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PARTICULATE MATTER

EPA Has Started to
Address the National
Academies'
Recommendations on
Estimating Health
Benefits, but More
Progress Is Needed



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Highlights of [GAO-06-780](#), a report to congressional requesters

Why GAO Did This Study

A large body of scientific evidence links exposure to particulate matter—a widespread form of air pollution—to serious health problems, including asthma and premature death. Under the Clean Air Act, the Environmental Protection Agency (EPA) periodically reviews the appropriate air quality level at which to set national standards to protect the public against the health effects of particulate matter. EPA proposed revisions to these standards in January 2006 and issued a draft regulatory impact analysis of the revisions' expected costs and benefits.

The estimated benefits of air pollution regulations have been controversial in the past. A 2002 National Academies report generally supported EPA's approach but made 34 recommendations to improve how EPA implements its approach. GAO was asked to determine whether and how EPA applied the Academies' recommendations in its estimates of the health benefits expected from the January 2006 proposed revisions to the particulate matter standards. GAO examined the draft analysis, met with EPA officials, and interviewed members of the National Academies' committee. In providing technical comments on the report, EPA officials said it was fair and balanced and noted the agency's progress in addressing recommendations via research and development and other analyses.

www.gao.gov/cgi-bin/getrpt?GAO-06-780.

To view the full product, including the scope and methodology, click on the link above. For more information, contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov.

PARTICULATE MATTER

EPA Has Started to Address the National Academies' Recommendations on Estimating Health Benefits, but More Progress Is Needed

What GAO Found

EPA has begun to change the way it conducts and presents its analyses of health benefits in response to recommendations from the National Academies. Specifically, EPA applied, at least in part, 22—or about two-thirds—of the Academies' recommendations to its health benefit analysis of proposed revisions to particulate matter standards. For example, in response to some of the recommendations, EPA took steps toward conducting a more rigorous assessment of uncertainty by, for instance, evaluating how benefits could change under different assumptions and discussing sources of uncertainty not included in the benefit estimates. In one case, EPA applied an alternative technique, called expert elicitation, for evaluating uncertainty by systematically gathering expert opinion about the uncertainty underlying the causal link between exposure to particulate matter and premature death. Consistent with the National Academies' recommendation to assess uncertainty by developing ranges of estimates and specifying the likelihood of attaining them, EPA used expert elicitation to develop ranges of reductions in premature death expected from the proposed revisions. EPA officials said that ongoing research and development efforts will allow the agency to gradually achieve more progress in applying the recommendations. We note that robust uncertainty analysis is important because estimates of health benefits can be highly uncertain, as the draft regulatory impact analysis for particulate matter illustrates. EPA viewed the estimates in this analysis as so uncertain that it chose not to present them in the executive summary.

For various reasons, EPA has not applied the remaining 12 recommendations to the analysis, such as the recommendation to evaluate the impact of using the simplifying assumption that each component of particulate matter is equally toxic. EPA officials viewed most of these recommendations as relevant to its health benefit analyses and, citing the need for additional research and development, emphasized the agency's commitment to continue to respond to the recommendations. For example, EPA did not believe that the state of scientific knowledge on the relative toxicity of particulate matter components was sufficiently developed to include in the January 2006 regulatory impact analysis, and the agency is currently sponsoring research on this issue. In addition, a senior EPA official said that insufficient resources impeded the agency's progress in applying the recommendations, citing, in particular, the limited availability of skilled staff, time, and other resources to conduct the required analyses and research and development. EPA officials also said that some of the recommendations the agency did not apply to the draft analysis, such as one calling for a summary table describing key analytical information to enhance transparency, will be applied to the analysis supporting the final rule. To the extent that EPA continues to make progress addressing the Academies' recommendations, decision makers and the public will be better able to evaluate the basis for EPA's air regulations.

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Abbreviations

Academies	National Academies
ACS	American Cancer Society
Council	Advisory Council on Clean Air Compliance
EPA	Environmental Protection Agency
NAAQS	National Ambient Air Quality Standards
OMB	Office of Management and Budget
PM	particulate matter
RIA	regulatory impact analysis
SAB	Science Advisory Board

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United States Government Accountability Office
Washington, D.C. 20548

July 14, 2006

The Honorable James M. Inhofe
Chairman
Committee on Environment and Public Works
United States Senate

The Honorable George Voinovich
Chairman
Subcommittee on Clean Air, Climate Change,
and Nuclear Safety
Committee on Environment and Public Works
United States Senate

A large body of scientific evidence links exposure to particulate matter—a ubiquitous form of air pollution commonly referred to as soot—to serious health problems, including asthma, chronic bronchitis, heart attack, and premature death. The many sources releasing particulate matter into the air include cars, trucks, power plants, industrial processes, forest fires, and waste incinerators. In 1971, the Environmental Protection Agency (EPA) first established national air quality standards to protect the public against the health effects of particulate matter, one of the six widespread criteria pollutants considered harmful to public health. Under the Clean Air Act, EPA determines the appropriate level at which to set national air quality standards, and the states must develop programs to achieve and maintain compliance with them. Further, EPA must review the standards every 5 years to determine whether they adequately protect human health and welfare, given the latest scientific information available, and revise them if they do not.

In January 2006, after its most recent review of the national air quality particulate matter standards, EPA proposed revisions to the standards and issued a draft regulatory impact analysis. Overall, the draft regulatory impact analysis discussed the scope and magnitude of the particulate matter problem, the likely benefits of the proposed revisions for public health and the environment, and the expected costs of implementing the standards. Regarding public health, the analysis presented estimates of expected health benefits for the particulate matter revisions in five major urban areas, including reductions in the number of premature deaths and emergency room visits for asthma. Among the changes EPA said it plans to make in its final regulatory impact analysis is providing national estimates

of expected health benefits. EPA is required under a court order to issue the final rule on particulate matter standards by September 2006.¹

In 2000, at the direction of the Senate Appropriations Committee, EPA asked the National Academies (Academies) to evaluate EPA's methodology for estimating the health benefits of proposed air pollution regulations.² According to the National Academies, these estimates have often been controversial, and the methods EPA has used to prepare them have been questioned. For example, some observers, such as researchers and industry groups, have expressed concerns that EPA does not adequately factor uncertainty into its estimates of health benefits. Some level of uncertainty is unavoidable, in part because the scientific information used to develop estimates, such as the inventory of particulate matter emissions, will never be perfect or complete. However, according to some observers, EPA's estimates of benefits appear more definitive than they really are because the agency does not adequately account for uncertainty in its analyses or in its reporting of health benefit estimates.

The National Academies' 2002 report on this subject generally supported EPA's approach to estimating health benefits but, nevertheless, made 34 detailed recommendations to improve how EPA implements its approach.³ Overall, these recommendations focus on conducting more rigorous assessments of uncertainty, increasing the transparency of how EPA estimates benefits, conducting more detailed analyses of exposure, and estimating the benefits of each regulatory option under consideration. Many of the recommendations include qualifying language indicating that it is reasonable to expect that they can be applied in stages, over time; and a number of the recommendations are interrelated and, in some cases, overlapping.

You asked us to determine whether and how EPA applied the National Academies' recommendations in its estimates of the health benefits expected from the January 2006 proposed revisions to the particulate matter standards. To respond to this objective, we reviewed EPA's draft

¹*American Lung Ass'n v. Whitman*, No. 1:03CV00778 (D. D.C. 2003).

²The National Academies comprises four organizations: the National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council.

³National Research Council, *Estimating the Public Health Benefits of Proposed Air Pollution Regulations* (Washington, D.C., 2002).

regulatory impact analysis presenting the costs and benefits of the proposed rule and met with senior officials from EPA's Office of Air and Radiation, which was responsible for developing the proposed rule and analyzing its costs and benefits, and with officials from EPA's Office of Policy, Economics, and Innovation. We also reviewed EPA's and the Office of Management and Budget's (OMB) guidance on conducting economic analyses, prior GAO reports on EPA's regulatory impact analyses, and other relevant reports. As requested, our work addressed the application of the National Academies' recommendations to EPA's draft regulatory impact analysis supporting the 2006 proposed particulate matter rule; thus, we did not examine how EPA applied the recommendations to other recent air rules. Our work focused on broadly characterizing EPA's progress toward applying the recommendations; we did not evaluate the effectiveness and quality of the scientific and technical actions the agency has taken to apply the recommendations. See appendix I for a more detailed description of the scope and methodology of our review. We performed our work from January 2006 to July 2006 in accordance with generally accepted government auditing standards.

Results in Brief

EPA has begun to change the way it conducts and presents its analyses of health benefits in response to the National Academies' recommendations, which focused on conducting more rigorous assessments of uncertainty, increasing the transparency of how EPA estimates benefits, conducting more detailed analyses of exposure, and estimating the benefits of each regulatory option under consideration. EPA applied, at least in part, about two-thirds of the recommendations to its health benefit analysis. Specifically, of the 34 recommendations, EPA applied 8 and partially applied 14. For example, EPA responded to some of the recommendations by taking steps to conduct a more rigorous assessment of uncertainty by, for instance, evaluating how benefits might change given alternative assumptions and discussing sources of uncertainty not included in the benefit estimates. More specifically, EPA applied an alternative technique for evaluating one important source of uncertainty in its analysis—the uncertainty underlying the causal link between exposure to particulate matter and premature death. Consistent with the National Academies' recommendation to assess uncertainty by developing ranges of estimates of benefits and specifying the likelihood of attaining that level of benefits, EPA systematically gathered expert opinions about this link—through a process called expert elicitation—and developed ranges reflecting the experts' confidence in attaining reductions in premature death expected from the proposed revisions. However, the health benefit analysis does not

similarly assess how the benefit estimates would vary in light of other key uncertainties as the Academies had recommended. Consequently, this represents a partial application of the recommendation. Agency officials told us that ongoing research and development efforts will allow EPA to gradually achieve more progress in applying this and other recommendations to future analyses.

For various reasons, EPA did not apply the remaining 12 recommendations to the analysis, such as the recommendation to evaluate the impact of using the assumption that the components of particulate matter are equally toxic. EPA officials viewed most of these recommendations as relevant to its health benefit analyses, but noted that the agency was not ready to apply specific recommendations because of, among other things, the need to overcome technical challenges stemming from limitations in the state of available science. These officials emphasized the agency's commitment to continue to respond to the recommendations. For example, EPA did not believe that the state of scientific knowledge on the relative toxicity of particulate matter components was sufficiently developed to include it in the January 2006 regulatory impact analysis, and the agency is sponsoring research on this issue. In addition, according to a senior EPA official, insufficient resources have impeded the agency's progress in applying the recommendations, including the limited availability of skilled staff, time, and other resources to conduct and oversee the required analyses and research and development. Finally, EPA officials stated that some of the recommendations the agency did not apply to the draft analysis, such as one calling for a summary table describing key analytical information to enhance transparency, will be applied to the regulatory impact analysis supporting the final rule. To the extent that EPA continues to make progress addressing the Academies' recommendations, decision makers and the public will be able to better evaluate the basis for EPA's air regulations.

We provided a draft of this report to EPA for review. EPA provided technical comments that we incorporated, as appropriate. Officials from EPA's Office of Air and Radiation noted in their technical comments that the report provides a fair and balanced representation of the agency's application of the recommendations to the particulate matter regulatory impact analysis and cited EPA's progress in meeting the National Academies' recommendations through other analyses of air programs and through research and development efforts.

Background

EPA is required by the Clean Air Act to conduct reviews of the National Ambient Air Quality Standards (NAAQS) for the six criteria pollutants, including particulate matter, every 5 years. The overarching purpose of such reviews is to determine whether the current standards are sufficient to protect public health and welfare at large, with an adequate margin of safety, given the latest scientific information available at the time of the review. Major steps in the NAAQS process include the following:

- developing a criteria document that synthesizes new research on health and environmental effects;
- preparing a staff paper that assesses the policy implications of the scientific information in the criteria document, which also discusses possible ranges for air quality standards; and
- determining whether and how EPA should revise the NAAQS.

If EPA decides to revise the NAAQS, the agency proposes the changes in the *Federal Register*. As part of the federal rule-making process, EPA is to comply with Executive Order 12866, which directs federal agencies to analyze the costs and benefits of proposed and final rules expected to affect the economy by \$100 million or more per year.⁴ In September 2003, the Office of Management and Budget (OMB) issued its Circular A-4, which presents guidance and best practices and states that agencies should analyze the costs and benefits in accordance with the principles of full disclosure and transparency. Further, in cases such as the particulate matter rule, where expected economic impacts exceed \$1 billion annually, Circular A-4 also states that agencies should conduct a comprehensive assessment of key uncertainties in their analyses of costs and benefits, which EPA also refers to as regulatory impact analyses.⁵ EPA's January 2006 regulatory impact analysis presents estimates of the costs and benefits for the proposed particulate matter rule.

⁴The Clean Air Act prohibits EPA from basing revisions to the national air quality standards on costs. Because most national air quality revisions qualify as significant actions under Executive Order 12866, EPA usually assesses the expected benefits and costs of the standards under the Executive Order.

⁵Specifically, Circular A-4 states that agencies should conduct a formal probabilistic assessment of key uncertainties underlying its cost-and-benefit estimates. OMB Circular No. A-4, Regulatory Analysis (Sept. 17, 2003).

The focus of the National Academies' 2002 report was on how EPA estimates the health benefits of its proposed air regulations. To develop such estimates, EPA conducts analyses to quantify the expected changes in the number of deaths and illnesses that are likely to result from proposed regulations. The regulatory impact analyses also estimate the costs associated with implementing proposed air regulations, although, under the Clean Air Act, EPA is not permitted to consider costs in setting health-based standards for the criteria air pollutants, such as particulate matter.

Soon after the National Academies issued its report in 2002, EPA staff identified key recommendations and developed a strategy, in consultation with OMB, to apply some of the recommendations to benefit analyses for air pollution regulations under consideration at the time. EPA roughly approximated the time and resource requirements to respond to the recommendations, identifying those the agency could address within 2 or 3 years and those that would take longer. According to EPA officials, the agency focused primarily on the numerous recommendations related to analyzing uncertainty.

Both the National Academies' report and the OMB guidance emphasize the need for agencies to account for uncertainties and to maintain transparency in the course of conducting benefit analyses. Identifying and accounting for uncertainties in these analyses can help decision makers evaluate the likelihood that certain regulatory decisions will achieve the estimated benefits. Transparency is important because it enables the public and relevant decision makers to see clearly how EPA arrived at its estimates and conclusions. In prior work on regulatory impact analyses, we have found shortcomings in EPA's analyses of uncertainty and the information the agency provides with its estimates of costs and benefits.⁶

⁶GAO, *Air Pollution: Information Contained in EPA's Regulatory Impact Analyses Can Be Made Clearer*, [GAO/RCED-97-38](#) (Washington, D.C.: Apr. 14, 1997); and *Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations*, [GAO/RCED-84-62](#) (Washington, D.C.: Apr. 6, 1984).

EPA Is in the Process of Addressing Many of the Academies' Recommendations

EPA applied—either wholly or in part—approximately two-thirds of the Academies' recommendations to its January 2006 regulatory impact analysis and continues to address the recommendations through ongoing research and development. The January 2006 regulatory impact analysis demonstrated progress toward an expanded analysis of uncertainty and consideration of different assumptions. EPA officials cited time and resource constraints, as well as the need to mitigate complex technical challenges, as the basis for not applying other recommendations. According to EPA officials, the agency did not apply some of the more complex recommendations because it had not achieved sufficient progress in the research and development projects under way.

EPA Applied, at Least in Part, about Two-thirds of the Recommendations to Its Particulate Matter Health Benefit Analysis in the Proposed Rule

The January 2006 regulatory impact analysis on particulate matter represents a snapshot of an ongoing EPA effort to respond to the National Academies' recommendations on developing estimates of health benefits for air pollution regulations. Specifically, the agency applied, at least in part, approximately two-thirds of the recommendations—8 were applied and 14 were partially applied—by taking steps toward conducting a more rigorous assessment of uncertainty for proposed air pollution regulations by, for example, evaluating the different assumptions about the link between human exposure to particulate matter and health effects and discussing sources of uncertainty not included in the benefit estimates. According to EPA officials, the agency focused much of its time and resources on the recommendations related to uncertainty. In particular, one overarching recommendation suggests that EPA take steps toward conducting a formal, comprehensive uncertainty analysis—the systematic application of mathematical techniques, such as Monte Carlo simulation—and include the uncertainty analysis in the regulatory impact analysis to provide a “more realistic depiction of the overall uncertainty” in EPA's estimates of the benefits.⁷ A number of the other recommendations regarding uncertainty are aimed at EPA's developing the information and methodologies needed to carry out a comprehensive uncertainty analysis.

⁷Monte Carlo simulation refers to a computer-based analysis that uses probability distributions for key variables, selects random values from each of the distributions simultaneously, and repeats the random selection over and over. Rather than presenting a single outcome—such as the mostly likely or average scenario—Monte Carlo simulations produce a distribution of outcomes that reflect the probability distributions of modeled uncertain variables.

Overall, the uncertainty recommendations suggest that EPA should determine (1) which sources of uncertainties have the greatest effect on benefit estimates and (2) the degree to which the uncertainties affect the estimates by specifying a range of estimates and the likelihood of attaining them. In response, EPA devoted significant resources to applying an alternative technique called expert elicitation in a multiphased pilot project. The pilot project was designed to systematically obtain expert advice to begin to better incorporate in its health benefit analysis the uncertainty underlying the causal link between exposure to particulate matter and premature death. EPA used the expert elicitation process to help it more definitively evaluate the uncertainty associated with estimated reductions in premature death—estimates that composed 85 percent to 95 percent of EPA's total health benefit estimates for air pollution regulations in the past 5 years, according to the agency.⁸ EPA developed a range of expected reductions in death rates based on expert opinion systematically gathered in its pilot expert elicitation project and provided the results of this supplemental analysis in an appendix to the regulatory impact analysis.⁹ However, the National Academies had recommended that EPA merge such supplemental analyses into the main benefit analysis.

Moreover, the Academies recommended that EPA's main benefit analysis reflect how the benefit estimates would vary in light of uncertainties. In addition to the uncertainty underlying the causal link between exposure and premature death that EPA analyzed, other key uncertainties can influence the estimates. For example, there is uncertainty about the effects of the age and health status of people exposed to particulate matter, the varying composition of particulate matter, and the measurements of actual exposure to particulate matter. EPA's health benefit analysis, however, does not account for these key uncertainties by specifying a range of estimates and the likelihood of attaining them, similar to estimates derived from the

⁸It is important to note, according to EPA, that quantified benefit estimates do not include other potential benefits, such as reduction in certain illnesses or environmental impacts, because of limited data. The fraction of total benefits attributable to reductions in mortality may therefore vary as other benefits are incorporated in the numerical estimates.

⁹The pilot expert elicitation, based on methods that were peer-reviewed, involved structured, daylong interviews with five experts about particulate matter exposure and death. EPA then analyzed the experts' responses to develop ranges reflecting the experts' confidence in estimated reductions in premature death associated with the proposed revisions. Pending completion of a peer review, EPA plans to include the analysis of a full-scale expert elicitation panel in the final regulatory impact analysis.

expert elicitation addressing causal uncertainty. For these reasons, EPA's responses reflect a partial application of the Academies' recommendation.

In addition, the Academies recommended that EPA both continue to conduct sensitivity analyses on sources of uncertainty and expand these analyses. In the particulate matter regulatory impact analysis, EPA included a new sensitivity analysis regarding assumptions about thresholds, or levels below which those exposed to particulate matter are not at risk of experiencing harmful effects. EPA has assumed no threshold level exists—that is, any exposure poses potential health risks.¹⁰ Some experts have suggested that different thresholds may exist and the National Academies recommended that EPA determine how changing its assumption—that no threshold exists—would influence the estimates. The sensitivity analysis EPA provided in the regulatory impact analysis examined how its estimates of expected health benefits would change assuming varying thresholds.

Another recommendation that EPA is researching and partially applied to the draft regulatory impact analysis concerns alternative assumptions about cessation lags—the time between reductions in exposure to particulate matter and the health response. The National Academies made several recommendations on this topic, including one that EPA incorporate alternative assumptions about lags into a formal uncertainty analysis to estimate benefits that account for the likelihood of different lag durations. In response, EPA has sought advice from its Advisory Council on Clean Air Compliance Analysis on how to address this recommendation and has conducted a series of sensitivity analyses related to cessation lags. EPA is also funding research to explore ways to address lag effects in its uncertainty analysis. According to an EPA official, specifying the probability of different lag effects is computationally complex, and the agency is working to resolve this challenge.

In response to another recommendation by the National Academies, EPA identified some of the sources of uncertainty that are not reflected in its benefit estimates. For example, EPA's regulatory impact analysis disclosed that its benefit estimates do not reflect the uncertainty associated with

¹⁰Recent EPA analyses used the natural background concentrations of particulate matter, rather than zero, for its assumption of no threshold level. The National Academies supported the assumption of no threshold level, but it recommended that EPA conduct a consistent and transparent sensitivity analysis to consider various threshold levels.

future year projections of particulate matter emissions. EPA presented a qualitative description about emissions uncertainty, elaborating on technical reasons—such as the limited information about the effectiveness of particulate matter control programs—why the analysis likely underestimates future emissions levels. EPA also applied the Academies’ recommendation on the presentation of uncertainty, which encouraged the agency to present the results of its health benefit analyses in ways that convey the estimated benefits more realistically by, for example, placing less emphasis on single estimates and rounding the numbers. EPA’s regulatory impact analysis presented ranges for some of the benefit estimates. Also, EPA sought to convey the overall uncertainty of its benefit estimates in a qualitative manner by clearly stating that decision makers and the public should not place significant weight on the quantified benefit estimates in the regulatory impact analysis because of data limitations and uncertainties.

Another example of EPA’s response to the National Academies’ recommendations involves exploring the various regulatory choices available to decision makers. The Academies recommended that EPA estimate the health benefits representing the full range of regulatory choices available to decision makers. In the particulate matter analysis, EPA presented health benefits expected under several regulatory options targeting fine particulate matter. Citing a lack of data and tools needed to conduct an accurate analysis, EPA did not estimate the benefits expected under the proposed regulatory options for coarse particulate matter but, consistent with the National Academies’ recommendation, presented its rationale for not doing so. Overall, we considered this a partial application of the recommendation. (See app. II for more detail on the recommendations that EPA has applied or partially applied to the draft particulate matter regulatory impact analysis.)

EPA Plans to Address Some of the Remaining Recommendations in the Final Rule and Has Research and Development Under Way to Address Others

EPA did not apply the remaining 12 recommendations to the analysis for various reasons. While EPA applied some recommendations—either wholly or in part—that require additional studies, methodologies, or data to its particulate matter analysis, the agency had not made sufficient progress in addressing others and therefore did not apply them to the analysis. EPA officials viewed most of these recommendations as relevant to its health benefit analyses and, citing the need for additional research and development, emphasized the agency’s commitment to continue to respond to the recommendations. According to a senior EPA official, insufficient resources impeded the agency’s progress in applying the

recommendations. This official cited limited availability of skilled staff, time, and other resources to conduct the required analyses and research and development. According to EPA, some of the more complex, long-term recommendations include the following: relying less on simplifying assumptions, such as the assumption that the various components of particulate matter have equal toxicity;¹¹ conducting a formal assessment of the uncertainty of particulate matter emissions; and assessing the expected reduction of any harmful effects other than air pollution or human health problems.

For example, EPA is in the process of responding to a recommendation involving the relative toxicity of components of particulate matter, an emerging area of research that has the potential to influence EPA's regulatory decisions in the future.¹² Specifically, the agency could, hypothetically, refine national air quality standards to address the potentially varying health consequences associated with different components of particulate matter. The National Academies recommended that EPA strengthen its benefit analyses by evaluating a range of alternative assumptions regarding relative toxicity and incorporate these assumptions into sensitivity or uncertainty analyses as more data become available.¹³ EPA did not believe the state of scientific knowledge on relative toxicity was sufficiently developed at the time it prepared the draft regulatory

¹¹Particulate matter is a highly complex mixture comprising particles emitted directly from sources and particles formed through atmospheric chemical reactions. Particles span many sizes and shapes and consist of hundreds of different chemicals. EPA identifies the major components of fine particulate matter as carbon, sulfate and nitrate compounds, and crustal/metallic materials such as soil and ash.

¹²Relative toxicity refers to the premise that different components of particulate matter have different levels of potency affecting premature mortality and illness. In the draft particulate matter regulatory impact analysis, EPA assumed equivalent toxicity, stating that "while it is reasonable to expect that the potency of components may vary across the numerous effect categories associated with particulate matter, EPA's interpretation of scientific information considered to date is that such information does not yet provide a basis for quantification beyond using fine particle mass." EPA, *Draft Regulatory Impact Analysis for the PM-2.5 National Ambient Air Quality Standards* (Washington, D.C., 2006), 3-21.

¹³In the context of the National Academies recommendations, a sensitivity analysis would assess how changes in one or more variables affect the outcome, whereas a comprehensive or formal uncertainty analysis would evaluate the probability distributions of multiple variables.

impact analysis to include this kind of analysis.¹⁴ However, EPA is sponsoring research on this issue. For example, EPA is supporting long-term research on the relative toxicity of particulate matter components being conducted by EPA's intramural research program, its five Particulate Matter Research Centers, and the Health Effects Institute, an organization funded in part by EPA. In addition, an EPA contractor has begun to investigate methods for conducting a formal analysis that would consider sources of uncertainty, including relative toxicity and lag effects. To date, the contractor has created a model to assess whether and how much these sources of uncertainty may affect benefit estimates in one urban area.

The National Academies also recommended that EPA incorporate an assessment of uncertainty into the early stages of its benefit analyses by characterizing the uncertainty of its emissions estimates on which the agency is going to base its benefit estimates.¹⁵ While the agency is investigating ways to assess or characterize this uncertainty, EPA did not conduct a formal uncertainty analysis for particulate matter emissions for the draft regulatory impact analysis because of data limitations. These limitations stem largely from the source of emissions data, the National Emissions Inventory,¹⁶ an amalgamation of data from a variety of entities, including state and local air agencies, tribes, and industry. According to EPA, these entities use different methods to collect data, which have different implications for how to characterize the uncertainty. Furthermore, the uncertainty associated with emissions varies by the source of emissions. For example, the analytical methods for evaluating the uncertainty of estimates of emissions from utilities would differ from those for car and truck emissions because the nature of these emissions and the data collection methods differ. In sum, to apply this recommendation, EPA

¹⁴In a separate report issued in 2004, the National Academies identified relative toxicity as a priority research topic, noting that technical challenges have impeded research progress. The Clean Air Scientific Advisory Committee also noted the need for more research and concluded in 2005 that not enough data are available to base the particulate matter standards on composition. OMB, however, encouraged EPA in 2006 to conduct a sensitivity analysis on relative toxicity and referred the agency to a sensitivity analysis on relative toxicity funded by the European Commission.

¹⁵Because the precise levels of total emissions are not knowable but rather approximations based on a sample of measurements, there is uncertainty about the true quantity of emissions.

¹⁶EPA compiles the National Emissions Inventory, a national database of air emissions data that includes estimates of annual emissions, by source, of air pollutants in each area of the country on an annual basis.

must determine how to characterize the uncertainty of the estimates for each source of emissions before aggregating the uncertainty to a national level and then factoring that aggregation into its benefit estimates. According to EPA officials, the agency needs much more time to resolve the complex technical challenges of such an analysis. EPA officials also noted that the final particulate matter analysis will demonstrate steps toward this recommendation by presenting emissions data according to the level emitted by the different kinds of sources, such as utilities, cars, and trucks.

Another recommendation that EPA is researching but did not apply to the draft regulatory impact analysis concerns whether the proposed revisions to the particulate matter standards would have important indirect impacts on human health and the environment. According to an EPA official, the agency could not rule out the possibility that the revisions could have indirect impacts on the environment, such as whether reductions to particulate matter emissions would reduce the amount of particulate matter deposited in water bodies, thereby decreasing water pollution. EPA has considered indirect impacts of air pollution regulations on sensitive water bodies in the past and plans to include a similar analysis in the final particulate matter rule. An agency official further noted that ongoing research about environmental impacts could reveal additional indirect impacts for future analyses.

Other recommendations that EPA did not apply to its benefit estimates in the regulatory impact analysis concern issues such as transparency and external review of EPA's benefit estimation process. For example, the National Academies recommended that EPA clearly summarize the key elements of the benefit analysis in an executive summary that includes a table that lists and briefly describes the regulatory options for which EPA estimated the benefits, the assumptions that had a substantial impact on the benefit estimates, and the health benefits evaluated. EPA did not, however, present a summary table as called for by the recommendation or summarize the benefits in the executive summary. As EPA stated in the particulate matter analysis, the agency decided not to present the benefit estimates in the executive summary because they were too uncertain. Specifically, officials said the agency was not able to resolve some significant data limitations before issuing the draft regulatory impact analysis in January 2006—a deadline driven by the need to meet the court-ordered issue date for the final rule in September 2006. According to EPA officials, EPA has resolved some of these data challenges by, for example, obtaining more robust data on anticipated strategies for reducing

emissions, which will affect the estimates of benefits. The officials also said that EPA intends to include in the executive summary of the regulatory impact analysis supporting the final rule a summary table that describes key analytical information. EPA officials also acknowledged other presentation shortcomings, including references to key analytical elements that were insufficiently specific, that officials attributed to tight time frames and the demands of working on other regulatory analyses concurrently. They said they plan to address these shortcomings in the final regulatory impact analysis.

Regarding external review, the National Academies recommended that EPA establish an independent review panel, supported by permanent technical staff, to bolster EPA's quality control measures for its regulatory impact analyses, such as the one for particulate matter. The National Academies noted that peer review of EPA's regulatory impact analyses would be advantageous when the agency designs and conducts its economic analysis.¹⁷ EPA has not directly addressed this recommendation. According to the Director of the Office of Policy Analysis and Review in EPA's Office of Air and Radiation, establishing and supporting independent committees is costly, making it important for EPA to take advantage of existing panels rather than set up new ones. Further, an official in the Office of Air and Radiation who oversees the development of regulatory impact analyses said that the cost of reviewing all regulatory impact analyses would be substantial. In this regard, EPA officials identified peer reviews the agency received from its existing independent committees, such as the Clean Air Scientific Advisory Committee and the Advisory Council on Clean Air Compliance.¹⁸ For example, to respond to the Academies' recommendations about lag effects, EPA sought independent advice on the assumptions it was developing regarding the time between reduced exposure to particulate matter and reductions in incidences of health

¹⁷In prior work on regulatory economic analyses, we recommended that OMB direct agencies to obtain peer review of these analyses. See GAO, *Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses*, GAO/RCED-98-142 (Washington, D.C.: May 26, 1998).

¹⁸The Advisory Council on Clean Air Compliance, composed of rotating membership, serves to advise the agency on choices relating to data, modeling, and methodology associated with air programs and does not review regulatory impact analyses. Established under the Clean Air Act and operated through the Science Advisory Board, the advisory council advises EPA, under Section 812 of the act, on developing the "statutorily mandated comprehensive analyses of the total costs and total benefits of programs implemented pursuant to the Clean Air Act." These analyses are commonly referred to as the 812 studies.

effects.¹⁹ Finally, EPA officials noted that although the agency does not have each regulatory impact analysis peer reviewed, EPA typically does have the methodologies that will be applied to regulatory impact analyses peer reviewed. (See app. III for more detail on these recommendations and others that EPA did not apply to the draft particulate matter regulatory impact analysis.)

Concluding Observations

While EPA has taken a number of steps to respond to the Academies' recommendations on estimating health benefits, continued commitment and dedication of resources will be needed if EPA is to fully implement the improvements endorsed by the National Academies. In particular, the agency will need to ensure that it allocates resources to needed research on emerging issues, such as the relative toxicity of particulate matter components; assessing which sources of uncertainty have the greatest influence on benefit estimates; and estimating other benefits, such as environmental improvements. In addition, it is important for EPA to continue to improve its uncertainty analysis in accordance with the Academies' recommendations. The agency's draft regulatory impact analysis illustrates that estimates of health benefits can be highly uncertain. In fact, EPA officials viewed these estimates as so uncertain that they chose to not present them in the executive summary of the regulatory impact analysis. While EPA officials said they expect to reduce the uncertainties associated with the health benefit estimates in the final particulate matter analysis, robust uncertainty analysis will nonetheless be important for decision makers and the public to understand the likelihood of attaining the estimated health benefits. According to EPA officials, the final regulatory impact analysis on particulate matter will reflect further responsiveness to the Academies' recommendations by, for example, providing additional sensitivity analysis and improving the transparency of the regulatory impact analysis by highlighting key data and assumptions in the executive summary. Moreover, these officials emphasized the agency's commitment to further enhancing the transparency of the analysis by presenting clear and accurate references to the supporting technical documents, which detail the analytical assumptions and describe the data supporting the estimates. To the extent EPA continues to make progress addressing the Academies' recommendations, decision makers and the public will be able to better evaluate the basis for EPA's air regulations.

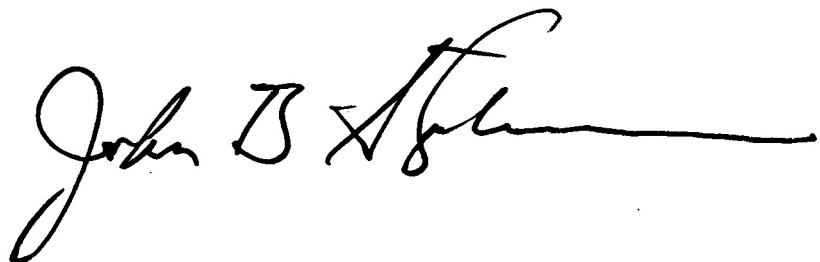
¹⁹In 2004, EPA asked for and received guidance from the Advisory Council on Clean Air Compliance on the lag estimates the agency should use in the particulate matter analyses.

Agency Comments

We provided a draft of this report to EPA for review. EPA provided technical comments that we incorporated, as appropriate. Officials from the Office of Policy Analysis and Review within EPA's Office of Air and Radiation noted in their technical comments that the report provides a fair and balanced representation of EPA's efforts to apply the National Academies' recommendations to the draft particulate matter regulatory impact analysis. However, these officials also cited progress made in applying the National Academies' recommendations through analyses of other air programs and through research and development efforts. We note that this report does identify, as appropriate, EPA's research and development efforts for recommendations EPA did not apply to the draft particulate matter analysis, its plans to apply some additional recommendations to the final particulate matter regulatory impact analysis, and the agency's responses to recommendations in prior rule-making analyses of air programs.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the EPA Administrator and other interested parties. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix IV.



John B. Stephenson
Director, Natural Resources and Environment

Scope and Methodology

We were asked to determine whether and how the Environmental Protection Agency (EPA) applied the National Academies (Academies) recommendations in its estimates of the health benefits expected from the January 2006 proposed revisions to the particulate matter national ambient air quality standards. In response to this objective, we assessed EPA's response to the Academies' recommendations and present an overview of the agency's completed, ongoing, and planned actions addressing the recommendations. To develop this overview, we reviewed EPA's particulate matter regulatory impact analysis, EPA's economic analysis guidelines, and Office of Management and Budget (OMB) guidance on regulatory impact analysis. We also analyzed documentation addressing current and future agency efforts to address the recommendations, such as project planning memorandums and technical support documents discussing the application of economic techniques. In addition, we met with senior officials from EPA's Office of Air and Radiation, which was responsible for developing the proposed rule and analyzing its economic effects, and with officials from EPA's Office of Policy, Economics, and Innovation to discuss the agency's responses to the recommendations. We interviewed several experts outside EPA, including (1) the Chair and other members of the National Academies' Committee on Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations, to clarify the basis for their recommendations; and (2) economists at Resources for the Future, to discuss the technical issues underlying the recommendations on uncertainty analysis.

While the 2002 National Academies' report is generally applicable to EPA air pollution regulations, our review focused on the application of the recommendations to the proposed revisions to the particulate matter standards, as requested. Our work focused on broadly characterizing EPA's progress toward applying the recommendations; we did not evaluate the effectiveness or quality of the scientific and technical actions the agency has taken to apply them. To assess whether and how EPA has made progress in responding to the recommendations, we developed the following recommendation classification continuum: applied, partially applied, and not applied. The applied and partially applied categories refer to completed and initiated actions in EPA's health benefit analysis of particulate matter that corresponds to components of the National Academies' recommendations. The not applied category includes recommendations that EPA did not apply when conducting the analysis for the January 2006 particulate matter regulatory impact analysis and identifies those for which ongoing research and development efforts were not far enough along to apply to the particulate matter analysis. We

Appendix I
Scope and Methodology

performed our work from January 2006 to July 2006 in accordance with generally accepted government auditing standards.

Recommendations Applied or Partially Applied to the Draft Particulate Matter Regulatory Impact Analysis

Table 1 provides a summary of the National Academies' recommendations that EPA has applied or partially applied to its draft regulatory impact analysis (RIA) for particulate matter (PM). This table also provides GAO's assessment of EPA's progress in applying each recommendation, in terms of steps EPA has taken thus far to address issues highlighted in the National Academies' report. The final column characterizes EPA's comments regarding each recommendation, including, as pertinent, contextual information, potential impediments to application, and intended next steps.

**Appendix II
Recommendations Applied or Partially
Applied to the Draft Particulate Matter
Regulatory Impact Analysis**

Table 1: Recommendations Applied or Partially Applied to the Draft Particulate Matter Regulatory Impact Analysis

	National Academies' recommendation	Status	GAO assessment	EPA's response
1	To the extent possible, EPA should estimate the benefits for several regulatory options that represent the full range of choices available to the decision maker. The regulatory options should include graded levels of stringency requirements and the time schedule for achieving reductions in emissions or exposures. If options are eliminated at an earlier stage, the rationale for doing so should be provided.	Partially applied	EPA estimated the health benefits for the base case and some of the proposed standards for fine particulate matter, but did not estimate benefits that represented the full range of choices available to the decision maker. In addition, EPA did not estimate the benefits for coarse particulate matter. While EPA provided an explanation as to why it did not estimate benefits for the regulatory options for coarse particulate matter, it did not present its rationale for not estimating the benefits of the full range of options for fine particulate matter.	EPA did not estimate benefits for coarse particulate matter primarily because of a lack of data and tools needed to conduct an accurate analysis. In addition, EPA said that time and resources limited the number of regulatory options to be modeled. EPA said that given these constraints, the agency selected regulatory options that represent reasonable bounds on alternatives.
2	EPA should modify the air quality models used in translating predicted emissions into predicted levels of ambient air quality to reduce resources required for air quality modeling. This change is necessary if EPA is to evaluate multiple regulatory alternatives and to evaluate each alternative at reasonable time intervals, such as every 5 years. Evaluation of the ambient air quality associated with more emissions scenarios is also essential if the uncertainty inherent in emissions estimates is to be carried through to the estimation of avoided cases of mortality and morbidity.	Partially applied	EPA has modified air quality models but has not yet demonstrated that these changes reduce resources. EPA reports faster modeling runs once it has designated a model but has also needed to conduct more complex model runs, which require time.	EPA characterized its response to this recommendation as a work in progress. EPA said that the agency has achieved greater efficiency in the models, but that the overall time and resources devoted to modeling have not decreased because of the increased complexity and increased volume of air quality model runs. Citing emissions data limitations as an ongoing challenge, EPA reported notable improvements to the emissions inventory that contributed to efficiency gains in air quality modeling runs. Overall, EPA is working to balance efforts to streamline models with the demands for more sophisticated analyses. In addition, EPA cited additional analytical requirements, such as new peer review policies and OMB's expanded data quality guidelines, that add to the complexity of, and therefore time and resources needed for, its models.

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Recommendations Applied or Partially
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	National Academies' recommendation	Status	GAO assessment	EPA's response
3	EPA should incorporate estimates of future trends in background mortality and morbidity for the major health outcomes, such as those that make up two-thirds of total deaths or lost life years that are under consideration.	Partially applied	EPA incorporated future trends in background mortality rates but did not do so for future morbidity trends.	EPA did not incorporate future morbidity trends because of time constraints. As time permits, EPA plans to incorporate such projections in the final analysis.
4	As in all other stages of the benefits analysis, EPA should justify and clearly describe the assumptions and methods used to assess exposure, choose health outcomes, and select studies and concentration-response functions, paying careful attention to assessing and communicating key sources of uncertainty.	Partially applied	The draft PM RIA presented EPA's justifications and included clear descriptions of a number of assumptions and methods used in the benefit analysis. As discussed elsewhere, EPA's assessment of key sources of uncertainty generally relied on qualitative discussion and sensitivity analysis (see recommendation 14). However, the extent to which EPA provided justifications and clear descriptions varied. For example, EPA included detailed information about why it chose studies related to the concentration-response function, but the agency did not present its justification for an assumption used to assess exposure.	EPA intends to include references in the final RIA, detailing the assumptions and methods underlying its health benefits analyses. EPA stated that rather than restating information from prior RIAs, it provides references to these discussions in order to manage the length of the RIA and save time. Furthermore, EPA stated that it is not necessary to document assumptions for tools that have already been peer reviewed, such as BenMAP, the model used to estimate health benefits.
5	Because pollution modeling rarely addresses the smaller-scale issue of how local concentrations from specific source categories interact with human time-activity patterns, EPA should examine how different major source categories—for example, mobile versus large stationary sources—affect total exposures per unit emissions.	Partially applied	EPA assessed local concentrations in terms of how different source categories, such as stationary and mobile sources of PM, affect total exposures. However, EPA has not yet assessed how human-time activity patterns, such as lifestyles, affect exposure to PM.	EPA focused on assessing the local concentrations from specific source activities but assumed the same time and activity patterns for each scenario. EPA stated that it does not intend to conduct a detailed analysis of micro-environmental issues or human-time activity patterns.
6	EPA should consider data from U.S. and non-U.S. studies to extrapolate beyond the age groups evaluated and incorporate other relevant outcomes not evaluated in its current benefit analyses.	Applied	EPA considered data from additional U.S. studies as part of its effort to expand the age groups in its estimates of the health outcomes (premature mortality and illness). EPA extrapolated beyond the age groups in some cases, but not all.	EPA determined, on the basis of advice from the Science Advisory Board, that it would only extrapolate data to other ages when it found a reasonable physiological basis for doing so. For example, EPA used data from a study on asthma in children ages 7 to 11 to estimate the reductions in asthma for the entire child age group—ages 6 to 18.

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Recommendations Applied or Partially
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	National Academies' recommendation	Status	GAO assessment	EPA's response
7	EPA provided little information in the benefit analyses reviewed by the committee on causal association between particular types of air pollution and adverse health outcomes. EPA should summarize the evidence for causality to justify the inclusion or exclusion of the health outcomes and to assess the uncertainty associated with the assumption of causality.	Applied	EPA referred readers to a prior RIA for information on the causal association between particulate matter and adverse health outcomes.	
8	EPA should investigate and, if necessary, develop methods of evaluating causal uncertainty relating to key outcomes so that this uncertainty can be represented in the final benefit estimates.	Applied	EPA investigated one method—expert elicitation—to evaluate how causal uncertainty affects final benefit estimates. See recommendation 14 for more details.	EPA intends to continue its effort to better characterize the uncertainty in key health outcomes.
9	Although the committee believes the use of the American Cancer Society (ACS) study to derive premature mortality estimates was reasonable, EPA should thoroughly review its selection of the best estimate for long-term effects of air pollution on mortality. Several new studies have been published since the ACS study, including an extended analysis of the ACS study, a new U.S. cohort study, and other non-U.S. studies. EPA should also consider whether the derivation of a weighted mean estimate from the cohort studies is appropriate following review of the database.	Applied	EPA reviewed its selection of the best estimate for long-term effects of air pollution on mortality and concluded that data from the extended analysis of the ACS study provided the best estimates of premature mortality. EPA consulted the Science Advisory Board to reach its decision to emphasize the ACS data. EPA also determined that it was not appropriate to derive a weighted mean estimate from cohort studies.	EPA incorporated new studies regarding estimates of premature mortality and justified the concentration-response functions derived from these studies. These justifications were included in technical appendices to the draft PM RIA. EPA also consulted with the Science Advisory Board regarding the best estimates for premature mortality. EPA decided not to derive a weighted mean estimate because the use of this estimate would risk losing the variability across cohort studies.
10	To evaluate short-term effects of air pollution, EPA should use concentration-response functions from studies that integrate over several days or weeks the exposure period and the time period to the event (cumulative or distributed lag models), rather than those that restrict these time periods to 1 or 2 days.	Applied	EPA used studies that integrate distributed lag models that account for the onset of health effects occurring more than several days after exposure.	
11	Although the assumption of no thresholds in the most recent EPA benefit analyses was appropriate, EPA should evaluate threshold assumptions in a consistent and transparent framework using several alternative assumptions in the formal uncertainty analysis.	Partially applied	EPA evaluated several different threshold assumptions in a sensitivity analysis but has not yet considered these assumptions in a formal uncertainty analysis. The sensitivity analysis was transparent—EPA clearly explained the basis for the different threshold assumptions.	EPA reported some progress toward improving its approach to characterize uncertainties and to conduct a formal uncertainty analysis. (See recommendation 14 for more information.)

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Recommendations Applied or Partially
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	National Academies' recommendation	Status	GAO assessment	EPA's response
12	The committee found little justification for the 5-year time course of exposure and outcome assumed in more recent EPA analyses and recommends that EPA more fully account for the uncertainty regarding lags in health effects by incorporating a range of assumptions and probabilities about the temporal relationship.	Partially applied	EPA sought advice from the Advisory Council on Clean Air Compliance (Council) and incorporated the advice by adjusting the agency's assumptions regarding lag times. As for the uncertainty surrounding lags in health effects, EPA conducted a series of sensitivity analyses on the temporal relationship but did not assess underlying probabilities.	Consistent with the recommendation made by the Council, EPA now uses a 20-year lag model. The revised lag model involves a higher percentage of mortality reductions occurring in the first year (30 percent) than the previous EPA lag model (20 percent). EPA told us that it will not include probability-based distributions in the final RIA because of computational complexities.
13	EPA is encouraged to estimate and report benefits by age, sex, and other demographic factors. The committee recognizes, however, that evaluating the differences for various subgroups adds complexity and uncertainty to the analysis and that caution must be exercised in the interpretation of such results.	Partially applied	EPA included some health benefit estimates for specific age groups in an appendix of the draft PM RIA. However, the agency did not report the primary benefit estimates according to age groups or other demographic factors.	EPA intends to present in the final RIA a detailed summary table with the age breakdown of its sample population. EPA will not, however, estimate and report benefits by other demographic factors because of time and resource constraints. EPA also cited data limitations, noting that it lacks data accounting for local variations in demographic factors. The agency intends to overcome this limitation using tract-level data, which captures details about local level conditions, from the U.S. Census data in future analyses.

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Recommendations Applied or Partially
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	National Academies' recommendation	Status	GAO assessment	EPA's response
14	<p>EPA should begin to move the assessment of uncertainties from its ancillary analyses to its primary analyses. This shift will require the specification of a probability distribution for each uncertainty source that is added to the primary analysis and, as necessary, the specification of joint distributions for the uncertainty sources that are not independent of each other. Expert judgment, as well as data, will be required to specify these distributions. Although the effect on the mean of the resulting probability distribution might increase, decrease, or remain the same, the effect on the spread of the distribution will be a predictable widening and, therefore, a more realistic depiction of the overall uncertainty in the analysis.</p>	Partially applied	<p>EPA has taken some steps toward the formal uncertainty analysis called for by this recommendation, but the primary analysis in the draft PM RIA generally addresses uncertainty in a qualitative manner. Overall, the numerical benefit estimates do not capture the key sources of uncertainty. The agency generally relied on sensitivity analysis to assess some uncertain factors one at a time rather than using more comprehensive techniques for assessing probability distributions of multiple variables. In addition, EPA used expert elicitation to help assess uncertainty relating to the concentrations of PM linked to premature death and the dollar value of risk reductions associated with reductions in PM. However, these results were presented in an appendix and not in the primary analysis in the draft RIA. In addition, the health benefit analysis did not present a quantitative assessment of how the benefit estimates would vary in light of other key uncertainties.</p>	<p>EPA reported some progress toward improving its approach to characterize uncertainties with particular emphasis on one source of uncertainty—premature death linked to PM exposure. Specifically, EPA used expert elicitation to begin to specify a distribution for the uncertainty in concentration levels of PM linked to premature death. The agency cited technical challenges, such as lack of data or reliable methods, and resource constraints, including limitations to its progress to fully characterize uncertainty. Moreover, EPA stated that its focus on the expert elicitation technique limited the time and resources necessary to address other aspects of uncertainty in premature death as well as illnesses linked to PM exposure.</p> <p>EPA applied another formal method for assessing uncertainty—Monte Carlo analysis—to a previous regulatory impact analysis but, according to EPA, did not have time to incorporate this work in the PM RIA. Time permitting, the agency plans to present the results of a Monte Carlo analysis in the final PM RIA.</p>
15	<p>Because the incorporation of expert judgment when data are unavailable will influence the estimates of health benefits as well as the uncertainty analyses, the committee also recommends that EPA clearly distinguish between data-derived estimates of some components, such as the concentration-response function, and expert opinions about other components that are lacking in scientific data, such as the degree of compliance with a particular regulation 30 years into the future. In this way, policymakers will better understand how existing data and expert judgment combine to produce estimates and where new data would be most valuable.</p>	Applied	<p>EPA distinguished between data-derived estimates and those from expert judgment. For example, in the appendix, EPA clearly distinguished between data derived from experts and the data based on an empirical study. In addition, EPA discusses the basis for assumptions, which require analytical judgment, either directly in the draft PM RIA or by reference to supporting documents.</p>	

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Recommendations Applied or Partially
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	National Academies' recommendation	Status	GAO assessment	EPA's response
16	As EPA begins the transition to incorporate additional sources of uncertainty into its primary health benefits analyses, it should continue the sensitivity analyses it has traditionally conducted. These analyses should be expanded, however, to consider sources of uncertainty jointly rather than singly.	Partially applied	EPA expanded the sensitivity analysis by, for example, considering how benefit estimates change according to different threshold assumptions, such as cut points—concentrations of particulate matter below which there would be no benefit to further reductions. This sensitivity analysis examined how different assumed cut points would change the estimates of avoided cases of death. EPA did not, however, conduct a sensitivity analysis to consider the sources of uncertainty jointly rather than singly.	EPA has begun to explore how to expand sensitivity analysis and consider sources of uncertainty jointly. EPA noted that in recent air pollution analyses, the agency considered sources of uncertainty jointly for the last stage of the benefit estimation process—valuing the benefits in dollar terms—by doing a probabilistic assessment of the value of a statistical life. In addition, EPA's policy and economics division has begun a long-term project to expand uncertainty analysis. EPA reports that one technique that considered how much different sources of uncertainty affect the estimates is not ready to be applied to a rule-making analysis.
17	In presenting the probability distribution for each health benefit produced by a primary analysis, EPA should emphasize even more than it has in the past the sources of uncertainty that remain unaccounted for in the primary analysis. These uncertainties should continue to be described as completely and realistically as possible.	Partially applied	EPA did not present a probability distribution for the primary benefit analysis but included some discussion of sources of uncertainty not incorporated into the benefit estimates. EPA also referred the reader to a previous analysis involving particulate matter for detailed discussions on sources of uncertainty. The citations are incomplete, however, leaving readers to search within the voluminous document for the relevant information.	EPA attributed incomplete or lacking references in the draft PM RIA to time constraints, noting that it would present clear references in the final version. EPA also clarified that it relies on references to other documents, rather than repeating information that has not changed, in order to keep the presentation to a manageable size. (See also recommendation 14 for EPA's basis for not including probability distributions.)

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Recommendations Applied or Partially
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	National Academies' recommendation	Status	GAO assessment	EPA's response
18	EPA should consider providing a preliminary analysis that estimates, in current populations, the health benefits resulting from hypothetical changes to current levels of emissions. These preliminary analyses would help EPA develop an idea of the lower bound on the uncertainty of future consequences and would have fewer uncertainties than analyses of the impacts of proposed regulatory actions on future exposures and health outcomes.	Applied	According to EPA, the agency considered providing the preliminary analysis described in this recommendation.	EPA determined that this information would not provide meaningful information to the draft PM benefit analysis. Aside from its questions about the technical feasibility of responding to this recommendation, EPA expressed doubts that doing this analysis for current populations would establish a lower bound on the uncertainty of future consequences. One EPA official concluded that the analysis could introduce more uncertainty into its benefit estimates because benefit projections will depend on controls implemented in the future. Finally, EPA clarified that, as provided by Circular A-4, it estimates benefits for a future year when the regulatory revisions become effective, not the current year, which would not account for changes in variables other than emissions.
19	EPA should continue to strive to present the results of its health benefit analyses in ways that avoid conveying an unwarranted degree of certainty. Such ways include rounding to fewer significant digits, increasing the use of graphs, presenting projected baselines along with projected health benefits, and placing less emphasis on single numbers (for example, the mean of the probability distribution for a health benefit) and greater emphasis on ranges (for example, the range between 5th and 95th percentiles of the distribution).	Applied	EPA followed some of the National Academies' suggestions to present the data in a way that avoids conveying an unwarranted level of certainty. EPA rounded the estimates to fewer significant digits. EPA increased the emphasis on ranges by presenting some data in ranges of benefit and cost estimates. EPA summarized the primary benefit estimates in a table.	

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Recommendations Applied or Partially
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	National Academies' recommendation	Status	GAO assessment	EPA's response
20	EPA should perform similar detailed analyses of uncertainty in the valuation of health benefits and in the regulatory cost analyses that the committee recommends for the health benefit analyses.	Partially applied	The draft PM RIA demonstrated some steps toward analysis of cost uncertainty but did not present an uncertainty analysis of the benefit valuation—the stage when it assigns a dollar value to the benefit estimates. In terms of cost uncertainty, EPA presented a qualitative discussion of the uncertainties about costs and the expected impact on the cost estimates but did not perform a formal uncertainty analysis for the costs.	<p>Overall, EPA cited technical challenges, including data limitations, as the primary reason for not applying a formal uncertainty analysis to the cost estimates in the PM RIA. According to EPA, the number and breadth of PM sources considered under the National Ambient Air Quality Standards rule poses a challenge to development of a characterization of all costs and their uncertainties. Moreover, EPA noted that the collection process for cost information is not systematic, and there is a limited amount of information about the cost of implementing some types of controls. Even when costs are known, it may be difficult to specify the underlying probability distributions.</p> <p>EPA told us that it will incorporate more refined information, such as emissions control analysis, affecting cost estimates in the final RIA. EPA expects the final RIA to include more reasonable cutoffs such that cost estimates will not be based on ineffective controls and excessive costs (i.e., controls that are not likely to be used).</p> <p>In terms of health valuation uncertainty, EPA has made progress toward a formal uncertainty analysis by doing a probabilistic assessment of the value of a statistical life. EPA conducted this analysis in prior RIAs but did not have enough time to complete model runs in time for the draft RIA. EPA plans to incorporate an uncertainty analysis related to the</p>

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National Academies' recommendation	Status	GAO assessment	EPA's response
			<p>mortality valuation in the final PM RIA.</p> <p>EPA has focused its expansion of uncertainty analysis more on benefits than on costs, in part because the benefit estimates for air rules tend to be much larger. EPA identified efforts to analyze cost uncertainty factors, including sensitivity analyses in previous RIAs and plans for accountability analysis comparing estimated costs to actual costs. Finally, EPA pointed out that the work it conducts to understand the benefits also carries over to the cost estimates.</p>
<p>21 EPA should provide health benefit estimates in ways that will support multiple kinds of analysis, including various approaches to mortality valuation and aggregation of benefits using quality-adjusted life years.</p>	<p>Partially applied</p>	<p>EPA's detailed breakdown of the benefit estimates and the reference to its benefit model allows others to apply various approaches to mortality valuation, such as alternative estimates of the value of a statistical life. EPA did not, however, aggregate benefits using quality-adjusted life years.</p>	<p>Although EPA used the quality-adjusted life years approach in a prior RIA to aggregate benefits, EPA did not use this approach in the draft PM RIA because of time constraints. EPA told us that it plans to aggregate the benefits using quality-adjusted life years in the final PM RIA.</p>
<p>22 Each analysis should provide results according to demographic or other subgroups when the expected changes in pollution and, thus, the health benefits are not distributed uniformly across the population. This information would aid decision makers in situations in which equity issues might be involved.</p>	<p>Partially applied</p>	<p>EPA included some health benefit estimates for specific age groups in an appendix, but the agency did not present the primary benefit estimates according to age groups or other demographic factors. (See also recommendation 13.)</p>	<p>EPA intends to present in the final RIA a detailed summary table with the age breakdown of its sample population. The agency noted that it will not present the benefits according to other demographic factors, such as race and income, because of political sensitivities and data limitations. EPA clarified that it lacks the data on local conditions but that it intends to overcome this limitation using tract-level data—which captures details about local conditions—from the U.S. Census data in future analyses.</p>

Source: GAO analysis of National Academies and EPA information.

Recommendations Not Applied to the Draft Particulate Matter Regulatory Impact Analysis

Table 2 provides a summary of the National Academies' recommendations that EPA has not applied to its draft regulatory impact analysis (RIA) for particulate matter (PM). This table provides GAO's assessment of EPA's progress to date regarding recommendations that required additional research and development, were deemed as not relevant to the PM National Ambient Air Quality Standards (NAAQS) by the agency, or were not included in the draft PM RIA due to time and resource constraints. The final column characterizes EPA's comments regarding each recommendation, including contextual information, potential impediments to application, justification for not addressing the recommendation, and intended next steps, if applicable.

**Appendix III
Recommendations Not Applied to the Draft
Particulate Matter Regulatory Impact
Analysis**

Table 2: Recommendations Not Applied to the Draft Particulate Matter Regulatory Impact Analysis

	National Academies' recommendation	Status	GAO assessment	EPA's response
1	The uncertainty in emissions estimates should be quantified and carried through the health benefit analysis to the calculation of avoided cases of mortality and morbidity.	Not applied—research and development under way	EPA has not quantified the uncertainty related to emissions because of limited data and computational complexities and has therefore not yet carried such uncertainty through in the health benefit analysis.	<p>EPA stated that the application of this recommendation—conducting a formal analysis of emissions uncertainty—requires long-term research and development. EPA reports that it discussed the possibility of conducting a quantitative uncertainty analysis for emissions in its particulate matter analysis, but the fixed timeline prevented EPA from doing this work. The primary challenge stems from the nature of the emissions inventory—data are collected from a plethora of entities, complicating the agency's ability to evaluate uncertainty.</p> <p>EPA told us that, currently, the only way to assess emissions uncertainty is through qualitative means. EPA also stated that its final particulate matter analysis will demonstrate steps toward this recommendation because it will present a sensitivity analysis of the emissions data and will present emissions data according to the level emitted by the different kinds of sources, such as utilities, cars, and trucks.</p>

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Recommendations Not Applied to the Draft
Particulate Matter Regulatory Impact
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	National Academies' recommendation	Status	GAO assessment	EPA's response
2	Because a regulation to improve air quality may affect pathways other than air, EPA should determine whether there are likely to be any important indirect impacts of a regulation on human health and the environment. If any such impacts are identified, EPA should include in the analysis a plan to assess them more completely.	Not applied—research and development under way	While EPA did not provide information in the draft PM RIA to show that it considered indirect impacts involving pathways other than air, EPA's ongoing research on the environmental impacts may identify important indirect impacts.	EPA stated that in past rules, the agency has looked at indirect impacts in terms of deposition of nitrogen and sulfates to sensitive water bodies. EPA plans to incorporate this analysis in the final PM RIA. EPA said it has not yet identified any other indirect impacts. While an EPA official suggested that this recommendation did not seem relevant to the NAAQS analysis in terms of human health impacts—EPA could not determine how human health would be affected by exposure to PM from pathways other than air—the agency is conducting research to identify important indirect impacts on the environment. EPA characterized environmental impacts as an area of research.

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Recommendations Not Applied to the Draft
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	National Academies' recommendation	Status	GAO assessment	EPA's response
3	EPA has typically made the assumption of equivalent potency across particle types because of insufficient scientific information. As more data become available, EPA should strengthen its benefit analyses by evaluating a range of alternative assumptions regarding relative particle toxicity and incorporate these assumptions in sensitivity or uncertainty analyses.	Not applied—research and development under way	Although EPA assumed equivalent toxicity in the PM RIA and did not include related sensitivity or uncertainty analyses, EPA is sponsoring research directed at incorporating its findings on relative toxicity into future analyses.	EPA stated that it does not have sufficient information to distinguish between particle components for the final rule. EPA is funding long-term research on relative toxicity, including technical studies to understand any differential toxicities as well as economic analyses to explore ways to characterize the uncertainty in benefit estimates. For example, an EPA contractor conducted a sensitivity analysis of relative toxicity of particle components, including carbons, nitrates, crustal material, and sulfates. To date, the contractor has created a model to assess whether and how much these sources of uncertainty may affect benefit estimates in one urban area. EPA is also supporting research to explore relative toxicity through its intramural research program, its five Particulate Matter Research Centers, and the Health Effects Institute, an organization funded in part by EPA. EPA's science grant program recently awarded \$40 million to the five Particulate Matter Research Centers.

**Appendix III
Recommendations Not Applied to the Draft
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	National Academies' recommendation	Status	GAO assessment	EPA's response
4	As it incorporates additional sources of uncertainty into its primary health benefit analyses, EPA should consider conducting analyses to determine which uncertainty sources have the greatest influence on the mean and spread of the probability distribution. The need for these sensitivity analyses will be particularly great for distributions that are based on expert judgment. The uncertainty sources that have the greatest consequences for decision making, including those that have the greatest impact on the spread of the distribution, should be given high priority for additional research.	Not applied—research and development under way	In the draft PM RIA, although EPA presented a qualitative discussion about the importance of its assumptions that impact uncertainty, it did not consider which sources of uncertainty have the greatest influence on the mean and spread of the probability distribution. EPA is sponsoring research to incorporate influence analysis in future analyses. (See recommendation 14; EPA did not specify probability distributions for uncertainty in its primary analysis).	<p>An EPA contractor is researching techniques for influence analysis, an expanded form of uncertainty analysis that would determine which uncertainty sources have the greatest influence on the benefit estimates. The influence analysis work targeted three sources of uncertainty, including the concentration-response function (which involves threshold and slope); lag effects; and relative toxicity. The contractor compiled a draft report discussing techniques to conduct this analysis and incorporate the uncertainty analysis in benefit estimates.</p> <p>EPA and the contractor stated that because these techniques are in the exploratory stage, it is premature to apply this work to a specific rule-making analysis. For example, EPA cited the need to determine how much uncertainty is explained by differential toxicity or by different thresholds. Finally, EPA stated that because it focused its resources on the expert elicitation work (see recommendation 14), the influence analysis received fewer resources and has not advanced as quickly.</p>

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	National Academies' recommendation	Status	GAO assessment	EPA's response
5	EPA should estimate the benefits over the regulatory time period, including both the implementation period and the expression period of all important health effects. Because calculating benefits for every future year is resource intensive and unlikely to show true increases in precision, calculations can be made, for example, every fifth year with simple interpolation techniques applied to estimate benefits for intervening years.	Not applied	EPA did not estimate benefits covering the implementation period and expression period of all important health effects. EPA estimated the benefits expected in one year only—the base case year, 2015. The year 2015 is the first attainment date when states should be in compliance with the new standards. The Clean Air Act allows for up to a 5-year extension for states that cannot meet the standards by the attainment year. Therefore, the implementation period for some states may extend to 2020.	EPA cited limited time and resources to estimate benefits for years other than 2015, but plans to also include estimates for 2020, in the final RIA. In addition, EPA did not think that this recommendation is particularly meaningful to the NAAQS analysis because the only variable change over the course of the PM implementation period is population. EPA concluded that there would not be much difference between the benefit estimates given in 5-year increments (i.e., 2010 and 2015).

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	National Academies' recommendation	Status	GAO assessment	EPA's response
6	The components of emissions estimates (such as number of vehicles in a class, average miles traveled per vehicle, and emissions per mile) should be presented with and without implementation of the regulation at the national level. This will help readers judge how reasonable these predictions are and will suggest which components of emissions estimates drive the emissions reductions associated with the regulation. Historical trends in these components should also be presented.	Not applied	EPA presented a qualitative discussion about emissions, but did not address components of emissions estimates or provide information to allow readers to understand which components of emissions estimates drive the reductions associated with regulation, such as activity level or emissions intensity. EPA did not present historical trends.	<p>EPA stated that the kind of information called for by this recommendation—key input data, assumptions, and intermediate modeling outcomes—would be useful in future rule-making analyses, but that the agency needs to review a large amount of data to determine which elements would be most helpful. EPA questioned the value of incorporating all of the recommended information in regulatory impact analyses, noting that it works to present enough information to readers while maintaining a document of manageable length.</p> <p>EPA stated that it needs time to design data reporting strategies that would be appropriate for the different scales and scopes of the regulatory impact analyses. EPA plans to explore this recommendation more thoroughly as part of its comprehensive economic analysis of the Clean Air Act. Finally, EPA officials suggested that the final PM RIA will respond to this recommendation in part by providing information about how emissions reductions might vary across PM sources in order to show the primary drivers of emissions reductions in the final RIA. EPA also plans to compare current data to the historical trends predicted in the past and show that EPA's current predictions are for the future.</p>

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	National Academies' recommendation	Status	GAO assessment	EPA's response
7	EPA should quantify uncertainties with regard to future population distributions and background disease rates. EPA should also summarize what is known about the potential importance of disease interactions and competing risks affecting the health outcomes of primary interest and discuss the possible biases that might be introduced in the final analysis by changes in those factors.	Not applied	EPA did not quantify the uncertainties related to future population distributions and background disease rates. EPA did not summarize what is known about the potential importance of disease interactions and competing risks affecting health outcomes of primary interest.	<p>EPA said its models are not configured to quantify these sources of uncertainty. EPA would need to modify the model in order to do this analysis. Agency officials noted that the agency tries to be selective when determining which sources of uncertainty to assess because the cost of doing this work might outweigh the value added from the information.</p> <p>In addition, EPA officials said the agency does not have all of the data necessary to reconfigure the models to quantify key sources of uncertainty. EPA disagrees with the National Academies' comment that lack of information should not preclude the quantification of uncertainty. EPA believes that using the techniques to quantify uncertainty without empirical data would generate results that could be more misleading than the results that do not account for uncertainty. EPA plans to add relevant uncertainty characterizations as it obtains data.</p>
8	The lack of clear categorization of severity of certain health outcomes in benefits analyses has implications for the quantification and the valuation of these outcomes. Although EPA has made some attempt to recognize this issue, it should continue to develop and improve methods used to reconcile differences between the severity of disease described in air pollution epidemiology and that commonly used to develop estimates of background disease prevalence and incidence.	Not applied	The model EPA used to estimate benefits, BenMAP, did not account for the potential variations in severity of illnesses and prevalence and expected incidence of health effects.	EPA has begun work on categorizing severity of some health outcomes, including chronic bronchitis and asthma incidence. EPA is continuing to refine its BenMAP model to better quantify and monetize health outcomes.

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	National Academies' recommendation	Status	GAO assessment	EPA's response
9	EPA should give more emphasis to the assessment, presentation, and communication of changes in morbidity. Although often difficult to quantify, these factors may begin to play a more dominant role in benefit analysis if the value assigned to mortality decreases.	Not applied	EPA did not place more emphasis on the assessment, presentation, and communication of changes in morbidity. Prior RIAs have quantified expected changes in morbidity, such as reductions in asthma and chronic bronchitis. The draft PM RIA did not include additional morbidity information. Moreover, the main benefit estimates in the draft PM RIA did not include morbidity estimates.	EPA acknowledged the importance of morbidity—i.e., illness—benefits and is working to expand that analysis. For example, EPA told us that it plans to include sensitivity analysis of changes in illnesses in the final PM RIA. EPA also stated that the final PM RIA will reflect updates to its model—EPA is working to include projections that will allow the agency to evaluate expected changes in illnesses such as asthma and chronic bronchitis.
10	There is a common misperception that a high degree of certainty is required for regulatory actions to take place to protect public health. As a result, primary health benefit analyses that more fully and accurately portray the uncertainties might not be considered useful. It is unrealistic for EPA to defer decisions until it can make them on the basis of perfect science. A careful and deliberate balancing of the benefits and costs is required, and this balancing must be informed by a fair assessment of the current levels of uncertainty and a realistic evaluation of the likely reductions in uncertainty attainable through further research.	Not applied	EPA did not balance the costs and benefits—the Clean Air Act prohibits EPA from basing revisions to the NAAQS on costs. We note that in response to other recommendations, EPA has taken steps toward assessing current levels of uncertainty—see appendix II, recommendations 14 and 20.	EPA characterized this recommendation as not germane to the particulate matter regulatory impact analysis because the Clean Air Act prohibits the agency from considering the costs when revising NAAQS.
11	EPA should provide a summary of the analysis containing information as outlined in the National Academies' report (table 6-1). This information would allow the reader to evaluate the study design and verify estimates obtained in the analysis.	Not applied	EPA did not provide the summary table in the executive summary as outlined in the National Academies' report, including a description of regulatory options, boundaries of analysis, regulatory baseline, and assumptions that have a significant impact on results of analysis.	Due to data and time constraints, EPA did not summarize its conclusions in the executive summary of the PM RIA.

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	National Academies' recommendation	Status	GAO assessment	EPA's response
12	<p>To enhance the quality of future regulatory benefit analyses, a standing, independent technical review panel should advise EPA in the initial stages of its benefit analysis. This panel should have expertise in regulatory options analysis, emissions and exposure assessment, toxicology, epidemiology, risk analysis, biostatistics, and economics and should be appointed with strict attention to avoiding conflict of interest, balancing biases and ensuring broad representation. This panel should be supported by permanent technical staff to ensure consistency of reviews over time. EPA should follow the panel's guidance on the need for peer review.</p>	Not applied	<p>EPA did not convene a standing group of experts to guide the agency's initial work on the draft PM RIA. In the course of developing economic methodologies, EPA sought and considered information from existing advisory committees on the soundness of certain assumptions, such as cessation lags.</p>	<p>EPA stated that in addition to the advice it sought from the National Academies, the agency continues to seek input from independent committees, including the Clean Air Scientific Advisory Committee, the Advisory Council on Clean Air Compliance Analysis, and subcommittees chartered by the Science Advisory Board's Environmental Economics Advisory Committee. The committees advised EPA on data, methods, and modeling choices applicable to various economic analyses, including the draft PM RIA.</p> <p>EPA stated that the costs involved in convening an entirely new panel could be prohibitively expensive, due to organizing costs and travel expenses and the scope of the Academies' recommendation. As a result, EPA said that it has attempted to take advantage of existing groups, such as the Advisory Council on Clean Air Compliance Analysis, rather than arrange for a new panel. Furthermore, EPA noted that new methodologies and assumptions used in the PM RIA were peer-reviewed and that previously used methods used in the RIA had already been reviewed and validated in a prior context.</p>

Source: GAO analysis of National Academies and EPA information.

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