerns. Neither the letter nor the individual comments by CASAC panel members suggests that CASAC actually reviewed Chapter 5, which contains the risk characterization. Because this particular meeting was conducted by teleconference, there is no meeting transcript.

E. EPA Attributes to Ozone Risks That It Has Previously Attributed to other Pollutants

In our RFC, we said EPA's risk assessment attributed to ozone health risks that the Agency had previously attributed to other pollutants – most notably, fine PM – through the device of single-pollutant models that exclude control for confounding air pollutants (National Association of Manufacturers 2007, p. 41). In its Response to Comments, EPA points to tables in the risk assessment that provide a range of alternative models (U.S. Environmental Protection Agency 2008e). EPA justifies the use of single-pollutant models for estimating mortality risk on the ground that there is "some evidence" that the effect of PM "may not be very substantial."

EPA's response is fully consistent with the EPA Staff Paper on Risk Assessment Principles and Practices (it is Agency staff policy to not to ever understate risk) and our Envelope Theory of EPA Risk Assessment (all science either points toward high risk or points nowhere at all).

IV. Information Quality Errors in the Assessment of Human Health Risk

In our RFC, we identified several broad information quality errors in EPA's health risk assessment, each of which had the effect of upwardly biasing the Agency's estimate of human health risk.

A. EPA Treats Transient and Reversible Effects as Adverse

We noted that EPA staff defined as "adverse" physiological effects that are transient and reversible (National Association of Manufacturers 2007, p. 42). Such effects have at least a dozen reported triggers (Sarafino et al. 2001), including laughter, which presumably EPA does not intend to count as adverse.

In its Response to Comments, EPA "strongly rejects" our position, claiming that we were contesting "the Administrator's judgments as to when O_3-related effects become regarded as adverse to the health of individuals" (U.S. Environmental Protection Agency 2008e, p. 62, emphasis added). This is false; we contested the EPA staff's characterization of the science of adversity, not any aspect of the Administrator's policy judgment. Any reference to the Administrator's policy judgment is diversionary, for EPA staff has sought to define adversity in technical and scientific terms that are covered by information quality principles; the Administrator's policy judgment is not.

This can be seen in the Criteria Document, for example, where EPA staff devote considerable attention to the task of defining criteria for determining adversity in scientific terms (U.S. Environmental Protection Agency 2006a, pp. 8-

65 to 68-69). The Criteria Document reprints respiratory effect size categories EPA first published in 1997, but neither the CD nor the Staff Paper transparently define adversity. By never defining it, EPA staff implicitly interprets all effects as adverse.[112]

It appears that as a tactical matter, EPA staff relied on CASAC to define adversity in terms of its members' policy views, then recharacterized those policy views as "science" (U.S. Environmental Protection Agency 2007d, Section 2.1). The script can be found in the discussion between EPA staff and CASAC during the CASAC meeting on August 24, 2006 (U.S. Environmental Protection Agency Science Advisory Board Staff Office 2006, pp. 142-150). EPA's Response to Comments implicitly attributes to CASAC the decision to treat transient and reversible effects as adverse, citing this very same discussion (U.S. Environmental Protection Agency 2008e, p. 65).

EPA's Response to Comments also cites a pyramidal spectrum of adverse respiratory health effects listed in guidance developed by a committee of the American Thoracic Society (1985), and it claims that this supports the EPA staff position that transient and reversible effects are adverse (U.S. Environmental Protection Agency 2008e, p. 62, footnote 4). This is false. In a subsequent guideline, also cited by EPA, the American Thoracic Society (2000) said it had "hinged the distinction between adverse and nonadverse effects on medical considerations" whose "boundary is further influenced by societal considerations" (p. 666).[113] Transient and reversible effects were not on this list, and the least adverse effect in the spectrum – "interference with the normal activity of the affected person or persons" – does not admit to objective interpretation.

Like its predecessor, the 2000 ATS guidance is a mixture of medical science and policy considerations, and for that reason it is even more difficult to interpret objectively than was the 1985 list. Nonetheless, with respect to transient and reversible respiratory effects, the ATS did not define them as adverse *per se*:

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[112] Perhaps the most obvious example is EPA's implicit characterization of the 1.5% to 2.8% group mean FEV_1 decrements reported by Adams (2006a) as adverse – even though in the Criteria Document EPA staff characterize effects ± 3% as equivalent to no effect at all.

[113] The committee apparently considered economics as a factor in determining adversity, but decided against doing so because it recognized that ATS lacked expertise in this area. See American Thoracic Society (2000, pp. 668-689).

> *Physiological impact*. The committee recommends that a small, transient loss of lung function, by itself, should not automatically be designated as adverse. In drawing the distinction between adverse and nonadverse reversible effects, this committee recommended that reversible loss of lung function in combination with the presence of symptoms should be considered adverse. This committee considered that any detectable level of permanent lung function loss attributable to air pollution exposure should be considered adverse (American Thoracic Society 2000, p. 672).

The ATS statement also specifically declined to endorse the EPA staff's definitions of adversity:

> The Environmental Protection Agency has also needed to address the interpretation of such data. The Environmental Protection Agency, in its 1989 review of ozone offered a graded classification of lung function changes in persons with asthma. Reduction of the forced expiratory volume in 1 s (FEV,) was graded as mild, moderate, or severe for reductions of less than 10%, l0-20%, and more than 20%, respectively. <u>This classification has not been validated</u> for acceptability or against other measures (emphasis added).[114]

B. <u>EPA Uses Important Scientific Terms and Language in Policy-directed Ways</u>

In our RFC, we objected on information quality grounds to EPA's use of probabilistic statements without ever defining what they mean in clear, accurate and understandable language (National Association of Manufacturers 2007, pp. 42-44). We focused particularly on EPA's use of the terms "likely" and "unlikely," which appear 144 times in volume 1 of the Criteria Document, 177 times in the Staff Paper, and 134 times in the NPRM – but in no case does EPA ever provide a definition. The terms "robust" and its adverbial variants (e.g., "fairly robust," "generally robust," "statistically robust") appear 54 times to describe associations in volume 1 of the Criteria Document, 48 times in the Staff Paper, and 28 times in the NPRM – but EPA never defines this term, either.

The model we presented of EPA's approach to causality (Figure B in Section III.C.6) illustrated the implications of EPA's linguistic nontransparency: a large number of studies is assembled, each of which has weak or ambiguous

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[114] Although the revised statement was published in 2000, the ATS committee did not comment on the graded scheme EPA published in the 1996 ozone Criteria Document (U.S. Environmental Protection Agency 1996a) and republished in the latest edition (U.S. Environmental Protection Agency 2006a).

evidence, but in combination they are transformed into predictions that are "likely," about which EPA staff is "confident" – another term EPA staff do not explain.

In its Response to Comments, EPA agrees in principle "where available information provides a basis for assigning quantitative values to probabilistic statements that it is generally appropriate to do so" (U.S. Environmental Protection Agency 2008e, p. 156). However, EPA does not agree that this principle imposes any duty in practice:

> EPA does not agree that it is appropriate to interpret information in quantitative terms if available information does not provide a basis to do so, which would have the effect of communicating a higher degree of precision than is warranted… (Id.)

There are several rebuttals to this reply.

1. *The definition of "likely" has nothing to do with "precision."*

A simple search of an English dictionary will show that the meaning of "likely" has nothing to do with precision and everything to do with the magnitude of probability.[115] In its response, EPA staff attempts to divert attention away from its persistent and consistent refusal to adhere to the Information Quality Act's requirement that it be transparent about the size of effects and their likelihood. When EPA staff describe a phenomenon or make a prediction that it calls "likely," it must be clearer about what "likely" means. By evading this legal responsibility, the EPA staff invites members of the public to substitute their own definitions of "likely." This abuse of qualitative probabilistic language makes EPA staff determinations neither testable nor reproducible. Moreover, EPA's Response to Comments indicates that this is entirely deliberate and intended for the purpose of obfuscation:

> [T]he word "likely" is intended to convey its common meaning, i.e., having the qualities or characteristics that make something probable. This meaning reflects a judgment, for which EPA provides a reasoned basis in these documents (U.S. Environmental Protection Agency 2008e, pp. 156-157).

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[115] A comparison of definitions across six online dictionaries reveals none that imply that "likely" conveys any notion of precision unless it is preceded by an adverb. See http://dictionary.reference.com/browse/likely. A similar review of multiple thesauruses reveals none that say "precise" is a synonym. See http://thesaurus.reference.com/browse/likely.

The use of partial synonyms is evasive. The "reasoned basis" EPA provides in the preambles to the NPRM and final rule concern the exercise of the Administrator's policy judgment, not the description or estimation of probabilities. EPA staff have no authority to make policy decisions on behalf of the Administrator, and the Administrator does not have the discretion to base probabilities on policy judgment. The Administrator's policy judgment applies to matters of public policy and the weighting of competing social values. The Clean Air Act does not authorize the Administrator to interpose policy judgments and social values into descriptions of scientific knowledge or facts; they must be objectively determined or estimated and accurately described.

2. *If there is no scientific basis for probabilistic language, EPA should not use it.*

EPA's Response to Comments says the EPA staff cannot be more quantitatively specific about what they mean when they use probabilistic words such as "likely" because "available information does not provide a basis" for it to do so. This implies that EPA staff themselves do not know what they mean when they use probabilistic language despite the frequency with which they invoke it. If this is true, then EPA staff must cease using probabilistic language. EPA cannot expect the public to understand what Agency staff mean by "likely" if Agency staff use the term without a clear factual basis.[116]

The EPA staff's responsibility is to provide the Administrator with objective factual information about such matters as probabilities – for example, the likelihood that a well-defined health effect is occurring at ozone concentrations below the existing primary NAAQS, and if so, to whom. To the extent that this likelihood is variable (i.e., it differs across individuals and subpopulations) or uncertain (i.e., there are limits to the precision with which it can be estimated or described), EPA staff have the duty to inform the Administrator about that as well. It is then the Administrator's responsibility (and indeed, his statutory authority under the Clean Air Act) to decide whether these objectively estimated or described likelihoods are large enough that the existing primary NAAQS is no longer "requisite" to protect public health. By refusing to disclose to the Administrator and the public what they mean when they use probabilistic words such as "likely," EPA staff are violating applicable

[116] EPA follows by saying: "NAM has not identified any specific instance in which the Agency's use of terms such as 'likely' or 'unlikely' is not consistent with the common meaning of these terms." This of course is true, for EPA staff have used these terms such that they cannot be reproduced by any third party, and thus they cannot be refuted.

information quality principles and guidelines and failing to provide the Administrator with information that satisfies the utility standard.

3. *EPA staff have available to them – and have used in other contexts – clearly defined meanings for probabilistic terms.*

In its Response to Comments, EPA implies that science does not provide a superior way to described probabilities when precise figures are not available. However, EPA has a record of being much more clear about the meaning of probabilistic statements in other contexts. EPA has several times cited approvingly a scheme that defines terms including "very likely" (> 90% probability), "likely" (> 66% but > 90% probability), "unlikely: (> 10% but < 33% probability), and "very unlikely" (< 10% probability) (U.S. Environmental Protection Agency 2007a; 2007n, p. 8, footnote 3). It is inconceivable that EPA staff are unaware of these documents.

4. *Ad hoc meanings for probabilistic language are not compatible with information quality.*

In conventional English, proper words mean very specific things and ordinary words are empowered with general or universal meaning. Lewis Carroll was the first to explore the logical implications of reversing this rule. Substituting the word "likely" for "glory," and EPA staff for Humpty Dumpty, the latter's conversation with Alice would have gone like this:

> "I don't know what you mean by 'likely.'" Alice said.
>
> EPA staff smiled contemptuously. "Of course you don't – till I tell you. It means 'there's a nice knock-down argument for you!'"
>
> "But 'likely' doesn't mean 'a nice knock-down argument,'" Alice objected.
>
> "When I use a word," EPA staff said, in rather a scornful tone, "it means just what I choose it to mean -- neither more nor less."
>
> "The question is," said Alice, "whether you can make words mean so many different things."
>
> "The question is," said EPA staff, "which is to be master -- that's all."[117]

"Likely" means whatever EPA staff say it means – nothing more and nothing less. It truly is a "knock-down argument."

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[117] Carroll (1960, p. 269, "Through the Looking Glass, Chapter VI).

EPA staff "disagree" that they have any obligation under information quality principles to be clear, accurate, and transparent. Doing so would not be an "appropriate use of Agency resources" (U.S. Environmental Protection Agency 2008e, p. 157).

We reiterate here what we said in our RFC:

> Where EPA uses probabilistic terms to describe statements of fact or knowledge, information quality principles require that the Agency show that its probabilistic terms are founded on science and comport with how decision makers and the public understand these terms. It is not enough merely to show that, once defined, scientists can consistently apply them. The terms and categories themselves must be consistent with scientific principles, objective in design, and have utility for the purpose to which they are used. Thus, it is a violation of the information quality standard of objectivity to use terms such as "likely" or "probably" in ways that conflict with their actual use in an appropriate context or without clear definition.
>
> EPA needs to establish clear rules and procedures for how probabilistic language will be used in risk assessments and similar documents prepared to guide decision-making. Prescriptive consistency in language reduces uncertainty about how language is used in documents prepared by multiple authors or by agency committee and work group process, such as the documents subject to this RFC. Four principles should guide the development of these rules and procedures.
>
> First, because probabilistic statements are semi-quantitative, when scientists, decision-makers and the public use the same words, they should mean roughly the same thing. Without guidance, potential interpretative heterogeneity is unbounded. By assigning quantitative values to statements about likelihood, interpretative heterogeneity should be drastically reduced.
>
> Second, the values assigned by EPA to likelihood statements and probability descriptors must be consistent with both intuition and scientific research about such terms. That is, EPA cannot simply invent a rule that enables it to transform objectively weak scientific information into statements asserting high levels of confidence or likelihood. EPA must look at relevant research literature on the meaning of ambiguous terms and utilize this research in crafting the scales.
>
> Third, the values EPA assigns to probabilistic language must be transparent, and to a great degree, also reproducible with an acceptable

> degree of imprecision or error (Office of Management and Budget 2002, Sections V.5.a ["transparency"] and V.10 ["reproducibility"]). To adhere to applicable information quality standards, at a minimum EPA must make transparent what it means when it uses likelihood statements and probability descriptors. Further, it must re-examine its use of these statements and descriptors to ensure that the Agency is applying them consistently throughout.
>
> Finally, EPA must be forthcoming with full and complete documentation of what it proposes, and subject its work to pre-dissemination review (such as peer review by qualified psychologists). Applications of this guidance must be challengeable under the Agency's error correction procedures.

C. EPA Confuses Variability and Uncertainty

In our RFC, we noted that EPA had presented scientific and technical information about variability and uncertainty in a confused manner (National Association of Manufacturers 2007, pp. 42-44). Reasons for EPA's confusion were hard to fathom; the distinction between variability and uncertainty is well established and understood in the risk assessment field (Morgan et al. 1990). Nonetheless, EPA's documents consistently confuse these terms – or, more specifically, they frequently use *uncertainty* to refer to both *uncertainty* and *variability,* particularly the documents (and sections of documents) most likely to be read by policy officials.

This problem infects more than just the magnitude of risk estimates. Sampling error receives almost all of the EPA staff's attention, but among sources of uncertainty, it may be the smallest. It is technically incorrect and fundamentally misleading to provide the Administrator information about sample variability but describe that information as characterizing the bounds of scientific uncertainty. The National Academy offered EPA guidance on this point 13 years ago:

> A distinction between uncertainty (i.e., degree of potential error) and interindividual variability (i.e., population heterogeneity) is generally required if the resulting quantitative risk characterization is to be optimally useful for regulatory purposes, particularly insofar as risk characterizations are treated quantitatively (National Research Council 1994)

In the ozone review, EPA has not followed the Academy's recommendations.

In short, EPA has presented the Administrator data and analyses that led him to be much more confident than is scientifically justified that ozone exposure

below the current NAAQS poses human health risks. The EPA staff's characterization of various risks as "likely" is not accompanied by any indication of what probabilities are implied. Point estimates of health risk with confidence intervals capture only statistical variability for the selected models, not scientific uncertainty. Information about variability, which is small relative to the magnitude of variability and uncertainty combined, has no utility to the Administrator unless it is placed in proper context with information about uncertainty. The Administrator's statutory assignment is to decide whether there is sufficient evidence that exposure below the current standard poses a sufficient incremental risk to warrant revising the NAAQS downward. That cannot be done without clear and accurate characterizations of probabilities.

In its Response to Comments, EPA says that it "explicitly discussed" these material analytic weaknesses in its Staff Report (U.S. Environmental Protection Agency 2008e, p. 87). In EPA's view, it is sufficient to acknowledge that "the uncertainty ranges reported in the risk assessment do not reflect all of the uncertainty in the risk estimates" without disclosing the extent to which its risk estimates are reported with unrealistically narrow confidence intervals. Information quality principles and guidelines do not require EPA to perform perfect risk assessments. They require EPA to be honest about the extent to which its risk assessments are imprecise and unintentionally biased, and to avoid utilizing procedures that purposefully impart bias.

EPA "does not agree that the preponderant effect of all of the sources of uncertainty is to create an upward bias in EPA's risk estimates" (U.S. Environmental Protection Agency 2008e, p. 87, emphasis added). We highlight the qualifier "all" because it converts our information quality complaint into a straw man; we never claimed that every aspect of EPA's risk assessment was upwardly biased.

Further, "EPA does not agree that other researchers have presented a credible, balanced, peer-reviewed integrated uncertainty analysis that shows the large majority of probability in the estimates falls far below the primary estimates that EPA reported" (U.S. Environmental Protection Agency 2008e, p. 88). The example of an "integrated uncertainty analysis" that EPA cites as lacking "credibility" and "balance" – terms that EPA nowhere defines, by the way -- is a competing analysis of mortality risks (Smith and Gibbs 2007) that is not, and does claim to be, an "integrated uncertainty analysis." EPA purports to discard Smith and Gibbs (2007) because it deals only with mortality risk and relies on assumptions different from (but at least as plausible as) the assumptions used by EPA staff. EPA's Response to Comments implies that EPA staff intend to reject any competing analyses submitted through the public comment process unless, at a minimum, they improve upon each and every aspect of the Agency's risk

assessment and secure peer review -- all within the public comment period, which in this case was 90 days.

D. EPA Does Not Disclose a Credible Analysis of Uncertainty

In our RFC (National Association of Manufacturers 2007, pp. 46-47), we noted that since at least 1994 EPA has been advised by the National Academy of Sciences to perform quantitative uncertainty analysis in its most important risk assessments (National Research Council 1994). The Agency was criticized then for relying on point estimates, especially when those estimates were described as "plausible upper bounds." Such risk estimates were criticized as misleading or untrue. Uncertainties needed to be explicit and presented "as accurately and fully as is feasible and needed for risk management decision-making" (Ibid. p. 185).

Thirteen years later, in a risk assessment supporting one of the Agency's most far-reaching regulatory actions, EPA continues to rely on plausible upper-bound point estimates and declines to conduct or disseminate a formal uncertainty analysis.[118]

In a 2002 report to EPA specifically about the assessment of health risks from air pollution regulations, a committee of the National Academy of Sciences examined previous EPA health risk assessments and reached several conclusions, including:

- In its primary analyses of health benefits, EPA reports the uncertainty as a probability distribution. Only one source of uncertainty, the random sampling variability of the estimated concentration-response function, is given with an emphasis on the mean of the probability distribution. The absence of other sources of uncertainty makes the results of the primary analyses appear more certain than they are.
- To address other sources of uncertainty, EPA uses ancillary analyses, such as alternative and supplementary calculations and sensitivity analyses. With the exception of concentration-response function estimates, these ancillary analyses usually examine only one source of uncertainty at a time and only for the impact on the mean value of the probability distribution from the primary analysis. As a consequence, though laudable steps in the right direction, these ancillary analyses do

[118] EPA's review plan promised very limited efforts to analyze exposure uncertainty (U.S. Environmental Protection Agency 2005e, pp. 10-11), and EPA never wavered from that limited commitment (Langstaff 2006a, 2006b, 2007).

> not adequately convey the relative or aggregate degree of uncertainty created by the sources of uncertainty addressed in the analyses, nor, of course, do they depict uncertainty from other sources (National Research Council 2002, p. 146).

In its ozone health risk assessment prepared five years later, nothing changed. Just as EPA staff have cherry-picked data and studies to reverse-engineer scientific support for the new standards they wanted the Administrator to adopt, they have cherry-picked advice from the NRC.[119]

In its Response to Comments, EPA defends its decision to ignore the recommendations of this NRC committee, dismissing the 2002 report as irrelevant for EPA health risk assessment:

> [T]he 2002 NRC report cited by several commenters made recommendations with respect to EPA's regulatory impact analyses which are required under E.O. 120266 [sic] and not EPA's health risk assessments (U.S. Environmental Protection Agency 2008e, p. 88).

EPA misreads the Academy report, and apparently, it has forgotten its own Charge to the committee. The intersection between benefits assessment and health risk assessment is so strong that a retired commissioned officer of the Public Health Service and emeritus professor of public health, John C. Bailar, III, was selected to chair the NRC committee – not an economist familiar with Executive Order 12866 and its Regulatory Impact Analysis requirement. In fact, of the committee's 13 members, 10 were public health scientists and only one was an economist.[120] It is entirely plausible, if not certain, that none of these public health scientists would have agreed to serve if they had known in advance that EPA would dismiss their work as relevant only to Regulatory Impact Analysis.

E. <u>EPA's Particular Use of Default Values Violates Information Quality Principles</u>

In our RFC, we noted that the use of "inference guidelines" (National Research Council 1983) and "default options" (National Research Council 1994)

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[119] EPA (2008a) states that it adopted NRC (2002) recommendations for the selection of human health endpoints (Table 6.1), the choice of concentration-response functions associated with these endpoints (Table 6.2), reductions in school absences resulting from lowering the primary NAAQS (p. 6-18).

[120] See NRC (2002, pp. 166-170). Given the dearth of economics expertise on the committee, it is remarkable that the report contains as much economics content as it does.

has a long and checkered history (National Association of Manufacturers 2007, pp. 47-49). Regardless of the terminology used, it refers to a scientific concept, construct or fact which is uncertain, unknown or unknowable, and for which judgment of some sort is required to choose "among several scientifically plausible options" (National Research Council 1983). It became clear that there was an irreconcilable difference between those who thought default options ought to err on the side of overestimating risk (National Research Council 1994, pp. 601-627, Appendix N-1) and those who said they ought not (National Research Council 1994, pp. 629-640, Appendix N-2). The committee as a whole nevertheless reached agreement that EPA needed to "provide justification for its current defaults and set up a procedure such as that proposed in the report that permits departures from the default options" (National Research Council 1994). Fourteen years later, EPA has not established that procedure.[121]

More importantly, the federal Information Quality Act and its implementing guidance have superseded these debates. Information of a scientific nature now disseminated by federal agencies must be objective, in both substance and presentation. Default options consist of scientific information, and thus they are fully subject to these objectivity requirements. Whether to set standards that are health protective (i.e., aim to protect a relatively high percentile of the affected population), and if so, how protective (i.e., which percentile to aim to protect) are policy decisions solely within the discretion of the authorized decision maker – in this case, the Administrator of EPA. The Administrator's obligation is to be transparent and accountable with respect to these judgments, but he cannot do so if the scientific information on which he must depend is infected with default options that implicitly and surreptitiously contain policy judgments that he alone is authorized to make. In the words of Justice Breyer:

> The statute's words … authorize the Administrator to consider the severity of a pollutant's potential adverse health effects, the number of those likely to be affected, the distribution of the adverse effects, and the uncertainties surrounding each estimate. They permit the Administrator to take account of comparative health consequences. They allow her to take account of context when determining the acceptability of small risks to health. And they give her considerable

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"In many cases, the regulated parties may be willing to fund research that will enable health-protective default options in risk assessment to be replaced by more complex and less conservative alternatives" (National Research Council 1994).

> discretion when she does so (*Whitman v. American Trucking Ass'ns*, Inc, 531 U.S. 457, 495 (J. Breyer, concurring, internal citations omitted)).

Exercising this discretion requires accurate, reliable, and unbiased information about "the severity of [ozone's] adverse health effects, the number of those likely to be affected, the distribution of the adverse effects, and the uncertainties surrounding each estimate." This information must be presented in an accurate, clear, complete, and unbiased manner.

We said in our RFC that the documents subject to our information quality challenge systematically incorporate default options that fail the substantive objectivity test (National Association of Manufacturers 2007, pp. 48-49). Moreover, the degree to which policy judgments that belong solely to the Administrator's discretion have been subordinated to or restricted by the public policy preferences of Agency staff is nowhere made transparent. For that reason, these documents also violate the presentational objectivity test. The Administrator cannot reasonably be expected to discern, from the documents he has been provided, a clear, complete and unbiased picture of human health risks posed by ozone exposure below the 1997 NAAQS. The documents we challenge thus do not satisfy the utility standard of information quality. The Administrator cannot responsibly exercise the full breadth of his statutory authority; he can only exercise that portion of his statutory discretion left over after EPA staff have given him an inaccurate scientific record.

In its Response to Comments, "EPA rejects NAM's contention that it used default values and assumptions in its assessments" (U.S. Environmental Protection Agency 2008e, p. 157). EPA said we had failed to provide "specific examples of where EPA had used default values," by which we infer that the Agency takes an exceedingly narrow view of the concept of defaults and inference guidelines. At the cost of even greater redundancy, we list just a handful of defaults, each of upwardly biases EPA's estimates of human health risk or portrays these estimates as more precise than they actually are:

- Data, model selection, coefficient selection, and publication biases are negligible.
- Pulmonary tests are capable of distinguishing very small differences.
- Inter-maneuver variance in pulmonary function tests is zero.
- Ambient ozone concentrations can be assumed to be highly correlated with personal exposure even if they are not.
- Results from controlled human studies of personal exposure can be applied to ambient concentrations without adjustment for differences between personal and ambient exposure.

- Samples analyzed in critical epidemiological study are representative.
- There is no nonresponse bias in critical epidemiological studies.
- Self-reported data recorded in diaries are accurate.
- Weak epidemiological effects are causal if they are statistically significant and/or positive. Weak epidemiological effects have no information value if they are not positive.
- Asthmatic children are exposed to ozone the same as nonasthmatic children.
- All asthmatic children are equally susceptible.

EPA may reply that in each of these cases the staff was compelled by data gaps to exercise "judgment." We submit that EPA staff's exercise of judgment consistently imparted upward bias and excess precision to the Agency's risk estimates, consistent with the 2004 Staff Paper on Risk Assessment Principles and Practices (U.S. Environmental Protection Agency Office of the Science Advisor 2004b) and the Iron Law of EPA Staff Ozone Risk Assessment and Characterization. The use of "judgment" to impart purposeful bias and excess precision is incompatible with the information quality principles of substantive and presentational objectivity.

F. EPA Assumes Confidence Intervals Adequately Describe Variability and Uncertainty

In our RFC, we said that the EPA staff's approach to the various studies in its scientific database overstated confidence by assuming that variability and uncertainty were adequately described by reported confidence intervals (National Association of Manufacturers 2007, p. 49). EPA staff did this irrespective of whether the population studied was representative, irrespective of the sample response rate, irrespective of publication bias, and irrespective of model uncertainty. We cannot find any example in which EPA staff did more than "discuss" or "consider" these weaknesses before acting as if they did not exist.

In its Response to Comments, EPA addresses an unrelated question – the relative importance of statistical significance compared to "the pattern of results across various studies" (U.S. Environmental Protection Agency 2008e, p. 33). EPA further

> disagrees that most of the epidemiologic literature evaluated in the O_3 Criteria Document is based on non-random research designs. Not all epidemiologic studies evaluated in the O_3 Criteria Document use study populations that are generalizable to the entire population, but this does

> not mean that the study population was non-random (emphasis in original).

EPA's qualifying reference to the Criteria Document, which includes many studies EPA did not rely upon, is revealing. Focusing on the panel studies EPA cites in the NPRM as supporting the conclusion that the 1997 primary NAAQS is not requisite to protect public health, we see that they have a constellation of research design limitations:

- Sampling methods assumed but not demonstrated to be representative (Gent et al. 2003; Mortimer et al. 2002)
- Explicit convenience sampling (Korrick et al. 1998; Romieu et al. 1997; Romieu et al. 1996; Sarnat et al. 2005; Sarnat et al. 2000; Sarnat et al. 2001)
- Significant to severe non-response bias (Gent et al. 2003; Korrick et al. 1998; Mortimer et al. 2002; Sarnat et al. 2000)
- Reliance on unvalidated data recorded in diaries (Gent et al. 2003; Mortimer et al. 2002; Romieu et al. 1997; Romieu et al. 1996; Sarnat et al. 2000; Sarnat et al. 2001)
- The discard of inter-maneuver variability and uncertainty in FVC, FEV_1, or PEF testing (Korrick et al. 1998; Mortimer et al. 2002; Romieu et al. 1997; Romieu et al. 1996)

The amount of inflation in statistical significance is unknown, but it becomes increasingly important as effect sizes involved approach zero. Nevertheless, the EPA staff assume that the confidence intervals in the epidemiological studies accurately capture variability and uncertainty.[122]

Presentational objectivity demands at least a transparent acknowledgement of this problem and its importance, with the added advice that the results of such interpret such results with extreme caution. The NPRM shows that, in fact, EPA staff never acknowledged the problem of understated confidence intervals and interpreted their results with very little caution.

[122] EPA's limited uncertainty analysis consists of a Monte Carlo simulation of concentration-response functions assuming that the confidence intervals reported in the epidemiological studies accurately and completely capture uncertainty. See Langstaff (2007).

G. EPA Assumes that Ambient Monitors Provide Unbiased Estimates of Personal Exposure

In our RFC, we objected to EPA's reliance on ambient ozone levels as proxies for personal exposure despite overwhelming evidence that ambient and personal exposures are uncorrelated (National Association of Manufacturers 2007, p. 50). In its Response to Comments, EPA replies that this is okay because the epidemiological studies upon which it constructed its risk assessment also rely on ambient ozone levels rather that personal exposure (U.S. Environmental Protection Agency 2008e, p. 83). Further, EPA "does not agree that there is any requirement [under applicable information quality guidelines] to provide unbiased estimates of exposure for each subpopulation group of concern before it can use concentration-response relationships in its risk assessments" (emphasis added).

This response misrepresents our complaint, for we never claimed that EPA had any such duty. Rather, we said the use of ambient ozone levels "violates the objectivity requirement of information quality because it imparts purposeful and avoidable bias to the risk estimate." Moreover, EPA lacks an unbiased estimate of exposure for any subpopulation of concern, or for the population as a whole. While EPA (sort of) denies that the use of ambient ozone data results in biased risk estimates,[123] the Agency's Response to Comments never replies to any of the public commenters who provided evidence otherwise – or, most ironically, CASAC:

> **Error in Estimating Exposure to Ozone**
>
> The Ozone Staff Paper should consider the problem of exposure measurement error in ozone mortality time-series studies. It is known that personal exposure to ozone is not reflected adequately, and sometimes not at all, by ozone concentrations measured at central outdoor monitoring sites. Typically, personal exposures are much lower than the ambient concentrations, and can be dramatically lower depending on time-activity patterns, housing characteristics and season. In addition, and of particular importance for the ozone time-series studies, there can be no correlation between personal concentrations of ozone measured over time and concentrations measured at central outdoor sites. The population that would be expected to be potentially susceptible to dying from exposure to ozone is likely to have ozone exposures that are at the lower end of the

[123] "The fact that ambient concentrations may overstate actual personal exposure does not imply that the risk estimates are biased." See EPA (2008e, p. 83).

> ozone population exposure distribution, in which case this population would be exposed to very low concentrations of ozone indeed, and especially so in winter. Therefore it seems unlikely that the observed associations between short-term ozone concentrations and daily mortality are due solely to ozone itself.
>
> Another implication of ozone measurement error that is relevant to the NAAQS-setting process is that this degree of measurement error would be expected to have a substantial impact on the ability to detect a threshold of the concentration-response relationship below which no ozone effects are discernible. Pollutant exposure measurement error obscures true thresholds in the concentration-response relationship, and this effect worsens with increasing degrees of measurement error. Since threshold assumptions are incorporated in the Agency's risk assessment and risk analyses, this issue will need to be addressed (Henderson 2006b, pp. 3-4).

In the second draft Staff Paper, EPA staff responded to CASAC by digging in their bureaucratic heels[124] and erecting a huge impediment to objective

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[124] "O_3 concentrations measured at central ambient 10 monitoring sites may explain, at least partially, the variance in individual exposures; however, this relationship is influenced by other factors such as air exchange rates in housing and time spent outdoors which may vary from city to city. Other studies conducted in various cities observed that the daily averaged personal O_3 exposures from the population were well correlated with ambient O_3 concentrations, although substantial variability existed among the personal measurements. Thus, there is supportive evidence that ambient O_3 concentrations from central monitors may serve as valid surrogate measures for mean personal exposures experienced by the population, which is of the most relevance for time-series studies. This is especially true for respiratory hospital admission studies, for which much of the response is attributable to O_3 effects on people with asthma. Ambient monitors are more likely to correlate reasonably well with the personal exposures of children, who spend more time outdoors in the warm season and who are also more likely to have asthma than adults. Conversely, there is some concern about the extent to which ambient concentrations are representative of personal O_3 exposures of another particularly susceptible group of individuals, the debilitated elderly, and what impact that may have on mortality and hospitalization time-series studies. The correlation between ambient concentrations and personal exposure measurements has not been examined in this population. A better understanding of the relationship between ambient concentrations and personal exposures, as well as of the other factors that affect relationship will improve the interpretation of concentration-population health response associations observed with ambient O_3 concentrations (U.S. Environmental Protection Agency 2006f, p. 3-39).

exposure assessment – a default assumption that, absent the routine collection of personal ozone exposure data, they were committed to using ambient ozone for reasons of expedience:

> [P]opulation health risk estimates derived using ambient O_3 levels from currently available observational studies, with appropriate caveats about personal exposure considerations, remain useful (U.S. Environmental Protection Agency 2006f, p. 3-40).[125]

The practical consequence of EPA staff using ambient concentrations in lieu of personal exposures is to significantly bias the scientific record provided to the Administrator. Under the NAAQS program, EPA sets standards for ambient concentrations, not personal exposure. EPA acknowledges that ambient concentrations exceed personal exposures by 2- to 4-fold,[126] interprets this as implying that ozone is more potent,[127] then discards this algebraic relationship. Adams (2002, 2006a) estimated group mean decrements in FEV_1 of approximately 1.5% compared to 0.04 ppm (2.8% compared to filtered air) when subjects were exposed to personal exposures of 0.06 ppm. EPA staff thus should be multiplying by 2- to 4-fold to obtain the ambient concentration equivalent. Instead, they treat personal exposures in controlled experiments as if they were the same as ambient concentrations in epidemiological studies. The results obtained by Adams at 0.06 ppm in personal exposure are roughly equivalent to 0.12 to 0.24 ppm in ambient concentration equivalents, using EPA's own conversion metric.

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[125] EPA never defines the meaning of "useful," nor does it explain the significance of these "appropriate caveats."

[126] "Using ambient concentrations to determine exposure generally overestimates true personal O_3 exposures (by approximately 2- to 4-fold in the various studies described in the Criteria Document, section 3.9)…" EPA (2008b, p. 16458).

[127] "[A]ssuming the relationship is causal, [this] would result in biased descriptions of underlying concentration-response relationships (i.e., in attenuated effect estimates). From this perspective, the implication is that the effects being estimated in relationship to ambient levels occur at fairly low personal exposures and the potency of O_3 is greater than these effect estimates indicate" EPA (2008b, p. 16458).

H. EPA Assumes that Associations Observed in Short-Term Time Series Studies Are Significant and Meaningful, but the Absence of Associations in Long-Term Cohort Studies Is neither Significant nor Meaningful nor Logically Inconsistent

In our RFC, we asked EPA to reconcile the Agency staff's view that short-term time-series studies which show positive associations with mortality are supportive evidence of risk, but long-term cohort studies which do not show such associations are not evidence of the absence of risk (National Association of Manufacturers 2007, p. 50). We inferred that EPA was concluding "ozone causes premature mortality in the short-term that cannot be observed over the long-term."

In its Response to Comments, "EPA rejects NAM's contention that it has reached inappropriate conclusions about associations between O_3 exposure and premature mortality" (U.S. Environmental Protection Agency 2008e, p. 53, emphasis added). EPA resolves inconsistency by implying that long-term epidemiological studies also would have supported the staff's inference that ozone causes mortality, if only they too had been statistically significant and/or positive. Precisely because these studies were "not consistent," they were effectively discarded.

EPA repackages our complaint about scientific inconsistency into a sterile debate about "appropriateness," a complaint we never raised because "appropriateness" has no scientific meaning. Wherever EPA's scientific statements are illogical, inconsistent, non-reproducible, or otherwise controlled by undisclosed and illegitimately exercised staff views about air pollution policy, Agency staff abandon any pretense to be evaluating science and instead assert the right to exercise unfettered judgment under the cloak of science.

I. EPA Assumes Causality

In our RFC, we objected to EPA's method of handling causality, which may be the most important scientific issue in the entire ozone review (National Association of Manufacturers 2007, pp. 50-51). Nowhere in any of EPA's supporting documents does the staff make its method of determining causality transparent to the Administrator or the public, nor is its method reproducible by third parties. It is therefore impossible to test or refute it utilizing scientific methods and procedures. The EPA staff have discarded causality as a scientific concept and replaced it with opinion.

In its Response to Comments, EPA denies that it has any obligation under information quality guidelines to describe causality in a probabilistic (i.e., scientific) manner (U.S. Environmental Protection Agency 2008e, pp. 84-85).

Similar to other crucial scientific concepts that EPA staff do not want to be transparent about, "causality" is whatever the EPA staff say it is; nothing more, and nothing less.[128]

J. EPA Does Not Explain the Effects of Ozone with Reference to Any Non-Air Pollution Context

We have pointed out several times elsewhere that the EPA staff approach is best explained as an Iron Law of EPA Staff Ozone Risk Assessment and Characterization. In our RFC, we noted that for a presentationally objective characterization of human health risks actually or purportedly due to ozone exposure below the NAAQS it was necessary to place ozone-associated health risks in context (National Association of Manufacturers 2007, p. 51). In its Response to Comments, EPA says it

> believes it has provided sufficient context in its discussion of respiratory effects in the Criteria Document and Staff Paper and that there is no specific requirement to make the type of comparison suggested by [NAM] (U.S. Environmental Protection Agency 2008e, p. 99).

It is hard to understand the basis for EPA's conclusion that it faithfully adhered to the information quality standard of presentational objectivity given that none of EPA's supporting documents ever mention the subject. EPA needs thousands of pages to explain what it knows about the health risks from ozone, but zero pages to explain why these thousands of pages are presentationally objective.

K. Double-counting

In our RFC, we said we sympathized with EPA concerning the difficulty of parsing effects into those associated with air pollution and those that are associated with other factors; and among air pollutants, effects associated with ozone from effects associated with $PM_{2.5}$ and NO_x. (National Association of Manufacturers 2007, pp. 51-52) Still, as we said in our RFC, double counting is simply not acceptable under information quality principles. EPA's risk assessment relies on many studies that estimate effects of ozone along with other air pollutants. We said EPA had an obligation to allocate health risk across these competing sources to ensure that it was not double-counting.

In its Response to Comments, EPA admits that double-counting is possible but says that if it occurred its magnitude was small (U.S. Environmental

[128] See the discussion in Section IV.B beginning on page 111 about EPA's serial abuse of probabilistic language.

Protection Agency 2008e, pp. 87-88).[129] The basis for EPA's confidence is a single meta-analysis (Levy et al. 2005). The authors considered only single-pollutant models in their main analysis (p. 459), and performed only a sensitivity analysis with respect to the confounding effect of $PM_{2.5}$ (p. 463).[130] It is the one-paragraph description of this sensitivity analysis that EPA staff rely on as the basis for dismissing our concern about double-counting of risks.

L. EPA's Alternative Risk Estimates

In our RFC, we noted that substantive objectivity requires that information be presented in an "accurate, reliable, and unbiased" manner, and we observed that EPA did not adhere to this requirement in the reporting of alternative risk estimates (National Association of Manufacturers 2007, pp. 52-53). EPA characterizes some of its risk estimates as "primary" and others as "secondary." This language implies that one set of estimates have a stronger scientific foundation and are more likely to be correct than the other set of estimates. However, nowhere does the Agency use science or statistical method to show that this distinction is grounded in either science or probability.

We said that EPA's "primary" risk estimates were those that most tended to support a policy preference for a more stringent NAAQS, and EPA's "secondary" risk estimates are those that provided less support. This distinction is purely arbitrary. It cannot be characterized as "accurate, clear, complete, and unbiased." Accuracy and clarity require that EPA avoid language suggesting any scientific or statistical foundation for claims that cannot be supported with science or statistics. As an organization, of course, EPA is entitled to prefer more stringent air pollution standards. Nevertheless, information quality guidelines

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[129] EPA also admits that it has a preference for single-pollutant models because, in multi-pollutant models, the coefficients for ozone lose stability. Coefficient instability across model specifications is a common indicator of model specification error (Kennedy 1985). EPA ignores this and characterizes its results as "robust." See the discussion about "robustness" in Section IV.B beginning on page 111.

[130] EPA's inferences are much stronger than these made by the authors: "The less robust influence of NO_2, along with the weak effect of $PM_{2.5}$, is hard[] to interpret. Given the evidence demonstrating a relationship between ambient $PM_{2.5}$ and mortality, a stronger association for he $PM_{2.5}$-ozone association may have been anticipated… Our findings could be related to difficulties in identifying causal factors in a multivariate context, limitations in our ambient pollution data, or might indicate that the use of air pollution regression coefficients in hierarchical linear models is not the optimal approach for evaluating confounding" (Levy et al. 2005, p. 465).

prohibit it from mischaracterizing these policy preferences as scientific, or informed by science, when they are not.

In its Response to Comments, EPA says "NAM's contention that EPA's risk estimates are characterized as 'primary' or 'secondary' in the Staff Paper or proposal notice is incorrect" (U.S. Environmental Protection Agency 2008e, p. 100, emphasis added). In our RFC, however, we said nothing about the Staff Paper or the NPRM. The section in which this complaint appeared concerned EPA's risk assessment. EPA's risk assessment makes a very clear distinction between the staff's "primary" risk estimates…

> [T]he exposure-response functions used in the primary analyses are based on the assumption that the relationship between exposure and response has a logistic form with 90 percent probability and a linear (hockeystick) form with 10 percent probability.

… and its "secondary" risk estimates:

> In this sensitivity analysis, we considered the impact of two alternative exposure-response functions, based on an 80 percent logistic/20 percent linear split and a 50 percent logistic/50 percent linear split, in five locations – Atlanta, Chicago, Houston, Los Angeles, and New York.[131]

Bias in EPA's risk assessment is rather obvious. Its most controversial aspect is the assumption that the extraordinarily weak associations observed in selected epidemiological studies are causal.

The public must look to EPA's Regulatory Impact Analysis – a document that was not completed until after the Administrator made his decision -- to uncover the implications of assuming causality, especially for mortality risk. In the RIA, EPA acknowledges that the value of mortality risk reductions from NAAQS standards has historically comprised 85% to 95% of total estimated health benefits (U.S. Environmental Protection Agency 2008a, p. 6-6). It would be negligent for the Administrator to have ignored that ratio, and of course, the EPA staff risk assessment reasonably led him to believe that these benefits were real.[132]

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[131] EPA (2007c, pp. 3-76 to 73-77).

[132] A common myth surrounding NAAQS rulemakings is that the Administrator cannot use the RIA to inform decision-making. The Clean Air Act prohibits the Administrator from taking account of the cost of achieving the NAAQS, but it does not compel him to also ignore benefits. Indeed, the whole point of regulating air pollution is to generate benefits. According to the RIA, the value in 2020 of assumed mortality

V. Information Quality Errors in the Consideration of Reports from CASAC

In this section of our RFC, we discussed a wide range of information quality errors in EPA's management of peer review by the Clean Air Scientific Advisory Committee (CASAC) (National Association of Manufacturers 2007, pp. 53-58). We noted that CASAC review is complicated by the inherently conflicted mission Congress established for it – to perform both a scientific review (which requires scrupulous attention to facts and data) and policy advice (which is fettered by no such constraints).[133] We said that this conflicted mission requires EPA to be extraordinarily careful in how it listens to CASAC to ensure that it clearly distinguishes between CASAC's scientific insight and its policy prescriptions. We noted that, as an independent body outside of the Agency's control, CASAC is exempt from federal information quality guidelines, but that EPA is not exempt when it disseminates or uses information provided by

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reductions from lowering the primary NAAQS to 0.075 ppm is 23% to 44% of total benefits. Between 50% and 99% of these benefits come from serendipitous reductions in $PM_{2.5}$. See EPA (2008a, p. ES-3).

[133] Clean Air Act, Section 109(d)(2):

> (A) The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.
>
> (B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 108 and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 and subsection (b) of this section.
>
> (C) Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

CASAC. We were pleased to read in EPA's Response to Comments that the Agency agrees wholeheartedly with this synopsis and demarcation of responsibilities (U.S. Environmental Protection Agency 2008e, p. 150).

Where we disagreed with EPA – and continue to disagree – concerns EPA's implementation of this common understanding. We said EPA cannot simply cite CASAC as a scientific authority without regard for whether the contents of statements are scientific and whether scientific statements adhere to applicable information quality standards. In any case where EPA disseminates covered information obtained from CASAC in a manner that a reasonable person would construe as Agency agreement, EPA must ensure that the information satisfies information quality standards. It cannot simply attribute the information to CASAC and assume that it is scientifically objective, or assume that it speaks to science and not policy.[134]

Policy advice provided by CASAC members generally is not subject to information quality principles because it lies outside the boundaries of the definition of *information*. However, EPA must be careful to correctly characterize policy advice it receives from CASAC as policy advice and not, explicitly or implicitly, describe it as science.[135] If it fails to make this distinction, EPA voids the "opinion exemption" in the definition and subjects policy advice to the same level of scrutiny to which scientific information must adhere. Fortunately, this problem is easy to solve, simply by properly distinguishing policy matters from science.

A. CASAC's Scientific Charge

CASAC's primary scientific responsibility is to perform a scientific peer review of EPA's various secondary risk assessment documents, including the Criteria Document and the Staff Paper. CASAC may, and perhaps ought, but is not required to, review the underlying studies cited and summarized in these secondary documents. CASAC is directed to "complete a review of the criteria

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[134] The information quality definition of *information* "does not include opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views (Office of Management and Budget 2002). However, once an agency adopts a third party's scientific statements as its own, then information quality principles apply. "Subsequent agency dissemination of [third-party scientific] information requires that the information adhere to the agency's information quality guidelines" (p. 8454, col. 2).

[135] This is true even if CASAC describes its input as scientific when it is in fact policy advice.

published under section 108" (§109(d)(2)(B)), which requires that air pollution criteria "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities" (§108(a)(2), emphasis added). In short, even though Clean Air Act § 109 preceded the Information Quality Act, CASAC's primary duty is to ensure that EPA's risk assessment is accurate, clear and unbiased. Without violating its statutory assignment, EPA cannot disseminate or use for decision-making a risk assessment that is inaccurate, incomplete, or fails to represent the latest scientific knowledge.[136] The problem facing CASAC is clear: how does the panel perform this scientific responsibility without allowing the infiltration of its members' policy views?

EPA could have made CASAC's job much easier if it had structured its charge around the information quality principles the Agency promulgated in 2002 (U.S. Environmental Protection Agency 2002) and elaborated upon in 2003 (U.S. Environmental Protection Agency 2003). Unfortunately, EPA instead decided to exclude from the charge to CASAC all information quality content. Nowhere in the charge did EPA discuss the crucial information quality concepts of *utility* and *objectivity*. Nowhere did it reference the Agency's own foundational information quality documents. CASAC can be forgiven for knowing nothing about information quality, because EPA apparently worked hard to keep its members in the dark.

In its Response to Comments, EPA acknowledges our complaint about the absence of information quality content from the CASAC charge, then proceeds to obfuscate the matter with statements that are irrelevant or literally fantastic (U.S. Environmental Protection Agency 2008e, p. 150). Irrelevancies include CASAC's separate status,[137] which has nothing to do with EPA's charge to CASAC; and the fact that CASAC's policy recommendations are exempt from information

[136] § 109(d)(2)(C) gives CASAC an important secondary scientific charge related to research needs ("areas in which additional knowledge is required"), disaggregate natural from anthropogenic contributions to ambient air pollution, and the quantification of substitution risks ("any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance").

[137] "CASAC is a separate entity from EPA and, as such, assesses scientific and other documents produced by EPA independently of Agency oversight."

quality,[138] something no one disputes. EPA claims to have incorporated information quality throughout its Action Development Process (ADP),[139] a claim that cannot be tested because the primary guidance document is hidden on the Agency's Intranet where it cannot be publicly examined.[140] Looking elsewhere for evidence, we note that in 2006 EPA publicly disseminated an ADP guidance document for children's health, and this document is silent about information quality (U.S. Environmental Protection Agency 2006d).

By far the most fantastic element in EPA's reply is its claim that the Agency has no responsibility to actually perform pre-dissemination review just because it had promised to do so:

> EPA's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated [sic] does not require the Agency to discuss, separately, whether the pre-dissemination review actually occurred (U.S. Environmental Protection Agency 2008e, p. 150).[141]

B. CASAC's Policy Advice Charge

CASAC's review of the EPA Staff Paper is necessarily different, for the Staff Paper contains a complex mix of science and policy recommendations from Agency staff. In principle, the design of the Staff Paper should make it relatively easy for CASAC to maintain a clear distinction between its scientific review and

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[138] "EPA cannot subject CASAC recommendations to information quality standards."

[139] "The [Information Quality] Guidelines, rather, provide a process for developing quality actions, of which the pre-dissemination review procedures are a part. This process is also a part of EPA's Action Development Process (ADP). EPA's ADP is a mechanism that assists the Agency in achieving the objectivity and transparency of information used in developing regulations."

[140] Environmental Protection Agency, "EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions," June 2004; http://intranet.epa.gov.adplibrary/index.htm.

[141] An unknown office within EPA issued pre-dissemination review guidelines in September 2006 (U.S. Environmental Protection Agency Office of Environmental Information 2006) and made them publicly available (http://www.epa.gov/region2/science/qmp/pdfs/pdr-guidelines.pdf). The text of these guidelines makes abundantly clear, however, that they were issued because program offices such as the Office of Air and Radiation and staff offices like the Office of Research and Development had failed to implement the pre-dissemination review requirements in the Agency's Information Quality Guidelines.

policy advocacy roles.[142] CASAC does not seem to have adhered to that principle; it is difficult to discern where it is commenting on science and opining about policy. To take just one obvious example mentioned in our RFC (p. 56), the list of bullets in its letter review of the Staff Paper contains both scientific comments and policy advice, often within the same bullet (Clean Air Scientific Advisory Committee 2006a, pp. 2-3).[143]

We noted in our RFC that CASAC's members are of course expected to provide the Administrator with their policy advice concerning how he ought to exercise his statutory discretion in revising or retaining the NAAQS. Because their principal charge is scientific, however, the public might reasonably expect CASAC members to limit their advice to matters of a strictly scientific nature, as befitting their technical expertise. However, the law does not limit CASAC to advising on matters of science, nor does it constrain them from providing pure policy advice reflecting their personal values and preferences.

The law invites CASAC to provide policy advice several ways. First, it specifies that one member of the committee must "represent[] State air pollution control agencies" (§109(d)(2)(A)). Like EPA, these agencies are regulatory rather than scientific in nature, function, or organization, and they are populated with personnel who quite reasonably share their agency's (and EPA's) air pollution control mission. Furthermore, the act of representation is inherently a stakeholder role, not a scientific one. When a person "representing" State air pollution control agencies gives advice, it is presumed that this advice will favor intensifying the stringency of federal air pollution standards if that is what the

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[142] Chapters 2, 4, and 5 should be strictly scientific. Chapters 3, 6, 7, and 8 are a blend of science and policy (U.S. Environmental Protection Agency 2007g).

[143] In its Response to Comments, EPA says:

> In this rulemaking, EPA is confident that it has been able to clearly differentiate CASAC's science advice from the policy advice on the appropriateness of new or revised NAAQS. NAM has not identified examples where it believes EPA has failed to so differentiate, nor examples where CASAC has improperly mixed science and policy in providing its advice." (U.S. Environmental Protection Agency 2008e, p. 149).

It is indisputable that CASAC mixed science and policy, so EPA must be saying that it was not "improper" for CASAC to do so. If that is so, then EPA also convicts itself of failing to differentiate science from policy in its use of input from CASAC.

governing authorities in that State prefer. It would be newsworthy only if this person recommended against more stringent federal standards.[144]

CASAC members also are asked to "recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate"(§ 109(d)(2)(B)). In short, they are invited to speculate as to how they think they would exercise the Administrator's statutory discretion if they were standing in his shoes. Despite the fact that CASAC members have scientific training and have distinguished themselves in one or more scientific fields, there is nothing scientific about giving policy advice.

The provision of policy advice by scientists is further confounded by two other phenomena, one that applies to scientists in general and one that applies specifically to this panel. The general fact is that all scientists are susceptible to the temptation to believe that their status as scientists endows them with special insights about public policy. Some scientists don't care about policy, but they are the least likely to be recruited to serve on panels such as CASAC or be interested in doing so. CASAC members work long hours for token financial compensation;[145] the ability to influence public policy is their primary reward.

The phenomenon that is specific to this panel is that many of them are authors of research papers in the scientific database on ozone. It is entirely natural for them to think that their own research is most relevant to the questions at hand.[146] This raises a serious question: Are CASAC members being asked to indirectly review their own work? This practice is permitted under the National Academy of Sciences' conflict of interest rules, but with an important limitation that, if it had been rigorously applied to CASAC, probably would have required many of them to be recused:

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[144] EPA selected as a State representative an official from Vermont. Among other things, Vermont has been a party to litigation against EPA advocating more stringent air pollution standards. The Administrator would have received completely different policy advice if he had appointed an official from a State whose elected leadership opposed more stringent air pollution standards. The act of selecting the statutorily-required State representative determines the content of "State" stakeholder input.

[145] See footnote 86 for an interesting exception in which a CASAC ozone panel member reveals having devoted about 12 hours per year to the review task.

[146] Some CASAC members are especially fond of their own work. CASAC's letter review of EPA's final draft Staff Paper cites for special emphasis six peer reviewed papers authored or co-authored by CASAC members Drs. Morton Lippman and/or Frank Speizer, all published between 1988 and 1993 (i.e., prior to the 1997 NAAQS review).

> [A]n individual should not serve as a member of a committee with respect to an activity in which a critical review and evaluation of the individual's own work (The National Academies 2003, p. 5 , document not paginated).

We noted previously that at least one crucial study for EPA's health risk assessment was co-authored by a CASAC ozone panel member.[147]

C. EPA Does Not Adequately Distinguish Between Scientific Insight and Policy Advice It Received from CASAC

The NPRM contains numerous subsections in which the input it received from CASAC is summarized. In our RFC, we noted that in some places this input is clearly described as scientific information or policy advice. In most instances, however, the line between science and policy is difficult to discern. We appreciate EPA's challenge because in many cases – particularly in its review of the Staff Paper -- CASAC itself did not make these distinctions clear. Nevertheless, adherence to information quality guidelines is EPA's responsibility and not that of CASAC. EPA's decision to shield CASAC from information quality principles and standards in its charge does not alleviate the Agency's responsibility.

D. EPA's Lack of Pre-Dissemination Review

To minimize the number of error correction requests they receive, agencies are required by OMB's government-wide information quality guidelines to establish effective procedures for pre-dissemination review:

> As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information (Office of Management and Budget 2002, p. 8459, emphasis added).

OMB's use of the imperative "shall" signifies that these requirements are not optional or merely suggestive, but rather they are mandatory. This is entirely consistent with Information Quality Act, which gave OMB similarly imperative language to implement in its government-wide guidelines, to which EPA and its guidelines are subordinate (Information Quality Act 2000).

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[147] See footnote 108

EPA's own guidelines commit the Agency to obey the directives of statute and OMB's government-wide guidelines for the establishment and implementation of sufficient pre-dissemination review procedures to ensure that information quality error is rare:

> Each EPA Program Office and Region will incorporate the information quality principles outlined in section 6 of these Guidelines into their existing pre-dissemination review procedures as appropriate (U.S. Environmental Protection Agency 2002, p. 29, emphasis added).

EPA's now-acknowledged failure to actually perform pre-dissemination review, combined with its steadfast claim it doesn't actually have to do so despite this commitment, implies that the Agency thinks both pre-dissemination review and compliance with the Information Quality Act is not "appropriate." If EPA really believes that it should be exempt from the principles of information quality because those principles are not "appropriate" for the scientific information supporting the ozone NAAQS, the Agency should say so transparently and explain its reasoning.[148]

VI. Information Quality Errors in the Rollback Assumption

In our RFC, we objected on information quality grounds to EPA's rollback assumption (National Association of Manufacturers 2007, pp. 58-60). EPA's approach violated information quality standards by failing to approximate how the States actually would respond to a lower NAAQS. This is relevant for estimating the incidence of various health effects avoided. In particular, EPA's model assumes that compliance with a lower NAAQS will result in reductions not just at the peaks, where a determination of attainment is made, but also throughout the entire distribution. We suggested that EPA validate its model by testing it against actual data from State implementation of the 1997 NAAQS. We also expressed concern that reductions at the low end of the distribution were

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[148] The dearth of pre-dissemination review is particularly notable for the one instance in which information quality principle of *objectivity* appears in the NPRM: EPA's summary of public comments saying that EPA had not examined "the evidence for both adverse and beneficial effects [of tropospheric ozone from UV-B shielding] with the same objectivity" (U.S. Environmental Protection Agency 2007h, p. 37881). In the Staff Paper and RIA, EPA's argument for failing to account for UV-B shielding is that "this beneficial effect of [UV-B] radiation has not previously been studied in sufficient detail" (U.S. Environmental Protection Agency 2008a, p. 6-21). This issue was first raised before the 1997 ozone NAAQS was issued (Lutter and Wolz 1997) and it became a central element of litigation. Since then, EPA has steadfastly refused to account for UV-B because it is incompatible with the Envelope Theory.

particularly problematic given both the uncertainty about true background and EPA's controversially low values for Policy Relevant Background (PRB). EPA may be crediting its new ozone NAAQS with reducing background ozone concentrations.

In its Response to Comments, EPA "concluded" that its model "generally best represented the pattern of reductions across the O_3 air quality distribution observed over an 8-year period in areas implementing control programs designed to attain the O_3 NAAQS" (U.S. Environmental Protection Agency 2008e, p. 90). Furthermore, EPA says "only reducing peak 8-hour daily maximum values that are at or near the standard level is unrealistic in that most O_3-related air pollution control measures are continuous in nature and have an impact on the entire distribution of 8-hour O_3 concentrations"

VII. Information Quality Errors in the Description of Policy Relevant Background

In the Staff Paper, EPA defines Policy Relevant Background (PRB) in a way that makes it ambiguous as to whether it is a scientific estimation or a policy-driven default assumption:

> For purposes of this document, background or policy relevant background (PRB) O_3 is defined as the distribution of O_3 concentrations that would be observed in the U.S. in the absence of anthropogenic (man-made) emissions of precursor emissions (e.g., VOC, NO_x, and CO) in the U.S., Canada, and Mexico (U.S. Environmental Protection Agency 2007g, p. 2-47).

Despite the word "policy," in the title of the concept, *PRB* is a strictly scientific concept. That is, PRB should be defined as the level of ozone that would be present if all controllable anthropogenic U.S. sources did not exist.[149] EPA's PRB is unambiguously biased both by definition and in implementation.

A. EPA's *Definition* of Policy Relevant Background is Biased

As we noted in our RFC, EPA's PRB is biased because it assumes that ozone precursors from anthropogenic sources in Canada and Mexico are subject to control by U.S. air pollution policy and regulation (National Association of Manufacturers 2007, p. 60). This assumption is false. By treating these emissions as if they were controllable by State Implementation Plans, EPA understates the level of ozone that would exist if all U.S. anthropogenic sources were "turned

[149] The prefatory clause should be discarded, for this definition applies not just in the Staff Paper but throughout the package of documents.

off." This yields upwardly biased estimates of baseline risk and risk reduction from lowering the NAAQS.

In its Response to Comments and the preamble to the Final Rule, EPA asserts, in virtually identical language, that the Agency has the capacity to "influence" emissions from Canada and Mexico; that this capacity to "influence" arises from its ability to negotiate international agreements with Canada and Mexico; and that Canadian and Mexican emissions must be assumed to be controllable by EPA because EPA has defined PRB this way "over more than two decades" (U.S. Environmental Protection Agency 2008b, p. 16468; 2008e, p. 93). The first two of these arguments demonstrates that what should have been a scientifically defined quantity is purposefully biased by EPA staff, in violation of information quality principles. The EPA staff definition is not scientific but policy-driven; it deflates the estimated level of background ozone, inflates the amount of ozone reduction that in principle could be achieved by lowering the ozone NAAQS, and therefore inflates estimated reductions in risk.

The third argument is an appeal to tradition: EPA has erred for more than 20 years, and errors committed over that long a period ought to be exempt from information quality principles. Of course, nothing in the Information Quality Act or any of the relevant implementation guidance documents exempts information that is inaccurate or biased just because it has been used before, or for a long time. The only test for applicability is met if EPA is currently disseminating the information. That test is clearly satisfied. Moreover, though our RFC we have invoked the statutorily prescribed process for correcting information quality error. It is illegal for EPA to decline to correct error because it has a history of committing similar errors and correcting the error now is inconvenient.[150]

A closer look at the history of the 1997 ozone NAAQS review shows that EPA also was not transparent about the exclusion of Canadian and Mexican emissions from the definition of PRB. A search of the 1996 Criteria Document, the 1997 Staff Paper, the 1996 NPRM and the 1997 final rule preambles reveals no discussion whatsoever on this point. In that review, EPA stated that background was assumed to be 0.04 ppm (U.S. Environmental Protection Agency 1996b, p. 65726), and there does not seem to have been much controversy over the point. If

[150] The NPRM did not disclose to the public this important aspect of EPA's definition of Policy Relevant Background. That alone was a violation of the presentational objectivity standard. We have noticed that EPA has rectified this error in the final rule by explaining that precursor emissions from Canada and Mexico are not included in PRB because EPA assumes that its regulatory actions can and will target them (U.S. Environmental Protection Agency 2008b, p. 16433, footnote 13).

in fact EPA has for more than 20 years counted Canadian and Mexican emissions as controllable by Agency action, then these prior actions also were biased and violated information quality guidelines.

CASAC appears to have accepted this policy-driven assumption at the outset because EPA staff built it into CASAC's charge, thereby removing it from the scope of the panel's scientific – and policy -- review:

> 1. Policy Relevant Background (PRB) Ozone. PRB ozone concentrations will ultimately be taken into account by OAQPS in analyses to be included in the Ozone Staff Paper that attempt to estimate risks to human health and environmental effects associated with exposures to ozone concentrations attributable to anthropogenic sources of precursors emitted in the United States, Canada and Mexico (i.e., to ozone levels above PRB concentrations). The estimation of PRB ozone concentrations precludes the use of observational data alone because of substantial production and transport from anthropogenic sources in the United States and bordering countries. Contributions to PRB ozone arise from intrusions of stratospheric ozone, biogenic and other natural sources of ozone precursors, and anthropogenic sources outside of the U.S., Canada and Mexico. The modeling approach that has been adopted for estimation of PRB concentrations is based on peer reviewed journal articles describing the GEOS-CHEM model, its evaluation and application to the calculation of PRB ozone values. See Henderson (2005a, pp. B-1 to B-2, emphasis added).[151]

Still, CASAC ultimately distanced itself from the EPA staff's policy-driven approach:

> [W]ith respect to policy-relevant background (PRB), the Ozone Panel wishes to point out that the Final Ozone Staff Paper does not provide a sufficient base of evidence from the peer-reviewed literature to suggest that the current approach to determining a PRB is the best method to make this estimation. One reason is that part of the PRB is not controllable by EPA. It would require international cooperation beyond the bounds of North America. A better scientific understanding of the PRB and its

[151] Note also that the charge also precludes CASAC review of the merits of observational data. EPA staff faced some resistance on this point; see, e.g., the comments by CASAC panel member Barbara Zielinska (Henderson 2005a, p. C-133). For CASAC as a group to have objected, however, they would have had to decide to overrule their charge – an unlikely and highly controversial act.

> relationship to intercontinental transport of air pollutants could serve as the basis for a more concerted effort to control its growth and preserve the gains in air quality achieved by control efforts within the U.S.[152]

The NPRM acknowledges that CASAC was disturbed by other technical aspects of EPA's model for estimating PRB and, in a footnote, committed to reopen the matter:

> Recognizing the importance of this issue, EPA intends to conduct additional sensitivity analyses related to policy-relevant background and its implications for the risk assessment (U.S. Environmental Protection Agency 2007h, p. 37857, footnote 40).

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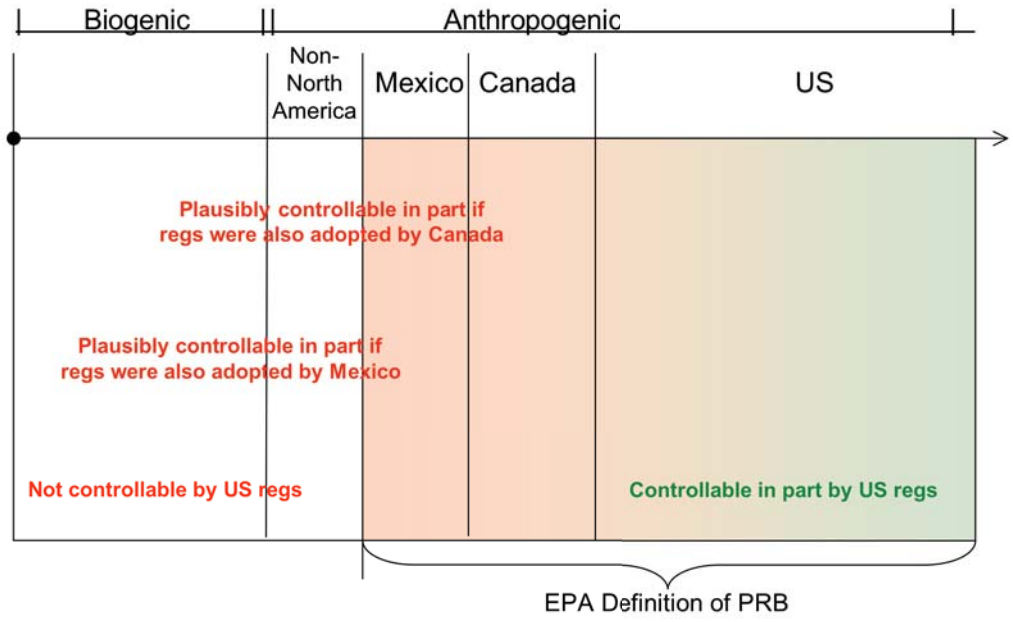
[152] Henderson (2007a, pp. 2-3, emphasis added, internal citations omitted). We have omitted the remainder of the paragraph (reprinted verbatim below) because it is not germane to the issue of whether Canadian and Mexican emissions of ozone precursors belong in background:

> In any case, there is no apparent need to define PRP [sic] in the context of establishing a health-based (primary) ozone NAAQS. The effects of inhaled ozone on decreases in respiratory function have been seen in healthy children exposed to ozone within ambient air mixtures in summer camps. Furthermore, the concentration-response functions above 40 ppb are either linear, or indistinguishable from linear. Thus, PRB is irrelevant to the discussion of where along the concentration-response function a NAAQS with an 8-hour averaging time that provides enhanced public health protection should be.

Figure C: Policy Relevant Background and Rollback:Which Emissions Belong? Which Can Be Controlled?



During the interregnum between proposal and final, however, EPA seems to have abandoned its intent to conduct additional sensitivity analysis. To allay legitimate concerns that what EPA "intends" to do is bury this issue until the next ozone NAAQS review, EPA must, at a minimum, publicly disclose the contribution of Canadian and Mexican precursor emissions, show what effects including them in PRB has with respect to risks and benefits, and inform the public concerning what impacts this will have on affected States' efforts to achieve attainment.

In our RFC, we illustrated the combined effect of these two critical assumptions (see Figure C reprinted below). Ozone emissions were scaled on the horizontal axis and divided into biogenic and anthropogenic sources, with the latter category further subdivided into U.S., Canada, Mexico, and non-North American sources. The distances between the vertical boundaries were arbitrary. EPA's Policy Relevant Background (PRB) is shown by the transparent rectangle that ranges from green on the right to red on the left. The colors are selected to represent the feasibility of control. The left side is red for two reasons. First, EPA has no jurisdiction over anthropogenic emissions from Canada and Mexico. Its ability to affect those emissions depends on either those sovereign nations deciding to implement all or part of EPA's standard, or States (especially those

on the borders) states obtaining external emission reductions where that is cost-effective.

B. EPA's *Estimates* of the Magnitude of Policy Relevant Background Are Biased

In our RFC, we objected to EPA's estimates of PRB because they are biased by design (see Section A above), and because they are based on modeling that appears not to have been validated (National Association of Manufacturers 2007, p. 61). Other public commenters have raised concerns about the lack of spatial and dynamic resolution in EPA staff's modeling approach (Brauer et al. 2007; Smith and Gibbs 2007). Limited resolution is not *per se* an information quality defect. Nevertheless, it appears to be undisputed that the public health significance of any choice of primary ozone standard depends crucially on how PRB is modeled or estimated, and that makes the estimation or modeling of PRB an information quality issue of paramount concern and relevance.

Smith and Gibbs performed a sensitivity analysis to determine how health risk estimates differ depending on the choice of PRB. They report that EPA's health risk estimates "would typically be 90% to 100% lower" if 0.04 ppm had been used as PRB instead (Smith and Gibbs 2007, p. 16). They also attempted to validate EPA's modeling results by comparing them to data from Trinidad Head CA, and found that if these observational data had been used as background, health risk estimates would be 65% lower in Sacramento and 72% lower in Los Angeles. They did not find any city in which EPA's new approach to PRB resulted in a lower risk estimate.

In its Response to Comments, EPA dismisses these information quality concerns on the ground that they "were considered by EPA's scientific staff and the CASAC Panel during the course of reviewing the Criteria Document" (U.S. Environmental Protection Agency 2008e, p, 94, emphasis added) – a boilerplate reply. Having "considered" an information quality error and done nothing about it is not compatible with EPA's obligations under the Agency's Information Quality Guidelines, nor can EPA hide behind a peer review in which information quality principles, policies and procedures played no role.

EPA implies that the selection of the PRB is a matter of policy discretion, but the Agency defines the PRB in scientific terms. EPA has the statutory discretion to decide how much protection from health effects should be provided, but it does not have the authority to alter scientific principles and concepts in the service of these policy objectives."

VIII. Conclusion

We identified a large number of information quality errors in our RFC. In its Response to Comments, EPA dismisses virtually all of them, often without bothering to provide either as logical or evidentiary basis. In many case, EPA's Response to Comments mischaracterizes our complaint and responds only to its own mischaracterization. Sometimes, EPA describes the information quality complaint correctly but "answers" it by discussing irrelevant or unrelated matters. Finally, the general tone of EPA's Response to Comments is one of opinion – that is, EPA "disagrees" with or "rejects" our information quality complaints as if they are matters of opinion rather than knowledge or fact. In this broad sense, EPA's Response to Comments fails to fulfill the Agency's duty under information quality guidelines to fairly and objectively address challenges to its representations of knowledge or fact. EPA apparently seeks to evade the discipline of information quality principles by erroneously characterizing all disputes as matters of opinion.

It has been said that the absence of evidence is not the same as evidence of absence. That adage does not hold sway in this case, however. The absence of evidence of information quality principles in every EPA staff work product; the absence of any pre-dissemination review; the absence of information quality from the EPA staff's charge to CASAC, and its corresponding absence from CASAC's review; and the absence of information quality principles and analysis in the preambles to both the NPRM and final rule, make clear beyond any reasonable doubt that EPA staff did not comply with the Agency's information quality principles and guidelines at any time since the ozone review began in 2005.

By law, the EPA Administrator has sole discretion to make crucial policy judgments concerning the ozone NAAQS. It is beyond the role and authority of Agency scientists and program managers to exercise this judgment on his behalf. For the Administrator to legally exercise his statutory authority, the Clean Air Act requires that the scientific information presented to him "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities" (§108(a)(2)). These requirements foreshadowed the enactment of the Information Quality Act, which directed the establishment of government-wide criteria for information quality. These criteria are consistent with the directives in Clean Air Act § 108. Nothing in that section, or in § 109, authorizes the Administrator to set air quality standards based on scientific information that is inaccurate, and failure to adhere to information quality principles prevents the EPA staff from producing the accurate scientific record that the Clean Air Act requires.

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Attachment 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 15 2009

OFFICE OF
AIR AND RADIATION

Bryan L. Brendle
Director, Energy and Resources Policy
The National Association of Manufacturers
1331 Pennsylvania Avenue, NW
Suite 600
Washington, D.C. 20004

Dear Mr. Brendle:

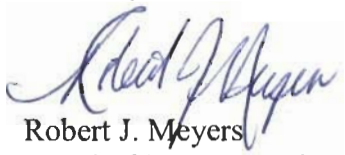
On October 16, 2008, you submitted a Request for Reconsideration (RFR) under the U.S. Environmental Protection Agency Information Quality Guidelines (EPA IQG) on behalf of the National Association of Manufacturers (NAM). In this request, you asked EPA to reconsider its decision on the NAM Request for Correction (RFC 08001). In the EPA letter dated January 1, 2008, the Agency communicated its decision to treat the NAM RFC as a public comment on the Notice of Proposed Rulemaking for the National Ambient Air Quality Standards (NAAQS) for ozone. Your October 16, 2008, request does not ask EPA to reconsider that decision. Rather, you request that the Agency provide more "cogent answers" than EPA provided in the final Response to Comments document included in the docket for the NAAQS for ozone.

As you know, the ozone NAAQS Rule that is the subject of your IQG request has been challenged in the U.S. Court of Appeals for the District of Columbia Circuit. The Ozone NAAQS Litigation Group, of which NAM is a member, is one of the petitioners challenging this rule. Since the issues raised in your RFR may be related to the on-going litigation, EPA is deferring consideration of your request at this time.

However, if at the conclusion of the litigation your data quality concerns have not been addressed, you may resubmit this request. If you choose to submit an RFR, please send your written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Processing Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Ave., N.W., Washington, D.C. 20460) ; electronic mail epa.gov); or fax (202-565-2441). Additional information about how to submit an RFR is listed on the EPA IQG Web Site (www.epa.gov/quality/informationguidelines).

Thank you for your interest in EPA's information quality.

Sincerely,



Robert J. Meyers
Principal Deputy Assistant Administrator