STATEMENT OF

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Hearing on "Improving EPA's Scientific Advisory Processes"

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Major Points of Testimony of Roger O. McClellan – March 20, 2013

(1) The U.S. Environmental Protection Agency's approach to creating and using scientific advisory committees and panels has continued to evolve over the 40 plus year history of the Agency. The rate of change needs to accelerate.

(2) The Scientific Advisory Committee activities are only loosely guided by specific statutes and heavily influenced by the Federal Advisory Committee Act.

(3) The proposed legislation advanced by the Sub-Committee has some clear strengths which should aid in further improving the scientific advisory committee process. I am concerned that it is narrow in its focus.

(4) The potential for major improvements in the EPA's advisory committee process requires (a) a broad review of past EPA advisory committee activities operations, (b) identification of best practices based on EPA experience and experience in both the public and private sector, and (c) potential modifications of the Federal Advisory Committee Act. The in-depth review needs to consider the interface with the public, advisory committee responsibilities and internal EPA deliberations (behind the Administrator's door) involving appointment of both committee members and consultants.

(5) Changes in the process should seek to engage the broader scientific community including scientists and engineers employed in the private sectors that are currently under-utilized in EPA's Advisory Committee activities either as Committee Members or Consultants.

(6) Changes in the advisory committee process should be directed toward achieving greater transparency in all phases of the nomination and appointment process, reduce bias related to past or future funding, avoid bias related to a Committee Member or Consultant's alignment with the Agency's policy goals and enhance true public participation from all sectors of the U.S. economy.

Good Morning, Mr. Chairman and Members of the Subcommittee. Thank you for the invitation to present my views on approaches to "Improving EPA's Scientific Advisory Processes."

My biography is attached to this statement (Attachment 1). 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 50 years of experience in comparative medicine, toxicology, aerosol science, and risk analysis. Prior to 1999, I provided scientific leadership for two organizations – the Chemical Industry Institute of Toxicology (1988-1999) in Research Triangle Park, NC and the Lovelace Inhalation Toxicology Research Institute (1966-1988) in Albuquerque, NM. The Chemical Industry Institute of Toxicology (now The Hamner Institutes for Health Sciences, was a not-for-profit research organization funded primarily by the chemical industry. The Lovelace Inhalation Toxicology Research Institute, continuing today as part of the Lovelace Respiratory Research Institute, was a non-profit research institute funded with both public and private funds. Both organizations, under my leadership, earned an international reputation for developing scientific information under-girding occupational and environmental health standards. During my career, I have held adjunct faculty appointments at 8 different universities and held major leadership roles in scientific organizations with membership from all sectors of the economy. The USA is fortunate to have well-qualified scientists engaged in all sectors.

The testimony I offer today also draws on my experience serving on numerous scientific advisory committees. This has included service on many EPA Scientific Advisory Committees from the origin of the Agency starting soon after the U.S. Environmental Protection Agency (EPA) was created by President Richard M. Nixon by Executive Order. At the time I was serving as Chair of the Environmental Radiation Exposure Committee to the U.S. Public Health Service (USPHS). When the USPHS radiation protection activities were transferred to the new EPA, the Environmental Radiation Exposure Advisory Committee became the responsibility of EPA along with dozens of other Advisory Committees that had operated as part of EPA's predecessor Agencies such as the National Air Pollution Control Administration. The Bureau of the Budget, the predecessor to the current Office of Management and Budget noted the large number of Advisory Committees and the hundreds of consultants. The Bureau of Budget thought there must be a more efficient way for the new Agency to secure scientific advice. The EPA responded, after seeking informal consent from the Congress, by creating a Science Advisory Board (SAB) under the Chairmanship of the late Dr. Emil Mrak, then Chancellor of the University of California-Davis. The SAB had umbrella committees organized along disciplinary lines; the key committees were Health, Engineering, and Ecology. I argued for an issue orientation of the committees and lost with my colleagues noting that "birds of a feather were comfortable together, that is the way we are organized in Academic institutions. Perhaps the radiation science field is different, so we will keep your Committee and have you join the SAB Executive Committee."

In one of my files I have a photograph of Administrator William Ruckelhaus providing me a certificate making my appointment official. Most of the early advisory attention focused on each Committee advocating for a bigger share of the budget from the EPA's newly created centralized Office of Research and Development.

One of the first major issues the EPA had to address was airborne Pb. The Natural Resources Defense Council (NRDC) had sued the EPA to have Pb listed as a criteria air pollutant under the Clean Air Act Amendments of 1970. When EPA lost the suit at the Appeals Court, it had to proceed with developing a Criteria Document to support its issuance of a National Ambient Air Quality Standard for Pb. Administrator Douglas Castle, on the advice of Dr. Mrak as Chair of the SAB, asked me to chair an *ad hoc* Committee to review the draft criteria document on airborne Pb. The Administrator appointed an appropriately diverse committee with multiple scientific and engineering disciplines represented. Within a week of the appointments being announced, I received a telephone call from one of the Committee members telling me that he had two problems with the Committee. One problem, as he expressed it, was that two committee members were "lackeys/toadies of industry." The second problem of concern to him was my serving as Chair – "I do not think you will advocate for a stringent airborne Pb NAAQS." Needless to say, the deliberations of the Committee, and especially the hallway conversations, were contentious. As the deliberations proceeded the EPA wisely decided to remove the recommendation of a specific Pb NAAQS from the criteria document recognizing that the concentration and averaging time were policy decisions. I am proud to note that when the ad hoc airborne Pb standard committee concluded its work the lead attorney from the NRDC congratulated me on my leadership of the Committee.

Thirty five years later two central concerns with EPA's Advisory Committee activities relate to (a) the role of scientists employed or engaged by industry versus academic scientists, and (b) the distinction between scientific advice and policy decisions.

Over the subsequent years I have served on the order of two dozen EPA Advisory Committees, including Chairmanship of a number of Committees and more than 20 years of service on the SAB Executive Committee. The SAB Executive Committee, consisting of about 12 individuals who chaired major SAB committees or had at-large appointments served a valuable role in coordinating the activities of multiple committees and, most importantly, advising the EPA Administrator on major scientific issues. I am disappointed the EPA SAB no longer has this kind of Executive Committee.

I am proud to say that the activities of the *ad hoc* Committee reviewing the Pb Criteria Document had a small role in the Congress amending the Clean Air Act in 1978 to formally require the EPA Administrator to appoint a Clean Air Scientific Advisory Committee (CASAC). I am pleased to have served as Chair of CASAC and in one of the seven positions mandated by the Clean Air Act and as a consultant on numerous CASAC Panels that considered all of the criteria pollutants. I note the role of both members of CASAC and consultants. In my opinion, appointment of CASAC members and consultants serves equal attention. The consultants frequently out-number the CASAC members. My last CASAC service was on the Particulate Matter (PM) Panel (2000-2007). The CASAC and the PM Panel struggled over the distinction between offering scientific advice and attempting to mandate the specific level of the NAAQS for $PM_{2.5}$. I was a minority on the Panel arguing that the specific concentration level and statistical forms of the NAAQS were inter-related policy decisions that should be informed by science. Science alone cannot identify the concentration and statistical form requisite to setting a NAAQS consistent with the language of the Clean Air Act. I have addressed this issue in a recent paper I authored entitled "Role of Science and Judgment in Setting National Ambient Air

Quality Standards: How low is low enough?" *Air Quality and Atmospheric Health* 5: 243-258, 2012.

In addition to serving on numerous EPA Advisory Committees, I have served on Advisory Committees to essentially all of the federal agencies that are concerned with environmental and occupational factors influencing the health of individuals and populations. I have also served on various committees of the National Research Council and the Institute of Medicine of which I am a member. In many cases, the issues at hand were at the interface between the physical and engineering sciences and the biological and medical sciences. Each of these disciplinary areas has different traditions and approaches to defining what is known and unknown on a given subject.

An issue of major concern for scientific advisory committees, irrespective of the issue being addressed, is how the deliberations and actions of the committee are influenced by funding the Committee members have received in the past or may receive in the future. This issue is of heightened interest as both federal and private sectors support for science are increasingly constrained. Indeed, the top priority for many organizations that are science-based is what can be done to make certain their scientific constituency receives its "fair share" of funding.

Many scientists hold the view that funding from federal agencies comes with no strings attached while anyone receiving private sector funding is indentured. In short, academic scientists are free of bias and conflicts of interest. I think such a viewpoint is open to question when the funding agency, such as the EPA, is also a regulatory agency. In my opinion, the agency needs to focus on reducing scientific uncertainty on a range of issues and take special precautions to avoid creating a funding environment focused on creating more stringent regulations. The creation of a more stringent standard or regulation should not be viewed as a criterion of success.

This brings us back to the importance of distinguishing between evaluation of the science and scientific advisory committees avoiding the temptation of entering the policy arenas and offering policy judgments. This is dangerous turf because many policy makers would like to say the science dictated the difficult policy decision; the Administrator was a mere bystander.

I am of the opinion that private sector funding is of critical importance to advancing scientific knowledge and its application. However, the interface between industry-funded science and its use in informing policy decisions needs the same kind of scrutiny as the science created with public funding.

An important underlying concern for the use of science to inform policy decisions is the availability of the underlying data for review and, indeed, re-analysis by others. In my opinion, any science used in the federal regulatory process should have been published in a high-quality peer-reviewed journal and the underlying data must be made available to qualified scientists for review and potential re-analysis. Key data used in the setting of several of the NAAQS in the past have not met the second test. As one academic scientist noted, "I do not want some industrial-hired gun wading through my data." I applaud the Johns Hopkins University team that created the National Morbidity and Mortality Air Pollution data set, used extensively in the

setting of several NAAQS, for making publicly available to others. My colleague, Dr. Suresh Moolgavkar, and I have recently used the NMMAPS data set to explore alternative approaches to data analysis (Moolgavkar, SH, McClellan, RO, et al, Time-Series Analyses of Air Pollution and Mortality in the United States: A Subsampling Approach. *Environ. Health Perspectives* 121(1): 73-78, 2013.). Likewise, I applaud the National Institute of Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI) for seeking ways to make the Diesel Exhaust in Miners Study (DEMS) available to qualified investigators. The complete data set acquired by federal employees and collaborators at a cost of over $12 million needs to be reviewed and re-evaluated by other scientists before it is used to establish federal regulations and standards.

Before leaving my discussion of service on EPA Advisory Committees, I would like to briefly note an EPA Committee I did not serve on – the CASAC Ozone Panel whose deliberations started in the early 2000s and concluded in 2008. When the CASAC Ozone Panel was being formed, I was encouraged by the Chair of CASAC to self-nominate for service on the Panel. I did so. Some months later I received a call from a Reporter asking if I had seen the letter a prominent NGO had sent to SAB concerning my services on the Panel. I said no. He said you need to see the comments; they are not very flattering. I promptly called the SAB offices and inquired about the letter. The SAB staffer acknowledged receipt of not one, but two letters concerning my potential service and that of two well-qualified colleagues. I asked if he would share the letters with me. His response was "I think you will need to file a Freedom of Information Act (FOIA) request." I told him "That is ridiculous – my fax machine is available and if I did not receive the letters within an hour I will take the matter up with the Administrator and my elected Senators and Representatives." I promptly received the letters via fax. The letters from two different NGOs were virtually identical. They questioned how I could be considered for membership on a CASAC Panel when I had previously served as President and CEO of the Chemical Industry Institute of Toxicology, a research laboratory principally funded by the chemical industry. To top it off, they suggested I was not qualified professionally to serve on the Panel since I was trained as a Veterinarian.

While I can appreciate the agency may wish to solicit comments on nominees to particular Committees, I think it should be with the understanding that any comments received by the Agency will be shared with the nominee. Indeed, if an organization is moved to comment on a nominee the organization should be willing to directly confront the nominee by sharing their concerns with the nominee. Appointments to scientific advisory committees should be made in an open and transparent manner and not influenced by sub rosea innuendos as to their qualifications. I will never know if those two letters influenced the Agency's decision to not appoint me to the Ozone Panel.

I appreciate the Subcommittee on Environment addressing the important topic of "Improving EPA's Scientific Advisory Process" and holding this hearing. I view this topic as part of a much bigger picture – <u>how do we move the economy of the USA forward building on this nation's remarkable pool of scientific talent?</u>

Let me provide some context for this statement. Last week at the Society of Toxicology meeting in San Antonio, TX, a senior EPA scientist/manager asked a question as to what were the most important factors influencing human health. I suspect he was interested in which of the

myriad of risk factors with relative risks of a few percentage points increases over background risk based on air quality a few decades ago deserved more research. My answer was simple – in my opinion, the single most important risk factor for the health of the U.S. citizens and other populations around the world is SOCIO-ECONOMIC STATUS (SES). Jobs and income matters! A study by Steenland et al (2004) showed the mortality ratio for all-cause mortality for men in the lowest quartile of SES over the top quartile is 2.02. In other words, a doubling of the mortality rate for individuals in the lowest quartile of SES versus those in the top quartile. Putting it another way, moving from the bottom quartile to the second quartile reduced the mortality ratio to 1.69 and a move from the second to the third quartile reduced the mortality ratio to 1.25. If the USA wants to improve the health of Americans we need to create employment – JOBS.

Some individuals reading this may argue that I am off track relative to the topic subject of this hearing. I am on track – let me explain.

The USA has a remarkable pool of scientific and engineering talent. We have excellent colleges and universities that attract students from around the world, including the world's most rapidly advancing economy – China. Historically, well-educated individuals have found an abundant of job opportunities in the USA. Indeed, many students who came from abroad elected to stay in the USA for the opportunities it afforded. The current job market for professionals in the USA is the softest I have seen during my professional career. I am optimistic the situation can change, however, major change will require many small and seemingly insignificant changes.

One change that is required is to start using ALL of the USA's scientific and engineering talent as candidates to serve as members or consultants on Scientific Advisory Committees such as those assembled by the EPA. In the past, EPA's scientific advisory committees have been composed largely of academic scientist and engineers. Using information from the EPA's SAB website I note that 41 of the 46 members of the chartered SAB are from academic institutions and 87 of the 110 members of seven standing committees are from academic institutions. I know many of these academicians personally; they are first-rate scientists or engineers. Do they represent the best and brightest of all the scientists and engineers in the USA? The answer cannot be Yes since that would mean the millions of scientists and engineers employed in the private sector somehow do not measure up. Baloney!

Some will quickly note that those in the private sector have financial conflicts of interest that preclude their service on EPA Advisory Committees because of requirements of the Federal Advisory Committee Act (FACA). If FACA is used to deny the EPA of the talents of individuals from the private sector, then I think the solution is quite simple – Congress should change FACA. Some academic scientists and EPA managers would argue that individuals in the private sector are biased – their primary motivation is making certain their employer stays profitable. I am glad they have that motivation, it is important. It is consistent with the best interests of the USA. I have worked with many private sector firms and employees. I can assure you they understand the importance of getting the science right to ensure long-term profitability. I am tired of some scientists telling me that the actions of the U.S. Tobacco industry are proto-typical of all U.S. industry. That statement is clearly false.

One might ask why it is important to broaden the talent pool for service on EPA Advisory Committees. One good reason is context. EPA's scientific committees deal with complex issues, not abstract scientific facts, but science interpreted in the context of complex issues. The question is not just whether a chemical or technology is hazardous, but, also how can the use of the chemical be changed or the technology advanced to reduce health hazards and increase efficiency and effectiveness. Private sector scientists and engineers deal with these concepts daily and could bring the concepts to bear in Committee discussions. Everyone wins when all participants contribute to the dialogue and everyone takes something home to their university or private sector job.

In preparation for this hearing I reviewed the SAB website to determine the status of formation of several new committees. I found lists of nominees for two committees – "Hydraulic Fracturing Potential Impacts on Groundwater Resources" and "Polychlorinated Biphenyls (PCBs) Review." I noted that there were 144 nominees for the "Fracturing Panel" and 55 nominees for the PCB Panel. I was encouraged that the "Hydraulic Fracturing" nominees included a number of individuals employed in the private sector, including many with real-world experience in hydraulic fracturing. This is encouraging since I am aware of groups that have addressed health concerns of hydraulic fracturing without anyone on the Committee ever having visited a hydraulic fracturing site. I will be following with interest EPA's announcement of the composition of the final committee. I do hope it includes individuals from the private sector and environmental NGOs to complement the academic appointees. Moreover, I hope that the first meeting includes a visit to a hydraulic fracturing site with the committee members putting on fire retardant clothing, steel-capped boots and other protective gear as they learn what "hydraulic fracturing" is all about. I am confident everyone will learn something new!

Beyond that first meeting I hope that the remaining hydraulic fracturing committee meetings will be face-to-face meetings. This is important for committee members to get to know their fellow committee members and, moreover, face-to-face meetings encourage public participation. I hope that at least one-third of the time at each meeting is reserved for public comment and dialogue. I strongly discourage the use of "Tower of Babel" teleconferences. If a topic warrants assembling a Committee, it warrants face-to-face meetings of the Committee.

As the Committee proceeds with its deliberations I strongly encourage the use of both written and oral communications in which <u>every</u> committee member clearly states their scientific views on the topic at hand. If the topic is outside their professional expertise, they should note that. In my opinion, consensus views are fine for religious, labor and political assemblies. Science is best served by examining all facets of a scientific issue and making certain all of the nuances are explored and covered in the Committee's final communication to the Administrator and the public.

The PCB review activity noted earlier is part of the Agency's on-going Integrated Risk and Information System (IRIS). The Agency's IRIS activities are currently being revitalized with new leadership from Dr. Ken Olden. In my view that revitalization is long overdue and Dr. Olden has it on the right track. I learned earlier this week that the activities of the proposed PCB committee may be handled as a Subcommittee or Panel of the Chemical Assessment Advisory

Committee. However the Committee is assembled, I do hope that it will include an appropriate number of individuals from the private sector.

In conclusion, I want to emphasize the comments I have offered are my own personal views. They do not necessarily represent the views of any public or private organizations I have advised.

I will be pleased to address any questions you may have now or wish to forward to me.

ATTACHMENT 1

BIOGRAPHY

ROGER O. McCLELLAN, DVM, MMS, DSc (Honorary),
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ROGER O. McCLELLAN serves as an advisor to public and private organizations on issues concerned with inhalation toxicology, comparative medicine, and human health risk analysis focusing on issues of air quality in the ambient environment and work place. He has over three decades of experience studying the human health hazards of exposure to diesel exhaust and promoting advances in diesel technology to minimize any health hazards. 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 1988 through 1999. CIIT continues today as The Hamner Institute for Health Sciences. During his tenure, the organization achieved international recognition for development of scientific information under-girding important environmental and occupational health decisions and regulations. Prior to his CIIT appointment, Dr. McClellan was Director of the Inhalation Toxicology Research Institute, and President of the Lovelace Biomedical and Environmental Research Institute, Albuquerque, New Mexico. The Institute continues today as a core element of the Lovelace Respiratory Research Institute. During 22 years with the Lovelace organization, he provided leadership for development of one of the world's leading research programs concerned with the health hazards 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 those assignments, he conducted and managed 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 the major federal agencies concerned with human health. This included services 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, National Council on Radiation Protection and Measurements; Member, Advisory Council for Center for Risk Management, Resources for the Future; 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 currently serves 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 Institute of Medicine of the National Academy of Sciences. He is a Fellow of the Society for Risk Analysis, the American Association for Aerosol Research, the Health Physics Society, 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 the Outstanding Career Achievement Award of the International Dose-Response Society for contributions to understanding dose-response relationships and the David Sinclair Award of the American Association for Aerosol Research for sustained excellence in aerosol research and technology.

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.