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US Environmental Protection Agency  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

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**Written Comments of John Bachmann on behalf of the Environmental Protection Network.**

**To:** EPA Acting Administrator Andrew Wheeler and the Clean Air Scientific Advisory Committee (CASAC):

Thank you to CASAC and EPA for the opportunity to provide these written comments at this point in the review of the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM). I am representing the Environmental Protection Network (EPN), a volunteer organization of former EPA employees and others concerned about continuing protection of public health and the environment. I worked for EPA's Air Office for 33 years, many of them as Associate Director for Science/Policy and New Programs. I was heavily involved in all reviews of the PM NAAQS through 2006.

I am commenting mainly because EPN is concerned that the preemptive changes EPA has made to the NAAQS review process will undermine the quality and credibility of the NAAQS review process, and could lead ultimately to ill informed decisions that might adversely affect the public health and environmental protections that have been the hallmark of science-based air quality standards. The contribution of CASAC to the NAAQS review process is too important to short change, yet the unilateral changes made by EPA do so by eliminating the critical expertise and perspectives of the PM panel, as well as by imposing other unreasonable shortcuts to accelerate the review schedule. EPN also supports EPA's continued use of the core elements of the formal causal framework, which was developed with strong support of past CASAC panels over the last decade.

EPN's main points include:

1. *EPN strongly supports the recommendations of former CASAC and PM panel members, as well as concerns expressed by several current CASAC members, that the committee should recommend the reinstatement of a PM panel for this review.* No seven-member panel, including the current one, has the expertise or the breadth of perspectives of a CASAC supplemented by a panel of experts. All prior CASAC PM reviews, indeed every NAAQS review for which we have data, were supplemented by additional qualified scientific experts. Yet three CASAC members have been tasked with peer reviewing nine chapters covering a multiplicity of health-related scientific disciplines and totaling over 1200 pages of text, all in less than two months.

2. *EPN continues to strongly support its earlier recommendations that EPA should provide the time - as well as the expertise - needed to complete the PM and ozone reviews.* EPA's rush to complete both reviews is not driven by deadline suits or a concern about the five-year schedule.<sup>1</sup> The end goal of late 2020 first appeared in a May 2018 Pruitt memo on the NAAQS process, which was issued without first consulting with CASAC. As noted by former CASAC chair Chris Frey, based on past reviews, it would be very difficult even for a CASAC supplemented by a full expert panel to complete the needed reviews in that time.<sup>2</sup> Meeting the current accelerated schedule necessitates a less than rigorous peer review of all three major documents. It would provide no chance for CASAC to review second drafts, again contrary to CASAC's past practice in its review of the PM and other NAAQS.<sup>3</sup> The requirement that the Policy Assessment (PA) must be combined with and reviewed at the same time as the Risk and Exposure Assessment (REA) puts the cart before the horse, because the PA relies in part on the REA. In addition, the new open ended charge for CASAC to advise EPA on the health effects of implementing standards risks an impermissible inclusion of economic considerations by a group charged with making recommendations on standards. Moreover, EPA has no plans for providing a staff assessment on the topic for the committee to review.
  
3. *EPN supports EPA's continued use of core elements of the formal Framework for Causal Determinations contained in the separate Preamble to the ISA, and its application in the draft PM ISA.* This approach has been updated and improved over the last decade, in each case with the advice and support of multiple CASAC panels involving all criteria pollutants. This framework is a fundamental basis for the integration of multiple scientific disciplines in assessing the likelihood that PM "causes or contributes" to "adverse effects." The framework is not limited to a single discipline or branch of epidemiology. EPN supports air-related "accountability" studies and causal inference research as a component to be considered in the existing causal framework. However, the draft ISA search has found a very limited number of such studies for PM, some of which support a causal relationship and at least one that does not. As detailed below, investigators who have used causal inference and other experts on the issue recognize it as a useful approach for air pollution epidemiology, but one that has not yet delivered on its potential. It simply is not consistent with the judgement of the most recent CASAC reviews or the current state of the science to suggest that the core approach in the Framework for Causal Determinations and doing risk assessments that include reliance on past epidemiology studies should no longer be used in regulatory decision making.

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<sup>1</sup> If EPA's main concern was to meet the requirement for a five-year cycle for NAAQS reviews, it would have put the carbon monoxide review first, as it is the most out of date.

<sup>2</sup>H.C. Frey; Public Comment on the Integrated Review Plan for the Ozone NAAQS. Public written statement to CASAC, November 26, 2018.

<sup>3</sup> One of the casualties of a single ISA review is the ability to add any significant new studies relevant to standard setting in a second draft. This is particularly problematic for this review, because it appears the draft ISA has no studies published since 2017, and important new studies of interest have appeared since or are expected soon.

The following sections provide additional details on issues with the dissolution of the CASAC PM Panel, the compromises in the NAAQS review process and comments on causality. They are consistent with the EPN recommendations, but reflect my personal assessment of the information.

### *The need to reinstate the PM Panel.*

CASAC has had a central role in the review of the NAAQS since 1978.<sup>4</sup> The committee is charged with 1) ensuring the quality of EPA's assessment of the scientific criteria, including how PM and other criteria pollutants may cause or contribute to adverse effects on public health, 2) peer reviewing the agency's staff risk and policy assessments, and 3) based on these assessments, recommending whether the existing standards should be revised, and if so, recommending a range of standards (indicator, level, averaging time, form) that the Administrator should consider in deciding on standards that are requisite to protect public health. The importance of CASAC recommendations in the process is illustrated in the judicial review of the 2006 PM<sub>2.5</sub> annual standard. In that case, the court ordered that the standard be remanded to EPA because the Administrator had not adequately explained his reasoning for deviating from CASAC's recommendations to increase the protection of public health afforded by the annual standard.<sup>5</sup>

From the very beginning of CASAC reviews in 1978, the committee and EPA recognized that seven members would not be enough to conduct the peer review of scientific criteria and staff policy documents (originally called staff papers). They supplemented the main committee with consultants, and eventually it was termed a CASAC panel. The original group reviewing the PM and Sulfur Oxides criteria document, for which there were many fewer studies than exist today, totaled between 17 and 18, including 6 CASAC members. Dr. Frey's compilation from the CASAC web site ([www.epa.gov/casac](http://www.epa.gov/casac)) shows the number of PM panel members grew to address the continuing expansion in of PM related research that began in the early 1990s, from 21 in the 1994-1996 review to the now disbanded 2016-2018 panel, which had 26 members.

As noted above, the last 40 years has made it clear that no seven-member panel, including the current one, has the depth of expertise or the breadth of perspectives of a CASAC supplemented by a panel of experts. The current CASAC has experts in toxicology, controlled human exposures, and statistics/risk assessment, but no epidemiologists, a discipline that has always been central to the review of PM standards. The disbanded CASAC PM panel has *more experts with experience in epidemiology research than the total number of current CASAC members*. Clearly, each of the current CASAC members has the qualifications to serve on CASAC. Yet as a group, their capabilities, expertise and perspectives are greatly limited

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<sup>4</sup>Bachmann, J.D. 2007. Critical Review: Will the circle be unbroken: A history of the U.S. national ambient air quality standards. *J. Air Waste Manag. Assoc.* 57(6):652–697. doi:10.3155/1047-3289.57.6.650

<sup>5</sup> *American Farm Bureau Federation v. EPA*, 559 F. 3d 512, 521 (D.C. Cir. 2009)

compared to what would have been the case with the PM panel. While the Clean Air Act requires that the perspective of state agencies be part of the process by requiring one state member, having over half of the panel reflecting that regulatory perspective lacks balance. Most notably, it limits the inclusion of scientists actively working on relevant peer reviewed research. Again, reinstating the PM panel would increase the range of perspectives and broaden the discussion and debate over interpreting the science to provide sound, well vetted science/policy advice to the Administrator.

It stretches the imagination to understand what moved EPA to cripple the capabilities of the CASAC and the NAAQS review in such a dramatic way. I first learned of this possibility in a meeting last June with air Assistant Administrator Bill Wehrum, who graciously invited me to a session to hear my concerns with the “Back to Basics” NAAQS process outlined in a May 9<sup>th</sup> Pruitt memo.<sup>6</sup> There, he noted that the law only requires seven members.<sup>7</sup> I was surprised this was even a consideration given the overriding requirements of the Clean Air Act with respect to assessing the scientific information and reviewing the standards. This requires a “thorough” and “accurate” review, as required by sections 108 (a) (2) and 109 (d) of the Act. I pointed out why every NAAQS review since CASAC came into being, particularly those for PM and ozone, required larger numbers of expert consultants and why it would seriously degrade the quality of the review to exclude them. As outlined more fully in an attachment discussed below, I had already recommended that he meet with the chartered CASAC to discuss the changes in the NAAQS process, and I understood that the air office planned to discuss these process issues with CASAC. It is now clear there was no EPA consultation with the chartered CASAC Committee last summer before implementing these dramatic shifts, including eliminating the PM and ozone panels.

The failure to consult with CASAC members experienced with the process and the decision to eliminate the panels are unfair to the current CASAC members, who now are burdened with reviewing thousands of pages of ISA materials, while lacking both numbers to spread the burden as well as expertise in epidemiology, effects on visibility and climate, economics, and some other relevant disciplines. At least three current CASAC members expressed a desire to add more expertise to the review at the November meeting on ozone. It is also unfair to EPA staff, who are expected to deliver an ISA of such quality that it could achieve closure by CASAC after only a single review. This has rarely, if ever, been possible. EPA management is establishing unreasonable goals with inadequate resources, and it is both the quality of the review and the credibility of the process that will suffer.

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<sup>6</sup> “Back-to-Basics Process for Reviewing National Ambient Air Quality Standards.” Memorandum from E. Scott Pruitt, EPA Administrator, to EPA Assistant Administrators, May 9, 2018. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>.

<sup>7</sup> While seven members is the minimum required by the Act, neither the law nor the CASAC charter precludes the use of additional consultants to fill gaps in expertise needed to review criteria and standards for particular NAAQS pollutants. Moreover, using only seven members risks violating provisions in the law for a thorough review of the scientific evidence.

### *The need to provide sufficient time for a quality review*

I am attaching a copy of a letter sent to Bill Wehrum last June together with my detailed comments on the problems I found with the streamlined process for NAAQS review in the memorandum from Administrator Pruitt. I copied the members of the chartered CASAC on that letter. I certainly support steps to shorten the process, while maintaining the quality of the review, and made some suggestions in that regard. I commend these attachments to your attention. It is unfortunate that the agency never provided CASAC or the public a forum for discussing these issues over the last six months, as some of the issues might have been more favorably resolved before now. Indeed, consulting with CASAC was the first step in the process for shortening and improving the NAAQS review that began in 2006, which ultimately resulted in a more structured integrated assessment in the ISA, as well as adding separate REA and PAs that focused on science/policy issues.

CASAC is now in the process of reviewing the draft PM ISA. It is certain that the committee, though short-handed, is taking its job seriously, and will have many substantive comments. Yet the committee should take the time to consider seriously the issue raised by many commenters, including some current and many past CASAC members, that the dissolution of the PM panel was a mistake and that the current CASAC review should be supplemented by reviews from additional experts. Further, the committee may also find some revisions to the document are substantial enough that a second review should be required for those sections. Moreover, the ISA appears to be missing potentially important new studies published since 2017 or expected to appear soon.<sup>8</sup> Given these issues, the committee should not feel constrained by EPA's arbitrary deadlines that assume only a single review by a committee of seven. Unfortunately, this is CASAC's first and possibly only chance to weigh in on the recent changes to the process of this review that depart significantly from the original schedules and plans in the PM IRP that was reviewed and approved by CASAC in August 2016.<sup>9</sup>

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<sup>8</sup> Examples include a meta-analysis of 53 cohort studies (Vodanos A, Awad YA, Schwartz J. The concentration-response between long-term PM exposure and mortality: a meta-regression approach. *Environ Res* 2018;166:677-689) and the Phase I HEI studies of low levels of exposure to PM that HEI indicated in their Dec 5, 2018 comments would be available by April.

<sup>9</sup> Diez Roux, A. CASAC Review of the EPA's *Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016)*. CASAC Report EPA-CASAC-16-003. [https://yosemite.epa.gov/sab/sabproduct.nsf/368203f97a15308a852574ba005bbd01/9920C7E70022CCF98525802000702022/\\$File/EPA-CASAC+2016-003+unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/368203f97a15308a852574ba005bbd01/9920C7E70022CCF98525802000702022/$File/EPA-CASAC+2016-003+unsigned.pdf)

I wish to highlight two structural issues in the process noted above and discussed in some detail in the attachment. In the case of PM, EPA has permitted a separate review of the ISA, which is possible because the process was begun earlier. But now EPA is combining the REA and PA into a single document. Significantly, it no longer provides a chance for CASAC and the public to review even the planned approach for the REA; CASAC review of the approach as well as a subsequent review of the REA was promised in the Final IRP well before the PA. I continue to believe this combination is a mistake, because the REA is a key element in considering whether to revise the standards, and plays a role in determining what any revisions should be. For these reasons, it is unwise to issue a combined PA/REA without at least providing the promised CASAC and public review of EPA's detailed plans for conducting the risk and exposure analyses. As noted in the attachment, it would be more appropriate to produce an early draft of the PA, but not submit it for review until after the REA, or at least the plans for the REA, are reviewed. If the REA or plans receive a good review, the combined PA could be submitted for review in short order. If not, revisions could be made to the analyses so CASAC would receive a combined document based on a revised analytical approach adopted in response to CASAC comments. As noted by other commenters, reviewing a combination of two documents at a single meeting not only adds burdens to CASAC and EPA staff, but also limits the ability for public comment on the science and policy considerations, depriving both CASAC and EPA of important perspectives that should be considered in the process of conducting the analyses.

The second issue relates to EPA's decision to ask CASAC to provide advice on the adverse effects of implementing air quality standards. In addition to the obvious concerns of mixing the science and policy issues in the NAAQS review with economic considerations, this requirement presents a significant additional workload for CASAC. This committee has never been constituted with the full range of expertise needed to evaluate these issues. In the past, EPA and Congress have looked to the National Academy of Sciences (NAS) for scientific guidance and insights on implementation issues.<sup>10</sup> Unlike the NAS, CASAC does not evaluate the scientific literature and produce assessments, which can be costly and take substantial time. Instead, CASAC and other SAB groups have been of significant value in reviewing EPA science, risk, and policy assessments, providing insights and recommendations relevant to the topics at hand.

In this case, it appears EPA is not preparing any document on the adverse effects of implementing NAAQS for CASAC to review, so it is unclear how the committee will have the time and expertise to develop useful advice for the Administrator on this topic. At the same time, it adds another task to an already overburdened committee. While the Clean Air Act calls

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<sup>10</sup> Notable examples of such NAS reports include *Acid Deposition: Atmospheric processes in Eastern North America* (1983), *Rethinking the Ozone Problem in Urban and Regional Air Pollution* (1993), *Estimating the Public Health benefits of Proposed Air Pollution Regulations* (2002), *New Source Review for Stationary Sources of Air Pollution* (2006), and the landmark *Air Quality Management in the United States* (2004).

for such a review, EPA has never charged the committee with this requirement.<sup>11</sup> The Act does not require this review to occur simultaneously with review of the standard, and there are strong reasons not to do so — even the Pruitt memorandum acknowledges that this information is not relevant to the standard-setting process.

If EPA still wants such advice, it should consider establishing an ad hoc SAB or CASAC panel consisting of experts needed for this kind of review, consistent with a recommendation made by CASAC in a 2014 letter cited in the attachment. This group could examine these issues for multiple pollutants. Because it would largely consist of experts who did not provide advice on the standards, it would also better separate the science and standards review from economic and related effects of implementation that cannot be considered in decisions on the standards. Given EPA's new aversion to supplementing CASAC with needed expert panels, it appears they have rejected this recommendation. CASAC should therefore now consider the additional burden on its time and expertise, and request that EPA drop its request or provide a document on the topic for the committee to review as well as additional experts who would only participate in this topic to facilitate meeting this unprecedented charge to the committee.

#### *Support for Maintaining the Core Elements of EPA's Framework for Causal Determination.*

As summarized in the Preamble to all ISAs:

*The U.S. EPA assesses the body of relevant literature, building upon evidence available during previous NAAQS reviews, to draw conclusions on the causal relationships between relevant pollutant exposures and health or environmental effects. ISAs use a five-level hierarchy that classifies the weight of evidence for causation. This weight-of-evidence evaluation is based on the integration of findings from various lines of evidence from across health and environmental effect disciplines that are integrated into a qualitative statement about the overall weight of the evidence and causality.<sup>12</sup>*

The approach is one of many adaptations of the 1965 Bradford Hill framework for assessing causality in epidemiology and public health. As EPA and others have noted, the agency has used and CASAC has reviewed EPA's systematic framework since 2008, and over the years it has been improved in response to CASAC and public comments. In 2011, CASAC, augmented with additional experts to form the Ozone review panel, reviewed the first draft of the Ozone ISA and stated:

*The CASAC continues to support the use of the EPA's framework for causal determination that was first used in the ISA for particulate matter. This framework provides a comprehensive and*

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<sup>11</sup> The Clean Air Act also requires issuing of Control Techniques documents for NAAQS pollutants, but EPA stopped issuing them decades ago.

<sup>12</sup> EPA, 2015, Preamble to the Integrated Science Assessments, Research Triangle Park, NC: U.S. Environmental Protection Agency, 2015; Report No.: EPA/600/R-15/067.

*transparent approach for evaluating causality. Based on long-standing approaches in public health, as brought together in a recent National Academy of Sciences (NAS) Institute of Medicine (IOM) report, the framework employs a two-step approach that first determines the weight of evidence in support of causation and then characterizes its strength in a standard scheme for causal classification. The second step further evaluates the available quantitative evidence regarding concentration-response relationships and the duration, level and types of exposures at which effects are documented. The EPA's adoption of this framework has greatly improved the consistency and transparency of its assessment as compared to the approach seen in past reviews.<sup>13</sup>*

The 2011 committee went on to make additional recommendations for further improvements in terminology and other aspects in the approach. The recent CASAC review of the PM IRP in August 2016<sup>4</sup> had no comments on the substance of the framework, but expressed concerns that the PM IRP should be clearer about how to ensure transparency and consistency in applying the framework.

According to an analysis of the record prepared by former CASAC chair Chris Frey, over the last decade the Framework for Causal Determination and its application in specific ISA's have been evaluated by 74 experts over multiple panels and review cycles.

Given the nature of comments and discussion regarding the potential importance of recent applications of epidemiology studies using causal inference methods in the ozone IRP review, it is necessary to consider the appropriate role of causal inference studies in the application of the causal framework in this PM review and to provide some additional perspectives from those familiar with the issues.

Full disclosure: In my former role in Science/Policy at EPA I advocated strongly for what we termed "accountability" research. More recently, I not only also supported applications of causal inference methods but also had the privilege of working with Harvard investigators on their HEI study, which used causal inference to examine the health effects of air quality regulations. The results were of interest in showing how the methodology can be applied as well as the importance of real world considerations to ensure appropriate study design and interpretation. The HEI commentary on this work noted:

*The HEI Review Committee concluded that these accountability methods are an important addition to the "toolkit" and should continue to be further explored, but cannot wholly*

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<sup>13</sup> Samet, J., 2011, CASAC Review of the EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Second External Review Draft – September 2011) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2009; Report No.: EPA-CASAC-12-004.



*substitute for accountability assessments that rely on evidence from other scientific methods, including more traditional epidemiology analyses.*<sup>14</sup>

Two of the principal authors of that study recently published their own thoughts on “best practices” for examining causality in air pollution, including the appropriate role of causal inference work:

*More specifically, increased emphasis on methods for causal inference and their application to the field of air pollution epidemiology is creating a dangerous misconception. Statistical methods for causal inference have played a prominent role in advancing several areas of scientific inquiry (15); see Zigler et al. (9) and Zigler and Dominici (16) for a discussion specific to air pollution epidemiology. However, a false dichotomy is emerging that classifies studies as either causal or associational based solely on the statistical methods used for estimation. Studies that estimate exposure-response relationships with regression models typically do not use causal inference terminology and are consequently coined associational and considered less rigorous. Conversely, studies that use explicit causal inference terminology are labeled causal, which automatically endows them as a fail-safe solution for identifying the scientific truth. This misconception is dangerous in the context of environmental regulations and spreads a false message that studies using causal inference methods should always be considered more credible than studies using more traditional statistical approaches.*<sup>15</sup>

The authors go on to recommend that ISA consider using a critical assessment of the design decisions used in studies and provide some examples and criteria that EPA and CASAC should consider.

The situation with respect to the role of causal inference studies at this point calls to mind a parallel situation for PM epidemiology in the early 1990s. As detailed more fully in a case study,<sup>16</sup> at that time Joel Schwartz was publishing multiple PM studies using statistical approaches more widely used in economics; these studies found associations between daily PM and serious effects at levels lower than the PM<sub>10</sub> standards. Over a period of several years there were multiple reanalyses, stress testing examining confounders, exposures and methodologies, as well as replications. Based on the results of this vetting process, these approaches became more widely accepted in air pollution epidemiology.

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<sup>14</sup> Zigler, C.M.; Kim, C.; Choirat, C.; Hansen, J.B.; Wang, Y.; Hund, L.; Samet, J.; King, G.; Dominici, F. Causal Inference Methods for Estimating Long-Term Health Effects of Air Quality Regulations; Research Report 187; Health Effects Institute: Boston, MA, 2016.

<sup>15</sup> Dominici F, Zigler C. Best practices for gauging evidence of causality in air pollution epidemiology. *Am J Epidemiol.* 2017; 186(12):1303–1309. See also response by L.A. Cox. *Am J Epidemiol.* 2018;187(6):1338–1339.

<sup>16</sup> D.S. Greenbaum, Bachmann, J.D., Krewski, D., Samet, J.M., White, R. and R.E. Wyzga, Particulate Air Pollution Standards and Morbidity and Mortality: Case Study. *American Journal of Epidemiology*, Volume 154, Issue 12, 15 December 2001, Pages S78–S90, <https://doi.org/10.1093/aje/154.12.S78>.

Today, some investigators are adapting causal inference methods, which are more widely used in other fields, to air pollution epidemiology. At the 2018 HEI annual meeting former CASAC panel member Lianne Sheppard suggested that “causal methods in air pollution epidemiology are in their infancy.”<sup>17</sup> Indeed, whatever the future may bring, today there are very few studies included in the draft PM ISA that use causal inference, with results both supportive and non-supportive of a causal effect.

I believe the perspective of HEI’s Dan Greenbaum and Rashid Shaikh published this month is consistent with the current state of the science:

*In recent years, formal, statistical tests for determining causality have been developed. Although these may be valuable, it is difficult to foresee how a single statistical test could readily supplant EPA’s comprehensive approach to evaluate the overall strength and weight of evidence. Refinements to the current ISA framework, including possibly more formal methods for causality determination, may serve to enhance the current process; such changes are topics of discussion and debate.*<sup>18</sup>

*Attachment:* June 2018 Letter to Bill Wehrum transmitting comments on the “Back to Basics” NAAQS memorandum.

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<sup>17</sup> L. Sheppard and M. Carone. Causal Inference in Air Pollution Epidemiology: Has its time come? Health Effects Institute Annual Meeting. Chicago, April 29, 2018.

<sup>18</sup> D.S.Greenbaum and R. Shaikh. The Role of Science in Setting National Ambient Air Quality Standards. *EM*. December 2018.