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Comments on "Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter," Vol. 81, Number 75 (Tuesday, April 19, 2016), pages 22977-22978, Docket ID No.: EPA-HQ-OAR-2015-0072

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I. Executive Summary

The comments I offer are based on my four decades of experience as a scientist studying air quality and its impact on health and the use of the information acquired to inform policy decisions required to set National Ambient Air Quality Standards (NAAQS) for criteria pollutants. My advisory service on these matters precedes the establishment of the Clean Air Scientific Advisory Committee (CASAC) and includes services on numerous CASAC Panels and four years as Chair of CASAC.

The draft "Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter" is generally well prepared and identifies an appropriate path forward. However, the document is deficient in three areas. First, the plan does not clearly state the advisor role of CASAC in reviewing and commenting on the science that informs the policy-decisions exclusively delegated to the EPA Administrator in setting the NAAQS for PM. This lack of clarity is likely to impede that overall review process.

This review will conclude with the EPA Administrator having to make some of the most difficult and likely controversial, policy decisions yet made on the reaffirmation or revision of any NAAQS. These policy decisions must be informed by all of the available science on PM and context on air quality and health across the U.S. A failure to provide contextual health statistics for the U.S. in the review process will impair the EPA Administrator's ability to make sound science policy decisions on reaffirming or revising the NAAQS for the several PM indicators. The plan is deficient in not providing contextual health data.

The Integrated Review Plan is silent on how to address Section 109(d)(5)(c) requirements of the Clean Air Act. This matter needs to be addressed within the plan rather than issuing an apology for not addressing these requirements after a decision on the NAAQS for PM is resolved. Indeed, addressing these requirements in a thoughtful manner will be useful to the EPA Administrator in making policy decisions on the NAAQS for PM.

The abundant scientific information now available on particulate matter and its thoughtful review and interpretation are essential for informing the policy decisions to be made in reaffirming or reviewing the NAAQS for the several PM indicators. I have purposefully used the word, reaffirm because it is important to understand each NAAQS review need not end with revision of the NAAQS. Success should not be determined by whether the NAAQS was made more stringent but by the quality of the review. Science alone and scientific opinions are not sufficient to set the NAAQS. Science and scientists inform the EPA Administrator's policy decisions that set the NAAQS.

II. Introduction

This document, "Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter," EPA-452/D-16-001, April 2016, provides the foundation for the current review of the National Ambient Air Quality Standard (NAAQS) for Particulate Matter (PM). This review will culminate with the EPA Administrator's decision to reaffirm or revise the four basic elements of the PM NAAQS: the indicator, averaging time, level, and form. Thus, it is vitally important that plans presented in the document be comprehensive and complete

as to how all of the science that will inform the EPA's policy decisions on the setting of the NAAQS for PM will be assembled and presented.

As I will detail in these comments, the present draft document does not adequately detail a complete and integrated review plan and should be revised. The document has three major deficiencies. First, it is missing a key over-arching conceptual element that should be understood as the science is reviewed and integrated for policy making. Second, the plan does not include any provisions for assembling and presenting critical baseline health data on the population of the USA, information that is needed to provide context for the EPA Administrator's policy decisions leading to reaffirmation or revision of the NAAQS for PM. Third, the plan does not include any provisions for the assembly and review of information that addresses two responsibilities outlined in Section 109(d)(5)(c) of the Clean Air Act. Let me address each of these three issues.

III. Science Informing Policy Decision

The draft Integrated Review Plan fails to explicitly describe the NAAQS PM review process as one in which science is reviewed, integrated and presented to the EPA Administrator to inform the policy decisions that are the exclusive responsibility of the Administrator to make in reaffirming or revising the four elements of each NAAQS. It has been recognized since the earliest NAAQS were set that science alone cannot establish policy, i.e., the setting of the level and form of each NAAQS. For example, John Bachman (2007) described the setting of the first NAAQS for lead and noted – "As for all NAAQS decisions, the final choice on the Standard was constrained and informed by the scientific information, but ultimately based on the policy judgment of a politically responsible decision maker, the EPA Administrator." I recall this situation very well since I chaired the EPA Science Advisory Board Ad Hoc Committee that reviewed what was then called a Criteria Document that integrated the available science on the health effects of airborne lead. The Ad Hoc Committee was created to review the first criteria document on lead because the Congress had not yet authorized what is now called the Clean Air Scientific Advisory Committee (CASAC). The initial draft Criteria Document on the Health Effects of Airborne Lead was of poor quality and most significantly, recommended a specific numerical standard. This was clearly inconsistent with the intent of the Clean Air Act (CAA) to separate the scientific assessment of the relevant criteria and the setting of the specific NAAQS. Let me be clear there were some members of the Ad Hoc Lead Committee that wanted to focus on recommending a specific standard, i.e., their personal desired policy outcome, even in the absence of an acceptable comprehensive review of the science. Fortunately, good sense prevailed and the Ad Hoc Committee focused on reviewing the science in the Criteria Document and left the selection of the NAAQS for lead to the EPA Administrator, an action consistent with the intent of the CAA.

The contentious debate over the role of science and scientists informing policy decisions versus science and scientists dictating specific NAAQS values continues today. This was apparent when I listened to the CASAC teleconference on May 23, 2014 reviewing the draft Integrated Review Plan. It was apparent that some CASAC PM Panel members were already starting to focus on the policy outcome of the review rather than on the science that would inform the policy judgments. That is not surprising since many of the CASAC Panel members have invested substantial portions of their scientific careers conducting the research that will

ultimately be used in reaffirming or revising the NAAQS for PM. It is natural that they want to see the scientific information they developed used.

The failure of the EPA to provide clear guidance to CASAC over the past decade on its role in reviewing the science informing the policy decisions of the EPA Administrator has created much confusion and wasted valuable resources. I refer specifically to the letters from the CASAC Chair to the EPA Administrator beginning in 2006 relating very specific directions as to the level of the NAAQS (Henderson, 2006a,b,c). In my opinion, CASAC, by specifying the level of the NAAQS for ozone and PM within narrow bounds, was inappropriately moving to a standard setting rather than advisory role. It is my contention that EPA broadly, and certainly some EPA officials, contributed to the confusion by not making clear to CASAC that CASAC's role is to make certain the science is right and that CASAC, individually and collectively, should not step over the boundary and attempt to assume the EPA Administrator's role in making policy decisions that yield specific NAAQS. The Integrated Review Plan is the foundational document for the NAAQS review and setting process. It needs to make clear the roles of CASAC and the EPA Administrator in the science review and NAAQS setting process. I have previously discussed this issue in depth (McClellan, 2012).

It is already clear that the current review of the NAAQS for PM will be very contentious. I offer the opinion based on the nature of discussions at the February 9-11, 2015 workshop entitled – "Workshop to Discuss Policy-Relevant Science to Inform EPA's Review of the Primary and Secondary NAAQS for PM." As an aside, as revealed in the May 23, 2016 CASAC teleconference, an official summary of the February 2015 Workshop was not prepared. This is unfortunate. Thus, there are likely multiple views of what transpired at the Workshop. In my opinion, some participants, including CASAC PM Panel members, were already moving beyond discussing the science to considering their desired policy outcome – a revision and more stringent primary NAAQS for $PM_{2.5}$. A major issue discussed was the nature of the concentration-response function for mortality. Some individuals noted this relationship was linear to the lowest ambient concentrations of $PM_{2.5}$ studied in major epidemiological studies, ambient concentrations below the recently revised annual $PM_{2.5}$ NAAQS. They expressed the view that this was clear evidence of the need to reduce the NAAQS. These discussions failed to recognize that decision as to a specific numerical level and the associated statistical form for the $PM_{2.5}$ NAAQS are policy decisions informed by science not dictated by science and scientists. Some of this discussion spilled over into the May 23, 2016 CASAC PM Panel teleconference.

The draft Integrated Review Plan needs to be revised to explicitly define the role of the CASAC PM Panel in reviewing and advising on the PM science and the role of the EPA Administrator in making the policy decisions leading to reaffirmation or revision of the NAAQS for PM. Clarification of this critical issue now at the beginning of the NAAQS for PM review process will avoid needless debate later in the process.

IV. U.S. Health Data Required to Provide Context for Policy Decisions

The United States has made extraordinary progress in improving air quality since the Clean Air Act amendments of 1970 were passed. This improvement is apparent in many metrics, including those for each of the criteria pollutants such as particulate matter. This is illustrated in Figure 1 which shows data from the Harvard Six Cities study (Lepeule et al, 2012). Ambient concentrations, expressed as $PM_{2.5}$, are shown. For the earliest years, PM was measured using other metrics and has been converted to $PM_{2.5}$. In each of the communities there has been a steady decline in ambient $PM_{2.5}$. These trends are not unique to the Six Cities shown. Indeed, they are representative of what has occurred across the U.S.A. The question the nation, and the EPA Administrator, now face is how low is low enough? This is a policy decision that should be informed by scientific information. The CAA specifies how that question is to be addressed – assemble and integrate all the available science and use it to inform the policy decisions on how low is low enough. In my opinion, an important element of the decision-making process is context. I have discussed this matter in a paper that is in press (McClellan, 2016a).

An important element of the context for reviewing and then reaffirming or revising the NAAQS for PM are the baseline health data, both morbidity and mortality, for the U.S. and its various constituencies. These statistics are dynamic as shown in Figure 2. The U.S. is fortunate that it has a long-track record of continuous improvements in the health of the U.S. population. It is obvious that the United States is not monolithic and that the health status varies substantially across the various states and sub-populations.

The determinants of health of individuals and populations are extraordinarily complex, our inherited genetic makeup, our environment and our social economic status all influence our health. Some would argue that some of the improvements in health as illustrated in Figure 2 are attributable to improvements in air quality. This is no doubt true. However, it is clear that improved air quality is but one of many factors that have contributed to improved health in the U.S. over the past half century. Recall also that the health of the individuals who died in the past half century is also grounded in the earlier years of their lives.

The complexity of health and death is further illustrated in Table 1 showing causes of death for the U.S. population in 2010. The causes are varied and, in a generally healthy population like that of the U.S., are especially dominated by the diseases that are associated with old age, i.e., cardiovascular events and cancer.

When people die and what they die of is very complex. The tools we use to identify these associations are increasingly sophisticated and allow the statistical identification of very small, yet statistically significant associations between a range of factors, including air quality and different measures of health outcomes. The examination and interpretation of the small associations observed for differences in air quality needs to be done within a broader context of the multiple factors influencing health. For example, no one would consider interpreting for a particular population a set of findings on respiratory disease, including lung cancer, without asking about the smoking history of the population. The role of cigarette smoking is so dominant it must be considered.

The complexity of the situation is further illustrated by the data summarized in Table 2 taken from the landmark study of Steenland et al. (2004). These data clearly show the substantial impact of socio-economic status on health. It does matter whether one has a job and income and the level of income.

Some readers might be tempted at this point to argue that I have crossed the economic line that was settled in the landmark case, Whitman v. American Trucking Associations (2001), In that case, the court ruled "Section 109 does not delegate to the EPA authority to base the national ambient air quality standards, in whole or in part, upon the economic costs of compliance." However, this rule should not be interpreted as precluding the use of common sense in setting each NAAQS. The court clearly recognized that the setting of each NAAQS was not a mathematical exercise.

In my opinion, a careful reading of Justice Breyer's opinion in that case makes a compelling argument for the EPA Administrator to use context and common sense when making the policy decisions necessary to set standards that are "requisite to protect the public health" with "an adequate margin of safety." As Justice Breyer related, these words do not describe a world that is free of all risk – an impossible and undesirable objective. Nor are the words "requisite" and "public health" to be understood independent of context. Justice Breyer went on to advocate a comparative health risk context. Does the rule promote safety overall? He went on to note, a rule likely to cause more harm to health than it prevents is not a rule that is "requisite to protect public health."

It is my opinion that the Integrated Review Plan for the NAAQS for PM should include provision for a review and summary of U.S. Health Statistics that will provide context for the EPA Administrator's policy decisions that are necessary to either reaffirm or revise the NAAQS for PM. Such a summary is not only essential context for the EPA Administrator it will be valuable context for the CASAC PM Panel as it reviews the science available on PM and its health effects.

V. Section 109(d)(5)(c) Responsibilities

Section 109(d)(5)(c) of the CAA specifically states that CASAC "shall" (1) "advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity," and (2) "advise the Administrator of any adverse public health, welfare, social economic, or energy effects which may results from various strategies for attainment and maintenance of such national ambient air quality standards." These responsibilities have largely been ignored in past NAAQS reviews. For example, the issue of background ozone, to a large extent, was dealt with after the EPA Administrator had issued the final ozone NAAQS rule by issuing a white paper and holding a public meeting in Phoenix, AZ. The process was not totally satisfactory as I have related in comments to the Agency (McClellan, 2016b).

The issue of background PM versus anthropogenic origin PM is an important issue. This is especially the case where I live in the arid Southwest. It is important that it be addressed within the Integrated Science Assessment and other documents developed in the review. As with background ozone, the issue of background PM is at the interface between the NAAQS and implementation of the NAAQS. This suggests that it may warrant preparation of a white paper on this issue to be prepared by EPA staff and reviewed and commented on by CASAC and the

public during the NAAQS for PM review process. This approach rather than the "after the fact" approach used with background ozone should be more satisfying to multiple constituencies.

The issue of CASAC advising an adverse effects resulting from various strategies for attainment and maintenance of NAAQS is complex. Nonetheless, it must be addressed. I suggest a starting point is to address this issue in a forthright manner in the Integrated Review Plan. One approach would be for the EPA staff to draft a document on this topic and then proceed with CASAC review of the document. This might be done by a CASAC sub-committee in a manner similar to that used previously for review of EPA's monitoring plans for criteria air pollutants.

VI. Summary

In my comments I have identified three deficiencies in the "Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter." It is critical that these deficiencies be remedied in a revised final plan.

As I have emphasized, the continuing confusion over the role of CASAC in advising on the science that informs the EPA Administrator's policy decisions in setting the NAAQS versus its inappropriate incursion of CASAC into recommending prescriptive levels for the NAAQS must be resolved. The EPA staff, and indeed even some EPA Administrators, may find it expedient to have CASAC offer prescriptive recommendations as to the level and form of NAAQS for PM. However, that is a wrong-minded view that is not consistent with the requirements of the CAA. The policy decisions made by the EPA Administrator in this review leading to reaffirmation or revision of the NAAQS for PM will be among the most challenging of the policy decisions ever made on NAAQS.

It is crucial that the policy decisions on how low is low enough be made within a broad context of the remarkable progress made in improving air quality for PM and other air pollutants and the health of the U.S. populace. The factors that undergird further improvements in the health of the U.S. population are multiple and complex. A drive toward an estimated zero risk for PM, as some may advocate, can possibly be counter-productive. Inclusion of contextual information on the health of the U.S. population and the multiple factors influencing health of the U.S. population in the NAAQS review process will provide information that is essential to the EPA Administrator making wise policy decisions on "how low is low enough?" and, hence, reaffirmation or revision of the NAAQS for PM.

It is important that the requirements of Section 109(d)(5)(c) of the CAA be addressed. With the existing stringent $PM_{2.5}$ NAAQS, both annual and 24 hr, the issue of background levels becomes an important consideration as to whether the existing NAAQS can or cannot be attained. The issue of negative impacts associated with well-intentioned actions should not be ignored, but rather should be addressed in a thoughtful manner. Recognizing the issue in the Integrated Review Plan and recommending a path forward will be a positive step in the right direction.

VII. Figures and Tables

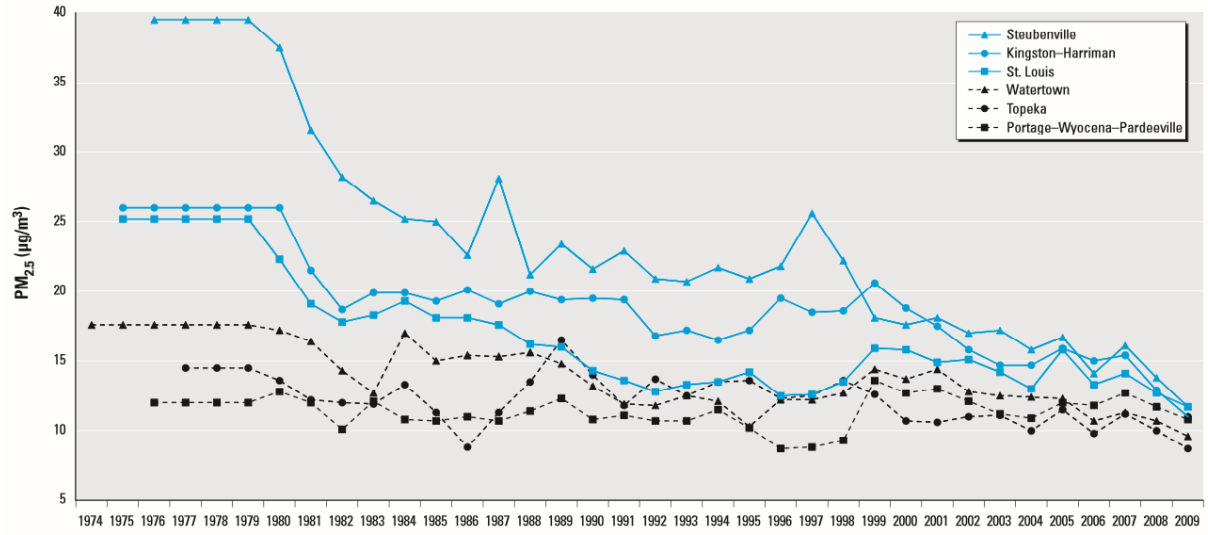

Figure 1 Annual mean $PM_{2.5}$ levels during 1974-2009 in the Harvard Six Cities study (Adapted from Lepeule et al (2012). The data points pre-1997 for $PM_{2.5}$ have been extrapolated from TSP and PM_{10} measurements.

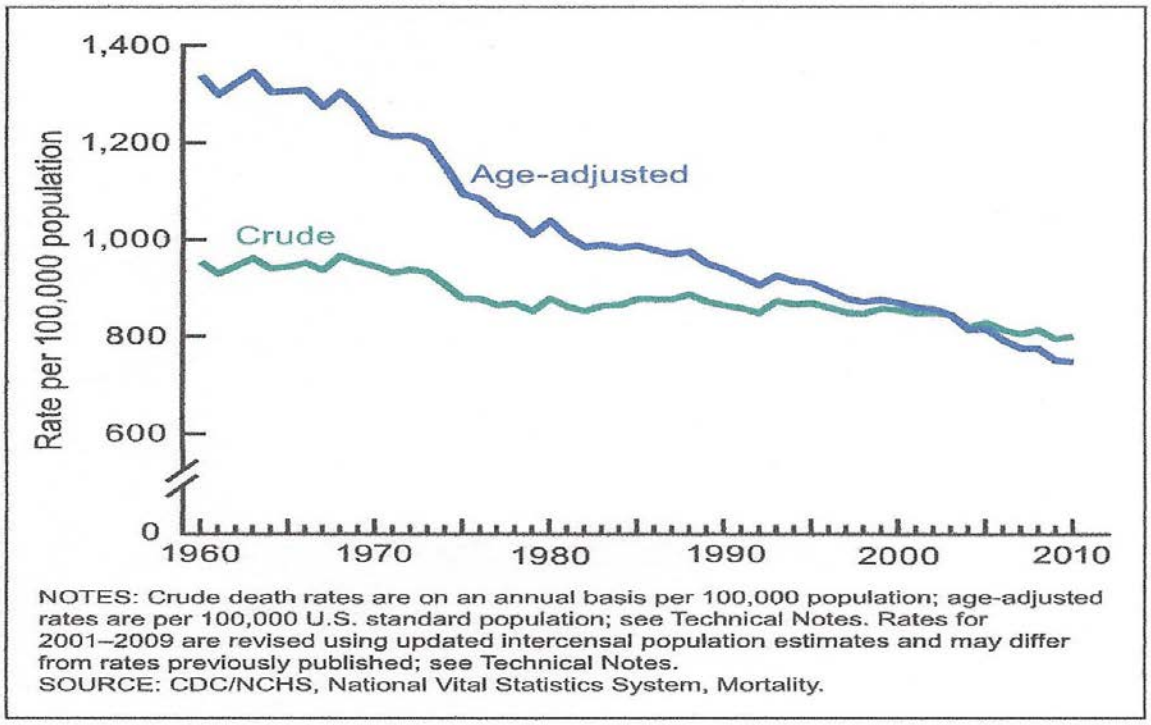

Figure 2. Crude and age-adjusted death rates: United States, 1960-2010 (Adapted from Murphy et al, 2013).

Table 1. Causes of Death for USA for 2010 by Major Causes (Murphy et al, 2013)

Rank	Cause of Death (based on ICD-10, 2004)	Number
…	All causes	2,468,435
1	Diseases of heart	597,689
2	Malignant neoplasms	574,743
3	Chronic lower respiratory diseases	138,080
4	Cerebrovascular diseases	129,476
5	Accidents (unintentional injuries)	120,859
6	Alzheimer's disease	83,494
7	Diabetes mellitus	69,071
8	Nephritis, nephrotic syndrome and nephrosis	50,476
9	Influenza and pneumonia	50,097
10	Intentional self-harm (suicide)	38,364
11	Septicemia	34,812
12	Chronic liver disease and cirrhosis	31,903
13	Essential hypertension and hypertensive renal disease	26,634
14	Parkinson's disease	22,032
15	Pneumonitis due to solids and liquids	17,011
…	All other causes	483,694

Table 2. The Impact of Socio-Economic Status on Mortality Rate Ratio[a] (adapted from Steenland et al, 2004)

Mortality	Men	Women
All causes	2.02 (1.95-209)[b]	1.29 (1.25-1.32)
Heart Disease	1.88 (1.83-193)	1.84 (1.76-1.93)
Stroke	2.25 (2.14-2.37	1.53 (1.44-162)
Diabetes	2.19 (2.07-2.32)	1.85 (1.72-2.00)
COPD	3.59 (3.35-3.83)	2.09 (1.91-230)
Lung Cancer	2.15 (2.07-2.23)	1.31 (1.25-1.39)
Breast Cancer	-	0.76 (0.73-0.79)
Colorectal Cancer	1.21 (1.16-1.27)	0.91 (0.86-0.96)
External Causes	2.67 (2.58-2.78)	1.41 (1.35-1.48)

[a] Mortality rate ratio = Mortality for lowest quartile of socioeconomic status / Mortality for highest quartile of socioeconomic status

[b] 95% Confidence Interval

VIII. Declaration of Interest

These comments were prepared by the author without any external funding. The viewpoints expressed and the recommendations made are exclusively those of the author.

IX. References

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BIOGRAPHY

ROGER O. McCLELLAN, DVM, MMS, DSc (Honorary), Dipl.ABT,
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ROGER O. McCLELLAN serves as an advisor to public and private organizations on issues of air quality in the ambient environment and work place using his expertise in inhalation toxicology, comparative medicine, and human health risk analysis. He received his Doctor of Veterinary Medicine degree with Highest Honors from Washington State University in 1960 and a Master of Management Science degree from the University of New Mexico in 1980. 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.

He served as Chief Executive Officer and President of the Chemical Industry Institute of Toxicology (CIIT) in Research Triangle Park, NC from September 1988 through July 1999. During his tenure, the organization achieved international recognition for the development of scientific information under-girding important environmental and occupational health decisions and 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. The Institute continues operation today as a core element of the Lovelace Respiratory Research Institute. 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 health effects of airborne radioactive and chemical materials. 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). In these assignments, he was involved in conducting and managing research directed toward understanding the human health risks of internally deposited radionuclides.

Dr. McClellan is an internationally recognized authority in the fields of inhalation toxicology, aerosol science, comparative medicine, and human health risk analysis. He has authored or co-authored over 350 scientific papers and reports and edited 10 books. In addition, he frequently speaks on risk assessment and air pollution issues 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 serves in an editorial role for a number of journals, including service since 1987 as Editor of Critical Reviews in Toxicology. He serves or has served on the Adjunct Faculty of 8 universities.

Dr. McClellan has served in an advisory role to numerous public and private organizations. He has served on senior advisory committees for all the major federal agencies concerned with human health. This included service as past Chairman of the Clean Air Scientific Advisory Committee, Environmental Health Committee, Research Strategies Advisory Committee, and Member of the Executive Committee, Science Advisory Board, U. S. Environmental Protection Agency; Member for 30 years, 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 (served as Chairman for 7 years), 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. He has served on the Board of Scientific Councilors for the Center for Environmental Health Research of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry and on the National Institutes of Health Scientific Advisory Committee on Alternative Toxicological Methods. He served on the National Aeronautics and Space Administration Lunar Airborne Dust Toxicity Advisory Group.

Dr. McClellan's contributions have been recognized by receipt of a number of honors, including election in 1990 to membership in the National Academy of Medicine. He is a Fellow of the Society for Risk Analysis, the American Association for Aerosol Research, the Health Physics Society, the International Aerosol Research Assembly, and the American Association for the Advancement of Science. In 1998, he received the International Achievement Award of the International Society of Regulatory Toxicology and Pharmacology for outstanding contributions to improving the science used for decision making and the International Aerosol Fellow Award of the International Aerosol Research Assembly for outstanding contributions to aerosol science and technology. In 2002, he was inducted into the University of New Mexico Anderson School of Management Hall of Fame for contributions to the effective management of multi-disciplinary research organizations. He received the Society of Toxicology Merit Award in 2003 for a distinguished career in toxicology and the Society's Founders Award in 2009 for contributions to science-based safety/risk decision-making. In 2012, he received a career achievement award from the International Dose-Response Society and the American Association for Aerosol Research and in 2014 from the Academy of Toxicological Sciences. In 2005, The Ohio State University awarded him an Honorary Doctor of Science degree for his contributions to comparative medicine and the science under-girding improved air quality. In 2006, he received the New Mexico Distinguished Public Service Award. In 2008, Washington State University presented Dr. McClellan the Regents Distinguished Alumnus Award, the highest recognition the University can bestow on an Alumnus.

Dr. McClellan has a long-standing interest in environmental and occupational health issues, especially those involving risk assessment, and air quality and in the management of multidisciplinary research organizations. He is a strong advocate of science-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