Copies of Visual Aids Shown by Ray Wassel (NRC staff)

at

the Quarterly Meeting of the FACA Clean Air Act Advisory Committee
Mobile Sources Technical Review Subcommittee

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RESEARCH PRIORITIES FOR AIRBORNE PARTICULATE MATTER:

I. IMMEDIATE PRIORITIES AND A LONG-RANGE RESEARCH PORTFOLIO

PREPUBLICATION COPY

Board on Environmental Studies and Toxicology

Commission on Life Sciences
Commission on Geosciences, Environment, and Resources

National Research Council
March, 1998

The Committee's Task

- Assess particulate matter research priorities
- Develop a conceptual research plan
- Monitor research progress toward improved understanding of the relationships between airborne particulate matter, its various sources, and its effects on public health
- Focus on PM-related research being conducted, funded, or planned by the U.S. EPA in the context of PM-related research being conducted, funded, or planned by other agencies and organization in the U.S. and abroad
- Prepare four reports over the 5 years of the study 1998-2002.
    - First report:

        - Required by Congress within four months of project initiation

        - Identify the most important short-term (3 years) research priorities relevant to evaluating, setting, and implementing primary NAAQS for particulate matter

    - Second report due November 1998:

        - Expand upon the assessment of the first report, identify longer-term research needs, and present conceptual plans for research and the monitoring and evaluation of research

    - Third report, due by the end of 2000, and fourth report, due by the end of 2002:

        - Evaluate research progress and update the research priorities and plans as warranted.

Committee on Research Priorities for Airborne Particulate Matter

Membership Roster

Jonathan Samet (Chair), Johns Hopkins University, School of Hygiene and Public Health, Baltimore, Maryland
Judith Chow, Desert Research Institute, Reno, Nevada
Robert E. Forster, The University of Pennsylvania, Philadelphia, Pennsylvania
Daniel S. Greenbaum, Health Effects Institute, Cambridge, Massachusetts
Maureen Henderson, University of Washington, Seattle, Washington
Philip K. Hopke, Clarkson University, Potsdam, New York
Petros Koutrakis, Harvard University, Boston, Massachusetts
Daniel Krewski, Health Canada and University of Ottawa, Ottawa, Ontario
Paul Lioy, University of Medicine and Dentistry - New Jersey, Piscataway, New Jersey
Joe L. Mauderly, Lovelace Respiratory Research Institute, Albuquerque, New Mexico
Roger O. McClellan, Chemical Industry Institute of Toxicology, Research Triangle Park, North Carolina
Günter Oberdörster, University of Rochester, Rochester, New York
Rebecca Parkin, American Public Health Association, Washington, D.C.
Joyce E. Penner, University of Michigan, Ann Arbor, Michigan
Richard Schlesinger, New York University, Tuxedo, New York
Frank E. Speizer, Harvard University, Boston, Massachusetts
Mark Utell, University of Rochester, Rochester, New York
Ronald White, American Lung Association, Washington, D.C.
Ronald Wyzga, Electric Power Research Institute, Palo Alto, CA
Terry F. Yosie, Ruder Finn, Inc., Washington, D.C.

Committee's Meetings and Sources of Information

- To date, the committee has held two working meetings at the National Academy of Sciences in Washington, D.C., on January 20-21 and February 18-19, 1998.

- Those meetings included public sessions at which the committee heard presentations from representatives of:

  EPA

  EPA's CASAC

  National Institute of Environmental Health Sciences (NIEHS)

  National Institute for Occupational Safety and Health (NIOSH)

  North American Research Strategy for Tropospheric Ozone (NARSTO)

  Health Effects Institute (HEI)

  Lovelace Respiratory Research Institute (LRRI)

  American Petroleum Institute (API)

  Chemical Industry Institute of Toxicology (CIIT)

  Electric Power Research Institute (EPRI)

  American Industrial Health Council (AIHC)

  National Resources Defense Council (NRDC)

- In addition, the committee received valuable documents and other written material from most of the presenters.

Expert Reviewers Chosen By The NRC

This report was improved by a separate group of expert reviewers, chosen by the NRC and anonymous to the committee members until completion of the report.

Joan M. Daisey, E.O. Lawrence Berkley National Laboratory

Arthur B. DuBois, Yale University

Clark W. Heath, Jr., retired, American Cancer Society

Carol J. Henry, American Petroleum Institute

Morton Lippmann, New York University Medical Center

Peter H. McMurry, University of Minnesota

Thomas W. Peterson, University of Arizona

Robert F. Phalen, University of California, Irvine

Joel Schwartz, Harvard University

John H. Seinfeld, California Institute of Technology

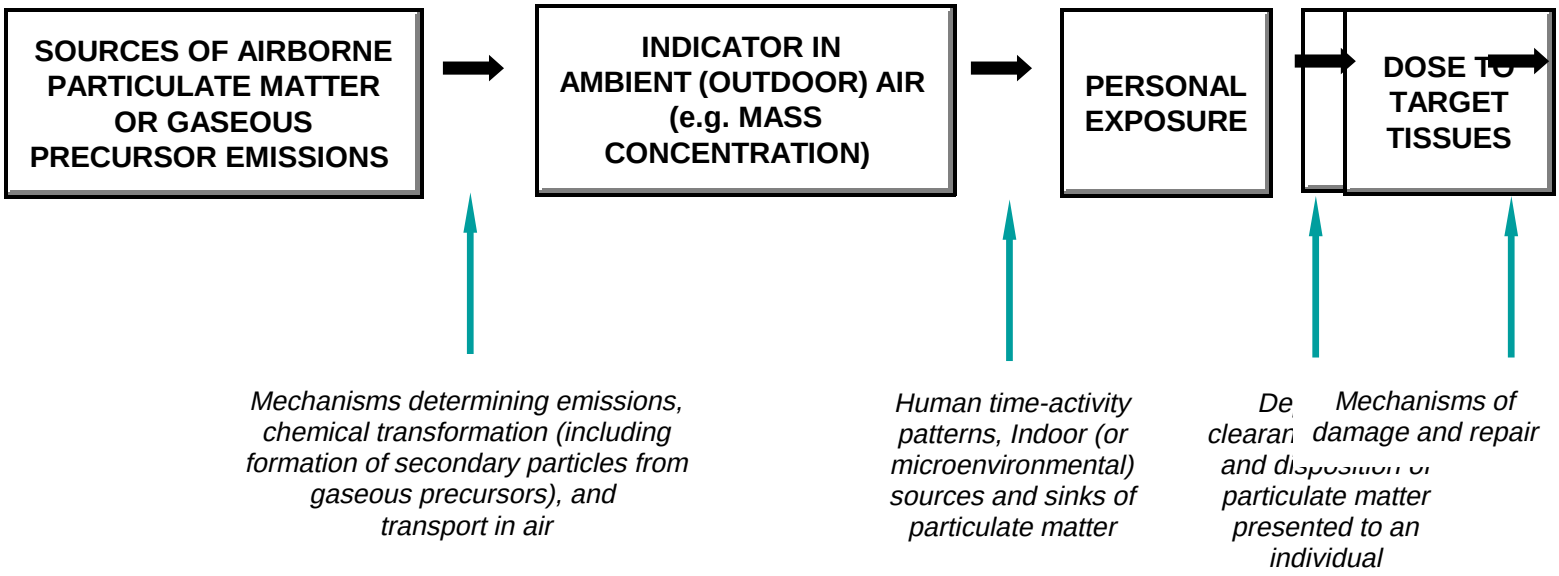
George T. Wolff, General Motors Corporation

The Committee’s First Report

- Offers a conceptual framework for an integrated national program of particulate-matter research
- Identifies the 10 critical research needs linked to key policy-related scientific uncertainties
- Describes the recommended short-term and long-term timing
- Estimates costs of such research in an integrated research strategy, or "research investment portfolio”
- The committee has made no attempt to evaluate the adequacy of the current scientific basis for EPA's new $PM_{2.5}$ standards, and no evaluation should be inferred, because the process of setting such standards also involves legal requirements and policy choices that the present committee was neither charged nor constituted to address.

Contents

A General Framework for Integrating Particulate-Matter Research



Modified from NRC 1983, 1994; Lioy 1990; and Sexton 1992.

Conceptual Framework

- The committee organized its evaluation of particulate-matter scientific uncertainties and research needs according to a simple, coherent, science-based conceptual framework. The framework has 5 main components:

    - Sources
    - Ambient Indicators
    - Exposure
    - Dose
    - Response

- In evaluating the key scientific uncertainties and assigning priorities to research needs on particulate matter, the committee used both strategic and practical criteria (see Chapter 3) organized in three categories:

    - Scientific value
    - Value of information for decisionmaking
    - Feasibility and timing considerations

- The committee judged 10 research topics to warrant the highest priority. The order in which these research topics are presented does not represent relative ranking or sequence of the research topics recommended by the committee. All 10 topics met the committee's ranking criteria, and they are highly interdependent and interactive within the committee’s research portfolio.

Key Scientific Uncertainties Related to the Source-to-Response Framework

Source → Concentration (or other indicator)

- Contribution of various emission sources to ambient and indoor particulate matter concentrations
- Relative contribution of various sources to toxic components of particulate matter

Concentration (indicator) → Exposure

- Relationship between ambient (outdoor) particulate-matter and the composition of particles to which individuals are exposed
- Contribution of ambient particulate matter to total personal exposure for:
  - Sensitive populations
  - General population
- Variation in relationship of ambient particulate-matter concentrations to human exposure by place
- Variation in contribution of ambient particulate matter to total human exposure over time
- Covariance of particulate-matter exposures with exposures to other pollutants
- Relationship between background ambient and personal exposures for particulate matter and co-pollutants

Exposure → Dose

- Relationship between inhaled concentration and dose of particulate matter and constituents at the tissue level in susceptible subjects
  - Asthma
  - Chronic Obstructive Pulmonary Disease (COPD)
  - Heart Disease
  - Age: infants and elderly
  - Others

Dose → Response

- Mechanisms linking morbidity and mortality to particulate-matter dose to or via the lungs
  - Inflammation
  - Host Defenses
  - Neural Mechanisms

The Committee's 10 Highest-Priority Research Recommendations

1. Investigate quantitative relationships between particulate-matter concentrations measured at stationary outdoor monitoring sites and the actual breathing-zone exposures of individuals to particulate matter and gaseous copollutants, taking ambient outdoor and indoor pollutant sources and human time-activity patterns into account, especially for potentially susceptible subpopulations.

2. Investigate exposures to the most biologically important constituents and characteristics of particulate matter that might adversely affect health, especially for potentially susceptible subpopulations.

3. Develop advanced mathematical, modeling, and monitoring tools to represent the relationships between specific sources of particulate matter and human exposures.

4. Apply modeling and other analytical tools to link sources of toxicologically important constituents and characteristics of particulate matter to exposed individuals and populations.

5. Assess through toxicological and epidemiological studies the most biologically important physical and chemical characteristics and constituents of particulate matter that produce adverse health effects.

6. Investigate the deposition patterns and fate of particles in the respiratory tract of individuals potentially susceptible to particulate matter.

7. Investigate through toxicological and epidemiological studies the interactions between particulate matter and gaseous copollutants in producing harmful short-term and long-term exposures and resulting adverse health effects.

8. Identify the human subpopulations that are potentially most susceptible to adverse health effects from particulate-matter exposures (e.g., children, the elderly, and people with chronic respiratory diseases, cardiopulmonary diseases, or compromised immune systems).

9. Investigate the toxicological mechanisms by which particulate matter produces mortality and acute or chronic morbidity, using laboratory-animal models, human clinical studies, and *in vitro* test systems.

10. Develop and apply advanced methods for statistical analysis of epidemiological studies and for dealing with measurement and misclassification errors in estimating adverse health effects of particulate matter.

Table 5.1 The committee's research investment portfolio: Timing and estimated costs* ($ million/year in 1998 dollars) of recommended research on PM

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
SOURCE/CONCENTRATION/EXPOSURE													
I. Outdoor vs. human exposure	**3.0**	**3.0**	**3.0**										
2. Exposure to toxic PM components				**4.0**	**4.0**	**4.0**	**4.0**	**4.0**					
3. Source-receptor measurement tools													
3a. Atmospheric modelling	**2.0**	**2.0**	**2.0**	**2.0**	**2.0**	**2.0**							
3b. Receptor modelling	**1.0**	**1.0**	**1.0**										
3c. Analytical methods	**1.0**	**1.0**	**1.0**	**1.5**	**1.5**	**1.5**							
4. Application of methods and models	**1.0**	**1.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**	**4.0**					
EXPOSURE/DOSE-RESPONSE													
5. Assessment of hazardous PM components													
5a. Toxicologic and clinical studies	**8.0**	**8.0**	**8.0**	**8.0**	**8.0**								
5b. Epidemiology		**1.0**	**1.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**
6. Dosimetry	**3.0**	**1.5**	**1.5**	**1.5**									
7. Effects of PM and copollutants													
7a. Copollutants (toxicology)	**3.0**	**3.0**	**4.0**	**4.0**	**4.0**	**4.0**	**5.0**	**5.0**	**5.0**	**5.0**	**5.0**	**5.0**	**5.0**
7b. Copollutants/long term (epidemiology)	**1.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**6.0**	**3.0**	**3.0**
8. Susceptible subpopulations	**2.0**	**2.0**	**3.0**	**3.0**	**3.0**	**3.0**	**3.0**	**3.0**					
9. Toxicity mechanisms													

9a. Animal models	**3.0**	**3.0**	**3.0**	**3.0**	**3.0**	**3.0**							
9b. In vitro studies	**3.0**	**3.0**	**3.0**	**3.0**	**3.0**	**3.0**							
9c. Human clinical	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**	**3.5**							
ANALYSIS AND MEASUREMENT													
10a. Statistical analysis	**0.5**	**1.0**	**1.0**	**1.0**	**1.0**	**1.0**							
10b. Measurement error	**1.0**	**1.5**	**1.5**	**1.5**	**0.5**	**0.5**							
SUBTOTALS ($ MILLION PER YEAR)	**36.0**	**41.5**	**46.5**	**52.0**	**49.5**	**41.5**	**28.0**	**28.0**	**17.0**	**17.0**	**17.0**	**14.0**	**14.0**
RESEARCH MANAGEMENT (ESTIMATED AT 10%)**	3.6	4.2	4.7	5.2	5.0	4.2	2.8	2.8	1.7	1.7	1.7	1.4	1.4
TOTALS ($ MILLION PER YEAR)	**39.6**	**45.7**	**51.2**	**57.2**	**54.5**	**45.7**	**30.8**	**30.8**	**18.7**	**18.7**	**18.7**	**15.4**	**15.4**

*The committee's rough but informed collective-judgment cost estimates for the highest-priority research activities recommended in this report. See Chapter 4 for explanations. These estimates should *not* be interpreted as a recommended total PM research budget for EPA or the nation, for reasons explained in the report.

**Research management includes research planning, budgeting, oversight, review, and dissemination, cumulatively estimated by the committee at 10% of project costs.

TABLE 6.1 ESTIMATED FY98 EPA RESEARCH ALLOCATIONS[a]

CATEGORY	INTRAMURAL (Laboratories)	EXTRAMURAL (Grants, Centers, HEI)[b]	INTERAGENCY	TOTAL
SOURCE				
Emissions Characterization	$2.9 (13%)	$0.3 (2%)	—	$3.2 (7%)
Atmospheric Chemistry/ Modeling	$3.2 (14%)	$1.3 (7%)	—	$4.5 (10%)
CONCENTRATION				
Monitoring Methods/ "Platforms"	$4.9 (22%)	$1.3 (7%)	—	$6.2 (14%)
EXPOSURE				
Exposure Relationships	$0.8 (4%)	$4.0 (23%)	—	$4.8 (11%)
DOSE				
Exposure-Dose-Response	—	—	—	—
RESPONSE				
Acute Health[c]	$8.8 (40%)	$2.5 (14%)	$3.0	$14.3 (32%)
Long-Term Health Effects	$1.0 (5%)	$8.0 (46%)	$1.0	$10.0 (22%)
NEW TECHNIQUES	$0.5 (2%)	—	$1.0	$1.5 (3%)
TOTALS	$22.1 (100%)	$17.4 (100%)	$5.0	$44.5 (100%)

[a] In millions of dollars (Source: Letter from J. Vandenberg, EPA, to J. Samet, 2/15/98)

[b] Derived from relative estimates of allocations for centers

[c] Includes susceptibility ($7.4), mechanisms ($5.4), biologically important (or key) components ($1.5)

Comparing the Committee's Recommendations with EPA's Research Plans

- Although the committee concludes at this early stage of its 5-year study that EPA's current and planned research activities generally appear to be reasonable and potentially useful, the committee disagrees with the early timing and funding of some elements of EPA's research plans, based on the briefings and documentation thus far provided by EPA staff.

- Most notably, the committee concludes that EPA should immediately devote more intramural as well as extramural resources to investigating the relationships between fixed-site outdoor monitoring data and actual human exposures to ambient particulate matter, and to identifying the most biologically important constituents and characteristics of particulate matter through toxicological studies.

- EPA's current plans appear to focus only about 4% of its intramural resources on investigating ambient- versus personal-exposure relationships, and only about 3% of EPA's entire particulate-matter research budget appears to be focused on biologically important components of the particulate-matter mixture. This is crucially inadequate.

- If the current mix of scientific expertise among the federal career staff of EPA's intramural laboratories is unable to respond expeditiously to this committee's recommendations, then EPA should look into the possibility of conducting this work extramurally.

- Source-Concentration: Nearly one-third of EPA's particulate-matter-research budget for 1998 appears to be directed at characterization of source emissions, atmospheric chemistry and modeling, and the development of new monitoring techniques and more sophisticated monitoring platforms. All of those components will eventually be needed in EPA's particulate matter research and regulatory program, and this committee has recommended a smaller immediate commitment of resources (approximately 14%) to develop improved methods for the activities. However, the committee recommends that the largest EPA investments in these areas be deferred until a few years from now, when an improved understanding of the biologically important components and characteristics of particulate matter will allow more productive and cost-effective investment in measuring the important particle components in source emissions and ambient air.

- *Exposure-Dose-Response*: Although the committee believes that major investments in dose-response research will not be very useful until further information on toxicological mechanisms is available, it recommends that carefully designed efforts begin immediately to develop biologically based models for deposition and fate of particulate matter in the respiratory tract of human subjects, especially for susceptible sub-populations.

- *Health Response:* The committee notes that EPA has apparently proposed to make an appropriately large allocation of funds to research on health effects of exposure to particulate matter—more than 50% of the total particulate-matter research budget. However, the area of biologically important particulate-matter components and characteristics appears to be significantly underfunded, and the area of long-term effects, which is important and merits sustained investment over the longer term, is given too large an immediate allocation by EPA.