Statement of
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Good morning, my name is George Gray, and I am the Assistant Administrator for the Office of Research and Development in EPA. I wish to thank you for the opportunity to discuss the EPA's evaluation of the scientific evidence for potential health effects of airborne particulate matter (PM). Last week the Subcommittee on Clean Air, Climate Change and Nuclear Safety heard from my colleague, William L. Wehrum, the Acting Assistant Administrator for Air and Radiation, on the EPA's review of the national ambient air quality standards (NAAQS) for PM. During that testimony he explained the crucial role of science in helping to inform decisions about the National Ambient Air Quality Standards.

Today, I would like to talk with you in more detail about this science: how it is prioritized and developed, and how it is synthesized and integrated. As Assistant Administrator for EPA's Office of Research and Development (ORD), I am responsible both for the development of new scientific information targeted to address critical Agency research needs and for the evaluation, synthesis, and integration of the world's peer-reviewed science literature into a document that informs EPA decision-makers. As we characterize the current state of our collective scientific knowledge, we are careful to point out the strengths and weaknesses of this large body of information, so that informed decisions can be made. It is clear that the scientists and staff of ORD play a crucial role in the development and evaluation of the world's scientific information to inform the review of National Ambient Air Quality Standards.

We all agree that environmental protection efforts must be based on high quality science. High quality science includes both the conduct of research—in the laboratory and in the field—and the careful evaluation of that body of research to inform policy making. High quality research is focused appropriately on generating new knowledge that addresses complex scientific issues and helps reduce important scientific uncertainties. It is carefully planned, well conducted, and thoroughly peer reviewed by independent scientific experts. The careful and balanced *characterization* of the body of knowledge created by high quality science requires an open process, interaction with appropriate subject matter experts, and serious consideration of the ways in which the results are communicated to decision makers. To me, an important component of high quality science is the characterization of the uncertainties related to individual studies and, more generally, the characterization of the weight of the scientific evidence.

First, let me discuss EPA's efforts to develop new and relevant science on particulate matter. The Agency has a longstanding and strong program to develop and use new scientific knowledge on the health effects of airborne PM. After the last review of the PM NAAQS in 1997, EPA embarked on a very ambitious research effort to advance our knowledge and address important uncertainties in the science related to PM. Congress requested that we sponsor the National Academies of Science (NAS) to provide us advice. The NAS Committee on Research Priorities for Airborne Particulate Matter in the National Research Council completed four reports, published between 1998 and 2004, which provided the scientific basis EPA used to target its resources to address the highest priority PM research needs. These needs are being addressed by the Agency's particulate matter research program, with more than $500 million during the past ten years committed by EPA in support of the highest priority research topics identified by the NAS. These funds have supported numerous research efforts by EPA's intramural laboratories, as well as extramural researchers funded through our competitively awarded Science to Achieve Results (STAR) program, our PM Research Centers, and interagency agreements with other federal agencies. EPA also coordinates closely with other federal agencies on PM research through the Committee on Environment and Natural Resources (CENR) Air Quality Research Subcommittee and its Interagency Working Group on Particulate Matter.

We learn about the potential health effects of PM through several different types of research, especially epidemiology and toxicology. Guided by the NAS and other advisors, the Agency has funded research in all of these areas. Epidemiologic studies supported by EPA and others provide key information in our evaluation of PM. This research includes population-based studies that evaluate potential associations between human exposure to PM and health outcomes, including death, hospitalization, illness, and potential precursors to illness. We have sponsored research on populations of tens to hundreds of thousands of individuals in the United States that evaluates the effects of long-term exposure to PM on illness and death. These include both cohort studies and panel studies. Other research uses a different design—called time-series studies—in which air pollution levels are tracked on a day-to-day basis and compared with daily variations in health statistics to evaluate the effects of short-term exposures to PM on health. These time-series studies included hundreds of communities and databases that describe millions of residents. Other epidemiologic studies attempt to identify factors affecting people's susceptibility and the role of co-pollutant exposures.

Toxicology studies, sponsored by EPA and others, provide both information to evaluate the strength and plausibility of the associations identified through epidemiology and hypotheses that form the basis of new epidemiological studies. Important studies include those that evaluate the components of PM that may be producing toxicity, and the mechanisms by which such toxicity might occur.

These research efforts have resulted in literally thousands of published studies in the peer-reviewed literature over the past several years. In 2005, EPA prepared a report, *Particulate Matter Research Program: Five Years of Progress,* which highlighted the early results of EPA's substantial investment in PM. When it came time to prepare the science basis for the next evaluation of the PM standards (the 2004 Air Quality Criteria Document), more than 4000 articles from the peer-reviewed literature were reviewed—many of which came from research EPA had done in our laboratories or had funded through our STAR grants.

A second, and equally important, function of EPA efforts is the synthesis and integration of these thousands of individual "acts of science" to provide a clear characterization of our knowledge and the degree to which we still are uncertain about aspects of PM health and environmental effects. We have a scientifically rigorous process by which we evaluate and interpret this important body of knowledge and ensure that our interpretation of them is complete, transparent, unbiased, and consistent with the array of views in the scientific community. A fundamental step in the review of the National Ambient Air Quality Standards is the evaluation of scientific evidence and the preparation of scientific assessments, by the National Center for Environmental Assessment of the Office of Research and Development, known as "criteria documents." The development of criteria documents involves the review of thousands of peer-reviewed research publications, evaluation of those studies most relevant to the review of the air quality standards, and integration of the scientific evidence across disciplines. The body of evidence must be reviewed, evaluated, weighed and then accurately and objectively described to inform our decisions about National Ambient Air Quality Standards.

For the current PM review, EPA evaluated research studies that addressed a wide range of issues including PM toxicology, epidemiology, atmospheric chemistry, human exposure, and other areas such as environmental effects. Thousands of studies were reviewed and over 2000 studies were referenced in the criteria document, many of which were conducted or funded by EPA's Office of Research and Development. Considered together, these new studies significantly advanced our understanding of PM's potential effects on public health and welfare and reduced the uncertainty associated with some important aspects of the science. Drawing on the evaluation of studies reviewed in the PM criteria document about health effects and dose-response, as well as information about exposures to PM, EPA also completed a risk assessment to estimate the degree to which various approaches for revising the standards would potentially affect the public health risks posed by PM. Further, the Agency prepared a document known as a "staff paper" that utilized the evaluation and characterization of scientific evidence in the criteria document together with the results of the risk assessment to help inform the policy judgments required in making decisions on the NAAQS.

Extensive independent external peer review was conducted on the criteria document, risk assessment, and staff paper by the Clean Air Scientific Advisory Committee (CASAC). CASAC, statutorily-mandated under the Clean Air Act, is a group of independent scientific and technical experts appointed by the Administrator to review EPA's evaluation and use of scientific and technical information related to air quality and make recommendations as appropriate. CASAC is made up of nationally-recognized scientists from a variety of relevant disciplines. For PM, CASAC was extensively involved in reviewing and commenting on several drafts of the PM criteria document, staff paper, and risk assessment. Their efforts, and those by EPA staff to address CASAC's comments, resulted in a PM science assessment that provides comprehensive, relevant information suitable to serve as the scientific basis for Administrator Johnson's decisions on the PM NAAQS.

Let me briefly highlight some scientific information available on particulate matter. First, as a scientist, I know that all scientific research includes aspects of uncertainty. For example, we often do not understand the mechanisms by which pollutants such as particulate matter produce health effects in the population. We know our measurements of environmental conditions and biological response contain some uncertainty due both to our understanding and technological limits. To have uncertainty is normal. Uncertainty is a factor to be characterized and considered in the evaluation of studies and other data. We always consider the strengths and limitations of the available evidence when drawing conclusions about what that evidence means for decision making.

For example, we highlighted the uncertainty in the evidence linking chronic exposure to PM 2.5 with premature mortality in the 1997 review of the PM NAAQS. In the next few years, EPA responded by funding a major reanalysis by independent investigators of two important long-term studies that used data from a Harvard Six Cities cohort and an American Cancer Society cohort. The quality of the data was evaluated, and an extensive series of sensitivity analyses were performed using various statistical models to test for the influence of many potential co-variables. The results duplicated the association between levels of chronic exposure to PM 2.5 and premature mortality. These analyses were important in reducing our uncertainty about the consideration of these data in the standard-setting process. In addition, the analyses identified other avenues of research. For example, one study indicated that the estimated effects of fine particles appeared to vary with education level.

In another example of our efforts to tackle uncertainty, EPA sponsored a number of multi-city epidemiologic studies designed to address the limitations inherent in single-city studies. Multi-city studies allow the assessment of risks of mortality or hospitalization across cities, thus reducing uncertainty regarding the effects of local features, such as differing mixes of pollutants and climates, on the interpretation of study findings. The results of these multi-city studies provide

additional evidence that levels of exposure to PM 2.5 are likely to be linked with serious health effects.

Another major area of uncertainty remaining from the previous review was the lack of demonstrated biological mechanisms or pathways by which PM exposure could result in the effects observed in population-based studies. An important factor in evaluating the associations uncovered in epidemiologic investigations is biological plausibility, i.e., whether there is a coherent way in which the reported association could be expected to occur in the body. As noted in our 2005 report, EPA-funded research has provided crucial insights into numerous hypothesized mechanisms; including evidence that exposure to particles may contribute to atherosclerosis development and affect cardiac rhythm, thus linking the findings of mortality in the epidemiologic studies to plausible biological mechanisms of toxicity.

Looking across the large landscape of study findings, our assessment of the research results for particulate matter finds evidence of a coherence of health effects associated with PM2.5 across many types of study designs, biological endpoints and time frames. The body of evidence—the thousands of studies from a wide variety of disciplines we have evaluated with the help of CASAC—demonstrates that PM2.5 exposure is likely causally associated with outcomes such as cardiovascular and respiratory morbidity and premature mortality from both epidemiologic and toxicology studies. Toxicology studies help us understand the mechanisms that provide some evidence of biological plausibility in the observations from epidemiological studies. We recognize that uncertainty exists, but uncertainty is not a barrier to decision-making; rather it is critical information to be factored into informed decisions.

We also recognize that science is not static. New studies on PM are being published in the peer-reviewed literature all the time. As a continuation of the scientific review process, EPA recently conducted a survey of the evidence reported in the scientific literature since completion of the literature review reflected in the 2004 criteria document. This new survey includes some 700 additional studies and has emphasized the studies most relevant to the PM NAAQS decision. The provisional assessment of these new studies has only just been completed. To provide the public with an opportunity to review the survey results, we will provide notice of the completion of this survey and post the results on our Web sites. In brief, the provisional assessment concluded that taken in context, the new information and findings provide additional support regarding the health effects of PM exposure made in the 2004 PM Air Quality Criteria Document but do not materially change any of the broad scientific conclusions.

In summary, the Bush Administration is committed to the development and use of the highest quality science to inform environmental decision making. The mission of the Office of Research and Development is to develop, evaluate, and

communicate relevant scientific information to the Administrator, and to assure that the Administrator is well informed of the nature, strengths, and limitations of this information. EPA has sponsored a targeted and effective research program on particulate matter and I am pleased to convey to you and others the value of this investment. We have made a great effort to evaluate and characterize the existing and new scientific results available on particulate matter, and I am personally pleased to share with you my views on this work. I look forward to addressing any questions you may have.

Thank you.