

STATEMENT OF

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Before the

Senate Environmental and Public Works Committee
Senate Subcommittee on Clean Air, Climate Change and Nuclear Regulation

Hearing on EPA's Proposed Revision to the National Ambient Air Quality
Standards for Particulate Matter

July 19, 2006

Executive Summary

- The scientific basis for policy decisions on setting the PM_{2.5} National Ambient Air Quality Standard remain highly uncertain.
- The continued use of the PM_{2.5} indicator is a default decision driven by EPA's past emphasis on regulatory compliance monitoring – “monitor that which is regulated.” As a result, there is no database for considering alternative PM indicators that might target specific PM constituents or exclude certain constituents.
- The scientific database provides a basis for the Administrator making policy choices for a PM_{2.5} NAAQS with 24-hour averaging time concentration in the range of 25 to 35 µg/m³, with a 98th percentile form, and an annual standard in the range of 12 to 15 µg/m³.
- The scientific database for policy decisions on setting a PM_{10-2.5} NAAQS is very weak and highly uncertain. A science-based decision, as contrasted with a judicial decision, would be to continue with a PM₁₀ NAAQS.
- There are major uncertainties in risks associated with exposure to ambient PM_{2.5} at current levels and the benefits of reducing PM_{2.5}. These uncertainties need to be clearly documented and conveyed in numerical calculations used for policy decisions and in the Agency's final Regulatory Impact Analysis.
- Expert elicitations of opinions on PM_{2.5} risks are very likely flawed with a blurring of the distinction between scientific evaluation and policy choices. Scientists, as do all citizens, have values that influence choices of standard setting options. However, scientific evaluations should be as free as possible of concern for the ultimate policy decisions.

Good Morning, Mr. Chairman and Members of the Subcommittee. Thank you for the invitation to present my views on the U.S. Environmental Protection Agency's current review on the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM).

My Background

My biography is attached to this statement. Since 1999, I have served as an Advisor to public and private organizations on issues related to air quality in the ambient environment and workplace drawing on more than 45 years of experience in comparative medicine, toxicology, aerosol science, and risk analysis. I served as President of the Chemical Industry Institute of Toxicology in Research Triangle Park, NC from 1988 to 1999, providing leadership for a research program directed to understanding the mechanisms of action of chemicals in producing either beneficial or harmful effects on humans. I was with the Lovelace organization in Albuquerque, NM from 1966 to 1988, providing leadership for one of the World's major research programs directed toward understanding the potential human health effects of inhaled materials.

The testimony I offer today draws on my experience serving on numerous scientific advisory committees. This has included service on many EPA advisory committees from the origin of the Agency to date, including the Clean Air Scientific Advisory Committee (CASAC), which I chaired from 1988 to 1992, all of the CASAC PM Panels as well as CASAC Panels that considered other criteria pollutants. My involvement in advising EPA on the setting of NAAQS for criteria pollutants began with my chairing in 1977 and 1978 an *ad hoc* committee to review the first lead criteria document, a committee that was required since the Congress had not yet authorized creation of CASAC. I also served on the National Academy of Sciences/National Research Council (NAS/NRC) on Research Priorities for Airborne Particulate Matter and the earlier NAS/NRC Committee that produced the report – "Science and Judgment in Risk Assessment." It is important to note that the testimony I offer today reflects my own views and is not being offered on behalf of any of the Committees I have served on for the EPA, the NAS/NRC nor for any other agencies or firms.

Setting National Ambient Quality Standards

Each NAAQS consists of four elements: (a) an indicator (such as PM_{2.5}), (b) an averaging time (such as 24 hours or annual), (c) a numerical level (such as 65 µg/m³ for PM_{2.5} averaged over 24 hours), and (d) a statistical form (such as a 98th percentile). The indicators for five of the criteria pollutants are for measurement of the mass concentration of specific chemicals such as O₃, SO₂, NO₂, CO and Lead. Only in the case of particulate matter is the indicator based on the mass concentration of airborne particulate matter in a specific size range, irrespective of the chemical composition of the PM.

Under the Clean Air Act, the EPA Administrator is required to review the NAAQS for the criteria pollutants at 5-year intervals to evaluate whether or not the four elements of the NAAQS are still deemed to be acceptable based on current scientific knowledge as it applies to the assessment of public health risks. In practice the interval between reviews has been longer. The process for review and promulgation of a NAAQS, either continuation of the existing standard or establishing a new NAAQS, consists of multiple phases. The initial phase, which is obviously on-going, consists of conduct of research on the various criteria pollutants. This includes a broad spectrum of activities; understanding emissions of pollutants, transport and transformation of pollutants in the atmosphere, ambient measurements of pollutants, estimation of personal exposures to pollutants, assessment of toxic effects and mechanisms of action in cells, tissues and animals, conduct of controlled exposure studies to pollutants in human volunteers and epidemiological investigations of human populations. Most of the research is funded by the EPA, some in the Agency's own laboratories and some in academic and other laboratories, the National Institutes of Health and, to a modest extent, private industry. The dominance of federal government support of research on criteria pollutants relates to their effects being of broad societal concerns with the pollutants, by and large, having no unique industrial emission source.

The findings of this research are used by the EPA's Office of Research and Development to prepare a criteria document (CD). Each CD traditionally has been essentially an encyclopedia of everything known about a given criteria pollutant and is used as a basis of information for the preparation of a Staff Paper (SP) by the EPA's Office of Air Quality Planning and Standards. This is a Policy Assessment of Scientific

and Technical Information; in short, an integration and synthesis of the information in the CD that is most relevant to setting the four elements of a NAAQS. In recent years, the Staff Papers have made substantial use of risk assessments for the criteria pollutant being considered. These risk assessments have been conducted by a single EPA Contractor organization. The various versions of the CD and SP are released to the public with an invitation to provide comments as a basis for improving the documents.

Throughout this process, a Clean Air Scientific Advisory Committee Panel, operating as an element of the EPA's Science Advisory Board, is involved in reviewing and advising on the scientific content of both the CD and the SP, including the related risk assessment. This has typically involved several revisions. Prior to the current cycle of PM review, the CASAC Panel sent a closure letter to the EPA Administrator when the CASAC was of the opinion that the revised documents were suitable for use by the Administrator in promulgating a NAAQS. In the current review, the "closure letter" process was abandoned.

At the next step, the Administrator proposes, via a Federal Register Notice, a NAAQS including specific proposals for each of the four elements of the NAAQS; the indicator, averaging times, numerical levels and statistical forms. Comments are solicited from the Public with the opportunity to submit written comments to a specific Docket. In the current PM review, the CASAC PM Panel offered written comments on the Administrator's proposal.

The next step is for the Administrator to promulgate a NAAQS consisting of the four elements discussed previously. I purposefully do not use the phrase – "final step," because the Courts may have a role in deciding whether the Administrator's proposed NAAQS will stand. The NAAQS are to be based on the available scientific information reviewed in the CD and SP and summarized in the notice of proposed standards. The primary, health-based NAAQS are to be set at a level that will protect public health, including sensitive populations, with an adequate margin of safety. The Administrator is precluded from considering cost in the setting of the NAAQS.

At this point, I would like to emphasize that there exists no absolute and unambiguous scientific methodology that can determine which specific indicator, the precise averaging time, numerical level or statistical form that will be adequate to protect

public health. The available scientific information can inform the NAAQS decisions, however, the Administrator must ultimately use policy judgment in making decisions on each of the four elements from among an array of scientifically acceptable options including consideration of their attendant scientific uncertainties.

Once the NAAQS are finalized, individual states have responsibility for planning and taking actions to meet the NAAQS. This includes the formal step of preparing “State Implementation Plans (SIPs). In developing strategies for meeting the NAAQS, the States can give consideration to costs in setting the pace for achieving the NAAQS. However, attainment of the NAAQS cannot be postponed indefinitely.

EPA Administrator Made Policy Choices Consistent with the Science

At this juncture, I note that I personally find acceptable the Administrator’s policy choices for the PM NAAQS, as published in the Federal Register (January 17, 2006) from among an array of science-based options, to be acceptable. Specifically, I find scientifically acceptable his proposal to use (a) a PM_{2.5} indicator with a 24-hour averaging time and a reduction in the concentration level from 65 µg/m³ to 35 µg/m³ with a 98th percentile form, (b) retention of the PM_{2.5} annual standard at 15 µg/m³ with additional constraints on the use of spatial averaging, and (c) use of a PM_{10-2.5} indicator with a 24-hour averaging time concentration level set at 70 µg/m³ with a 98th percentile form. I support the exclusion of any ambient mix of PM_{10-2.5} where the majority of coarse particles are rural windblown dust and soils and PM generated by agricultural and mining sources.

Of these several policy choices, I have the greatest reservation concerning the proposal for a PM_{10-2.5} indicator with a 24-hour averaging time concentration level set a 70 µg/m³ with a 98th percentile form. The scientific basis for the proposed PM_{10-2.5} standard is very weak and uncertain. I would have personally preferred to see the PM₁₀ standard continued to provide public health protection from particulate matter mass in the PM_{10-2.5} range. However, EPA personnel have related that this option has been precluded by Court decisions.

Selection of a PM Indicator – Chained to the Regulatory Compliance Monitoring Lamp Post

The primary scientific data used to select indicators for PM NAAQS has been derived from epidemiological investigations. Prior to 1970, there was limited regulation of particulate matter in air pollution. Limited monitoring, relative to that being carried out today, was conducted using relative crude metrics of Black Smoke and Total Suspended Particulates (TSP). TSP was the mass of particulate matter, not identified as to chemical form, collected on a filter in a high volume air sampler. This included material up to about 40 μm in size. Scientists studied the relationship between the air concentration of these TSP measurements and increases in health effects. This epidemiological data provided the basis for setting the 1971 PM NAAQS with TSP as an indicator. The 24-hour averaging time standard set at $260 \mu\text{g}/\text{m}^3$, not to be exceeded more than once a year, and an annual standard set at $75 \mu\text{g}/\text{m}^3$, annual geometric mean. The TSP indicator then became the “law of the land” and TSP began to be routinely monitored to determine regulatory compliance.

During the 1970s and early 1980s, an increased awareness emerged on the role of particle size in determining the fraction of inhaled particles that would be deposited and where they would be deposited in the respiratory tract. This led to some groups making measurements of ambient air particulate matter mass in different size fractions; less than 15 μm , less than 10 μm , less than 2.5 μm and less than 1 μm . However, the primary epidemiological data in the 1980s that could be used for standard setting was TSP – remember TSP was required to be measured for regulatory compliance.

In 1987, the PM NAAQS indicator was changed from TSP to PM_{10} . The choice of PM_{10} was heavily influenced by a decision in the international community to use a PM_{10} metric rather than a PM_{15} metric. The U.S. followed suit. Much of the epidemiological evidence for setting a PM_{10} NAAQS was based on extrapolations from epidemiological studies using the TSP monitoring data. The PM_{10} primary standards were set at $50 \mu\text{g}/\text{m}^3$, expected annual arithmetic mean over 3 years, and $150 \mu\text{g}/\text{m}^3$, 24-hour average, with no more than one expected exceedance per year. With the promulgation of the PM_{10} indicator the regulatory compliance monitoring shifted from TSP to PM_{10} . Unfortunately, ambient air monitoring of PM_{15} , $\text{PM}_{2.5}$ and $\text{PM}_{1.0}$ was

essentially discontinued. Obviously, it would have been expensive to continue, and, after all, it was not required for regulatory compliance.

In the early 1990s, epidemiological data began to be published on the association between elevated PM_{2.5} levels and their association with increased health effects. The data came principally from the Harvard Six Cities study that fortunately had included in its early years measurements of PM_{1.0} and PM_{2.5}. Other analyses were published based on an American Cancer Society cohort taking advantage of fragmentary PM_{2.5} ambient monitoring data. Other investigations conducted using the PM₁₀ ambient monitoring data were extrapolated to a PM_{2.5} indicator. These data provided the basis for promulgating a PM_{2.5} NAAQS in 1997. The PM_{2.5} NAAQS were set at 15 µg/m³, annual arithmetic mean, and 65 µg/m³, 24-hour averaging time with a 98th percentile of concentration at each population-oriented monitor. Associated with this was a change in the regulatory compliance monitoring network to emphasize PM_{2.5} mass measurements without regard to chemical composition. Because a PM₁₀ mass NAAQS was still in place measurements of PM₁₀ mass, not characterized as to chemical composition, continued. Using the difference between the PM₁₀ mass measurements and PM_{2.5} mass measurements, it was possible to *estimate* PM_{10-2.5} mass concentrations.

At various times there has been an interest in measuring PM sulfate mass concentration, a secondary pollutant arising in the atmosphere from conversion of SO₂ gas. There have also been some short-term monitoring campaigns in which extensive chemical characterization of a number of particulate matter constituents have been measured. However, the extent of this monitoring data is limited in comparison with that developed for regulatory compliance purposes on PM₁₀ mass and PM_{2.5} mass, not characterized as to chemical composition. Indeed, to date the database on specific PM constituents has been insufficient to set a NAAQS for a specific PM component. Obviously, Lead is an exception. Likewise, the data on specific PM constituents were not viewed as to exclude any constituent from regulation.

The most recent CD and SP focuses on the PM_{2.5} indicator. The focus on PM_{2.5} was not based on any careful scientific analysis that led to the conclusion that PM_{2.5} mass, not identified as to chemical composition, as the most appropriate metric to relate to an increase in health effects. The simple fact is that because of the EPA's emphasis on

regulatory compliance monitoring, the only PM air quality metrics that could be evaluated epidemiologically were PM₁₀ mass, PM_{2.5} mass and to a lesser extent PM sulfate and to an even lesser extent, PM_{10-2.5}. I will be so bold as to say the focus on PM_{2.5} mass, irrespective of chemical composition, was a default decision, not a science-based decision.

My discussion so far has focused on epidemiological evidence without considering the results of toxicological studies using cells, tissues or laboratory animals. As a toxicologist, I wish I could give more emphasis to the conduct and interpretation of toxicological studies. However, such studies have a very limited role in the PM NAAQS setting process. Although such studies can use new tools of modern molecular and cellular biology and genomics, the results are not necessarily relevant to setting the NAAQS. The challenges of extrapolating from laboratory animals to humans, from high to low levels of exposure, from studies of a few days or even a few months to human lifetimes and from studies of a few normal healthy young animals to large human populations including individuals with cardiopulmonary disease, principally from smoking, are substantial. At best, the toxicological investigations can help provide some guidance to the design and conduct of epidemiological investigations. The toxicological methods are simply too blunt and yield results that at best can be extrapolated *qualitatively* to human populations. I know of no scientific methods for using the results of toxicological studies with PM, not characterized as to chemical composition, or those conducted with specific PM constituents to develop *quantitative* numerical standards that are at the core of PM NAAQS.

A Shift in Monitoring Strategy to Facilitate Epidemiological Evaluations

What are the prospects for the next PM NAAQS review in 5 years including a rigorous evaluation of specific PM constituents? Without a major revolutionary change in the EPA's approach to ambient air monitoring, I think it will be more of the same. In short, because of the past focus on measuring PM_{2.5} and PM_{10-2.5}, these metrics will continue to be evaluated in future epidemiological studies. Because of the substantial and continuing improvements in air quality, including PM_{2.5}, PM₁₀ and PM_{10-2.5}, it will be even more difficult to detect associations between these PM mass metrics and health

effects. Future epidemiological studies will also be challenged due to continuing reductions in cardiopulmonary disease related to reductions in the primary risk factor for these diseases – *Cigarette Smoking*.

How can the prospects for improved epidemiological investigations be changed? If the EPA, in cooperation with States and Municipalities, radically modifies its ambient air monitoring network over the next 2 years, it may be possible to have the results of improved epidemiological studies in 8 to 10 years. The development of an improved ambient air monitoring network will require some tough decisions. It is obvious that the expense of an altered monitoring network will require that only a modest number of PM constituents be measured in multiple cities in different regions across the U.S. Some clear candidates would be sulfates, nitrates, organic carbon, elemental carbon, silica and some specific metals for which concern may exist as to their potential hazard. It is essential that all of the criteria pollutant gases, ozone, SO₂, NO₂ and CO, continue to be measured. With a richer array of monitoring data available it may be possible to test hypotheses as to the relative potency of the various PM constituents as well as the gaseous pollutants. In any long-term studies, it will be crucial to have accurate smoking history data if the very small potential effects of air pollution are to be separated from the large cardiopulmonary impacts of cigarette smoking. In addition, because of the relationship between PM-associated hydrocarbons and volatile and semi-volatile hydrocarbons these should be measured. In my opinion, it will be futile to measure dozens of individual chemical species with the view that these measurements could be useful in future epidemiological studies. The current highly uncertain signal of air pollution associated health effects is so small that “teasing out” effects related to any single PM chemical constituent will be extraordinarily challenging.

Selection of Averaging Times, Numerical Levels and Statistical Forms

Having selected an indicator, it is necessary to proceed to decisions on the averaging times, numerical levels and statistical forms for the NAAQS. These three elements are inter-related and are set based on the epidemiological database. The averaging times are driven by the temporal characteristics of the monitoring data, 24-hour measurements that can be aggregated to yield annual values which, in turn, are used in

the epidemiological investigations. Hence, it is reasonable to use 24 hour and annual averaging times.

The selection of specific numerical levels for the 24-hour standard has been guided primarily by considering the results of epidemiological studies of the association between daily changes in the PM indicator and changes in mortality (all cause, cardiovascular and respiratory mortality). The power of these studies is directly related to the size of the population being studied and the number of days being monitored. Thus, results can only be developed for quite large cities. This approach would not be feasible for small communities and rural areas.

The primary input for establishing the PM_{2.5} annual standard comes from long-term follow-up of cohort populations, the Harvard Six City Study of about 8000 individuals initiated in 1979 and the American Cancer Society cohort assembled starting in 1979. In these studies, sophisticated statistical techniques have been used to attempt to tease out an association between differences in PM_{2.5} ambient concentrations in different communities and the risk of death from various diseases. The analyses are very complicated because of the numerous factors that can influence the death rate including age, cigarette smoking, work history, education, socio-economic status, exposure to other pollutants as well as other factors.

The results of the cohort epidemiological studies are typically reported as a linear coefficient of increase in relative risk per 10 µg/m³ of PM_{2.5} using whatever PM_{2.5} monitoring data are available for the specific cohort. Thus, for the studies initiated in 1979, this may be PM_{2.5} measurements made in 1979-1983. Recall that in the 1980s, there was a move to regulate PM₁₀ measurements of PM_{2.5} were discontinued and not re-instituted until after the PM_{2.5} NAAQS was promulgated in 1997. The PM_{2.5} exposure of individuals in the cohort prior to 1979 is unknown although it is well recognized that in most areas air quality has substantially improved since 1970.

A major challenge in analyzing and interpreting the results of the cohort studies relates to the uncertain role of pollution exposures for the individual populations prior to initiation of the studies and the uncertainty in the statistical models used to attribute relative risk to the various risk factors including PM_{2.5}. The small size of the PM_{2.5} relative risk poses a special challenge. This includes the difficulty of determining the

shape of the exposure-health response relationship extending from past high levels down to current levels. Especially vexing is the issue of whether a threshold does or does not exist in the exposure-health response relationship. In my view, the exposure-response relationships are highly uncertain in the range of typical ambient PM_{2.5} concentrations in the United States. The substantial uncertainty in the applicability of the PM_{2.5} exposure-health response coefficients at current ambient concentrations requires caution in calculating either PM_{2.5} associated risks or the benefits of any reductions in PM_{2.5} concentrations.

Expert Advice Elicitation

In an attempt to better characterize the uncertainties in PM_{2.5}-associated health risks and, conversely, the benefits in reductions in PM_{2.5}, some individuals have suggested the use of an “expert advice elicitation” approach. I am familiar with this approach having served as one of the five experts in EPA’s pilot project to elicit opinions on the relationship between PM_{2.5} exposure and death. I have also participated in such approaches in the initial stages of planning and interpreting safety assessment studies. I think the expert opinion elicitation process may have merit in obtaining a *qualitative* assessment of the impact of exposure to hazardous materials. However, I have serious reservations as to its use in eliciting *quantitative* characterizations of risk for various levels of PM_{2.5} exposure for different populations in different parts of the United States.

The interviewers eliciting the expert opinions play a major role in determining the outcome of the process. In the session I participated in, I found the interviewer focusing on eliciting quantitative linear exposure-response coefficients. Since it is my professional opinion that it is very unlikely that a linear relationship exists between PM_{2.5} exposure and health responses down to and including current ambient levels, the interview and the follow-up discussions proved frustrating for both me and the interviewer. In short, the sponsor (in this case, the EPA) can influence the interviewer to frame a series of questions that will yield a pre-determined answer. In my case, I felt the desired answer was what linear risk coefficient (exposure health-response) would I prefer.

I am also concerned about the process used to select experts for participation. In my opinion, the process should be very transparent with regard to the criteria used to

include or exclude individual experts from a Panel. My concerns extend to the inclusion of individuals who may have conducted and reported on the key studies being used in the expert opinion elicitation process. It is human nature to want to have one's own data and analyses used in the same manner as originally reported.

Any additional concern with the process is the approach of using secondary interviews in an attempt to gain consensus from the experts as to the outcome. I understand that was done with the full-scale expert elicitation panel whose input is to be used in the final regulatory impact analysis. A major challenge in any elicitation of expert advice is separating the individuals science-based input from their personal sources with regard to a policy outcome. In my opinion, the results of that expert elicitation are likely to be seriously flawed. I would urge the Administrator to not use the results of the expert opinion elicitation as input for quantitative estimates of risks/benefits associated with PM_{2.5} exposure. Such an approach is not a substitute for more rigorous uncertainty analysis that attempts to characterize all the factors that impact on *estimating* risks of PM_{2.5} exposure and the benefits of reductions in PM_{2.5} exposure.

As an alternative to expert opinion elicitation, I urge CASAC to document the scientific views of each of the CASAC PM Panel members with regard to quantitative aspects of the PM NAAQS. This approach was used in the previous PM review that concluded with promulgation of the 1997 PM_{2.5} NAAQS. A copy of the table included in the CASAC PM Panel's "closure letter" is attached. As may be noted, individual Panel members had a wide range of views with regard to setting the PM_{2.5} NAAQS. I would personally prefer to see each of my scientific colleagues express their individual science-based opinions rather than have CASAC Panel participants cajoled to reach a consensus.

Scientific Evaluations Versus Policy Decisions

A major challenge I see for all scientists, and especially for CASAC PM Panel members participating in the NAAQS review process, is to recognize the distinction between scientific evaluations and policy judgments. In my comments to Mr. Bill Wehrum and Dr. George Gray on improving the NAAQS review process, I noted -- "It would be helpful if, at each step in the NAAQS process including each meeting of the scientists preparing the Criteria Documents and the Staff Paper and their review by

CASAC, if each participant were reminded – *“Every individual should recognize the distinction between scientific evaluation and policy decisions and recognize that the matters being dealt with are at the interface of science and policy. Each individual participant is asked to leave their individual ideologies and thoughts on policy decision outcomes at the door before deliberating on the science.”* This is not a matter of an individual’s employment, i.e., academic, government, industry, etc. or political affiliation. It applies to all participants. This is an especially vexing issue for scientists involved in evaluating their own research results or that of close colleagues. In today’s resource constrained world everyone wants to have their work used in the public arena, moreover, they would like to see the door left open or opened wider for them to do more work on the topic under consideration. Indeed, some individuals, including CASAC Panel Members, desire a “sense of accomplishment” – some individuals interpret that as – did we participate in lowering the NAAQSs? Some have suggested that there would be a “limited sense of accomplishment” if only the 24-hour PM_{2.5} standard were lowered and the Annual PM_{2.5} standard was left unchanged. Yes, scientific evaluations and policy decisions do get intertwined by individual scientists in expressing their own personal preferences on life science issues.”

From June 13, 1996 Closure Letter (EPA-SAB-CASAC-LTR-96-008)
Summary of CASAC Panel Members Recommendations
(all units $\mu\text{g}/\text{m}^3$)

| | | PM_{2.5} 24-hr | PM_{2.5} Annual | PM₁₀ 24-hr | PM₁₀ Annual |
|--------------------------|--------------------------------|-----------------------------------|------------------------------------|----------------------------------|-----------------------------------|
| Current NAAQS | | N/A | N/A | 150 | 50 |
| EPA Staff Recommendation | | 18 - 65 | 12.5 - 20 | 150 ¹³ | 40 - 50 |
| Name | Discipline | | | | |
| Ayres | M.D. | yes ² | yes ² | 150 | 50 |
| Hopke | Atmos. Sci. | 20 - 50 ³ | 20 - 30 | no | 40 - 50 ⁴ |
| Jacobson | Plant Biologist | yes ² | yes ² | 150 | 50 |
| Koutrakis | Atmos. Sci. | yes ^{2,5,6} | yes ^{2,5,6} | no | yes ⁴ |
| Larntz | Statistician | no | 25-30 ⁷ | no | yes ² |
| Legge | Plant Biologist | ≥ 75 | no | 150 | 40 - 50 |
| Lippmann | Health Expert | 20 - 50 ³ | 15 - 20 | no | 40 - 50 |
| Mauderly | Toxicologist | 50 | 20 | 150 | 50 |
| McClellan | Toxicologist | no ⁸ | no ⁸ | 150 | 50 |
| Menzel | Toxicologist | no | no | 150 | 50 |
| Middleton | Atmos. Sci. | yes ^{2,3,12} | yes ^{2,5} | 150 ^{3,13} | 50 |
| Pierson | Atmos. Sci. | yes ^{2,9} | yes ^{2,9} | yes ⁴ | yes ⁴ |
| Price | Atmos. Sci./ State Official | yes ^{3,10} | yes ¹⁰ | no ^{3,4} | yes ⁴ |
| Shy | Epidemiologist | 20 - 30 | 15 - 20 | no | 50 |
| Samet ¹ | Epidemiologist | yes ^{2,11} | no | 150 | yes ² |
| Seigneur | Atmos. Sci. | yes ^{3,5} | no | 150 ¹³ | 50 |
| Speizer ¹ | Epidemiologist | 20 - 50 | no | no | 40 - 50 |
| Stolwijk | Epidemiologist | 75 ⁷ | 25-30 ⁷ | 150 | 50 |
| Utell | M.D. | ≥ 65 | no | 150 | 50 |
| White | Atmos. Sci. | no | 20 | 150 | 50 |
| Wolff | Atmos. Sci. | ≥ 75 ^{3,7} | no | 150 ³ | 50 |

¹ not present at meeting; recommendations based on written comments

² declined to select a value or range

³ recommends a more robust 24-hr. form

⁴ prefers a PM_{10-2.5} standard rather than a PM₁₀ standard

⁵ concerned upper range is too low based on national PM_{2.5}/PM₁₀ ratio

⁶ leans towards high end of Staff recommended range

⁷ desires equivalent stringency as present PM₁₀ standards

⁸ if EPA decides a PM_{2.5} NAAQS is required, the 24-hr. and annual standards should be 75 and 25 $\mu\text{g}/\text{m}^3$, respectively with a robust form

⁹ yes, but decision not based on epidemiological studies

BIOGRAPHY

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ROGER O. McCLELLAN is currently an advisor to public and private organizations on issues concerned with human health risk analysis and inhalation toxicology focusing on issues of air quality in the ambient environment and work place..

He is President Emeritus of the Chemical Industry Institute of Toxicology, having served as Chief Executive Officer and President of the Institute from September 1988 through July 1999. The Institute has a mission of creating an improved knowledge base for understanding and assessing the adverse effects of exposure to chemicals. During his tenure, the organization achieved international recognition for the development of science undergirding important environmental and occupational health regulations. Prior to his appointment as President of CIIT, Dr. McClellan was Director of the Inhalation Toxicology Research Institute, and President and Chief Executive Officer of the Lovelace Biomedical and Environmental Research Institute, Albuquerque, New Mexico. He began his career with Lovelace in 1966. During his 22 years with the Lovelace organization, he provided leadership for development of one of the world's leading research programs concerned with the toxic effects of airborne materials. The Institute continues operation today as a core element of the Lovelace Respiratory Research Institute. Prior to joining the Lovelace organization, he was a scientist with the Division of Biology and Medicine, U.S. Atomic Energy Commission, Washington, DC (1965-1966), and Hanford Laboratories, General Electric Company, Richland, WA (1959-1964). He received his Doctor of Veterinary Medicine degree from Washington State University in 1960 and a Master of Management Science degree from the University of New Mexico in 1980.

Dr. McClellan has served in an advisory role to numerous public and private organizations. He is past Chairman of the Clean Air Scientific Advisory Committee (CASAC), *Ad Hoc* Committee to Review Criteria Document for Airborne Lead, Environmental Health Committee, Research Strategies Advisory Committee, service on CASAC Panels for all the Criteria Pollutants, and Member of the Executive Committee, Science Advisory Board, U. S. Environmental Protection Agency; Member, National Council on Radiation Protection and Measurements; Member, Advisory Council for Center for Risk Management, Resources for the Future; a former Member, Health Research Committee, Health Effects Institute; and service on National Academy of Sciences/National Research Council Committees on Toxicology (Past Chairman), Risk Assessment for Hazardous Air Pollutants, Health Risks of Exposure to Radon, Research

Priorities for Airborne Particulate Matter, as well as the Committee on Environmental Justice of the Institute of Medicine.

Dr. McClellan serves or has served as Adjunct Professor at Duke University, University of North Carolina at Chapel Hill, North Carolina State University, University of New Mexico, University of California-Los Angeles, University of Arkansas, Colorado State University, and Washington State University. In addition, he frequently speaks on risk assessment and air pollution issues at other institutions and meetings in the United States and abroad. He is active in the affairs of a number of professional organizations, including past service as President of the Society of Toxicology and the American Association for Aerosol Research. He recently served 2 years as Chair of the Board of Trustees, Toxicology Excellence in Risk Assessment. He serves in an editorial role for a number of journals, including service as Editor of CRC Critical Reviews in Toxicology. He is a Diplomate of the American Board of Toxicology and the American Board of Veterinary Toxicology and a Fellow of the Academy of Toxicological Sciences, the Society for Risk Analysis and the Health Physics Society.

Dr. McClellan's contributions have been recognized by receipt of a number of honors, including election in 1990 to membership in the Institute of Medicine of the National Academy of Sciences. He is a Fellow of the American Association for the Advancement of Science. In 1998, he received the International Aerosol Fellow Award from the International Aerosol Research Assembly for his contributions to aerosol science and technology. He received the Society of Toxicology 2005 Merit Award for a distinguished career in toxicology. In 2005, The Ohio State University awarded him an Honorary Doctor of Science degree for his contributions to the science under-girding improved air quality. He has a long-standing interest in environmental and occupational health issues, especially those involving risk assessment and air pollution, and in the management of multidisciplinary research organizations. He is a strong advocate of risk-based decision-making and the need to integrate data from epidemiological, controlled clinical, laboratory animal and cell studies to assess human health risks of exposure to toxic materials and to inform policy makers in developing standards and guidance to protect public health.