

## Summary Minutes

### **US Environmental Protection Agency Science Advisory Board SAB Parcitulate Matter Research Centers Program Advisory Panel Meeting**

#### **Public Meeting**

**October 1 - 2, 2008**

**8:30 am – 3:00 pm (Eastern Time)**

**Meeting Location:** SAB Conference Center 1025 F St., NW, Washington, D.C.

**Purpose of the Meeting:** The Meeting was held to allow for the PM Centers Program Advisory Panel to conduct a review of the PM Centers Program Plans of the US EPA. The meeting agenda is in Attachment A. The list of SAB and other participants follows.

#### **Meeting Participants:**

##### **SAB Parcitulate Matter Research Centers Program Advisory Panel Members Participating in the Meeting:**

Dr. David T. Allen, Chair  
Dr. Bryan Shaw  
Dr. Terry Gordon  
Dr. Frederick Miller  
Dr. Barbara Zielinska  
Dr. Steven Kleeberger

Dr. George Lambert  
Mr. Bart Croes  
Mr. Michael Greenbaum  
Dr. Peter Scheff  
Dr. Bruce Fowler

#### **MEETING SUMMARY**

##### **Wednesday, October 1, 2008**

This meeting was announced in the *Federal Register* (see 73 FR p 40576 of July 15, 2008 - Attachment B). The Panel Roster is in Attachment C.

**1. Convene the Meeting:** The DFO convened the meeting noting that it was a federal advisory committee meeting and that the Panel's deliberations are held as "public meetings" pursuant to the Federal Advisory Committee Act (FACA), its regulations, and the policies of the US EPA for advisory activities. Mr. Miller noted that no member of the public had requested time to make an oral statement to the Panel nor had anyone provided written input for the Panel's consideration.

Mr. Miller noted that SAB members must comply with Federal ethics and conflict-of-interest laws and that SAB ethics officials review relevant information to ensure that SAB panels reflect appropriate balance and that COI and bias issues are addressed and that the Panel members had submitted information on their financial and other issues and that as a result of this process no Panel members had been determined to not have any such issues within the meaning of the relevant ethics and conflict of interest requirements that apply to participation in these advisory activities.

Panel members and others attending the meeting introduced themselves at this point (see Attachment D in the physical FACA file only for those registering for the meeting).

Mr. Miller then turned the meeting over to the SAB Director who welcomed members and she then introduced the Panel Chair, Dr. David Allen, who implemented the agenda. Dr. Allen welcomed those participating in the review, noted the purpose of the meeting, and explained the nature of the review issue. He also summarized the Agency's charge questions to the Panel (see Attachment E1 and E2).

**2. Introductory Presentations by EPA Representatives:** Dr. Chris Zarba, US EPA National Center for Environmental Research, gave an "Overview of EPA's Extramural Research Grants Program" (see Attachment F). Dr. Zarba discussed the Office of Research and Development Organization, NCER's fit within ORD, the STAR research program, the research planning process, how requests for applications are evaluated, the general air research funded by ORD NCER, and highlights of the air grants program.

Panel Members mentioned a number of issues that were thought to be of importance to EPA as the program moves forward, including:

- a) The need for a more meaningful way of assessing the grants program other than the existing PART process;
- b) The new NRC process in their January 2008 report (*Evaluating Research Efficiency in the U.S. Environmental Protection Agency*) is thought to be a better approach to assessing research program quality;
- c) The difficulty in determining, in the literature, what studies were supported by EPA grant funding;
- d) Funding levels for grants that are likely and whether having specific line items in the budget would help attain stable funding; and
- e) The National Program Director's role in funding decisions;

**3. EPA's Air Research Program and the PM Research Centers:** Dr. Dan Costa presented an overview of EPA's air research program and the role of the Particulate Matter Research Centers within that program (see Attachment G). Dr. Costa discussed the history of the air program and the PM centers, the air research program structure, the important influence on the PM program of several NRC reports on airborne particulate matter, and the value of the centers to EPA's research program. He noted that Centers provide a complement to the intramural program and permit the accomplishment of cutting edge science on PM issues. Dr. Costa noted the major conclusions of the 2002 SAB PM Center report which recognized the benefits of the program, the advantage of a diverse research portfolio, and the need to continue to support intramural and extramural programs in PM research. He also highlighted the results of the last 10 years of progress made under the PM Centers program.

Panel Members mentioned the relationship among the centers and other air research programs – it is import that both components remain close so that the programs are truly complementary. Dr. Costa noted that this is intended and that the relationship continues to evolve. ORD provides a forum within which the Center Directors are able to talk with EPA about the programs.

**4. PM Centers Research in EPA's NAAQS Program.** Ms. Lydia Wegman, Director Health and Environmental Impacts Division of EPA OAQPS discussed the use of research results from the centers program in NAAQS development. She noted that ORD research is used in virtually every facet of the

NAAQS review process as well as in supporting implementation of the standards. Ms. Wegman gave an overview of the NAAQS standard setting process and highlighted the types of ORD research products that are used in supporting the efforts of each of the process stages (see [Attachment H](#)) to assess effects, exposure, sources, risk, etc. in past NAAQS and the current NAAQS review for PM. She also noted that the results of Centers research is also of great utility in NAAQS implementation.

Panel members were interested in the tradeoff of epidemiology study data with that from toxicology study; the influence of past research on future research directions; the changing nature of the regulatory process over time; and the way that PM research, including Centers, will be merged into the ORD and EPA one-air, multi-pollutant framing for the future. Ms. Wegman noted that the public health message is greatly benefitted by the PM Centers work and that there is a need to get this message out.

In a general question and answer session, a number of issues were discussed, including: the evolution of research centers activities from separate and distinct in the beginning, to increased integration in the current round of centers research. EPA's experience as that history evolved should be useful in the next step which will be research with more of a multi-pollutant focus. Dr. Costa noted that the challenges in the next steps will be greater than the more-horizontal integration of the past, but some lessons will be relevant to the future directions. The greater interaction between health scientists and those that focus on air quality will be helpful in going forward. There will also be benefits to be derived from greater interaction among the various perspectives in health research (clinical, epidemiology, effects, etc.).

**5. Future Directions of the Centers – The Charge:** Dr. Costa then discussed the Charge to the SAB Panel and its relationship to the program's future directions (see Attachment I). Dr. Costa discussed the Clean Air Multi-Year Plan for EPA's future activities in the air research program and the Board of Scientific Counselors (BOSC) support for the plan as well as the PM centers part in that plan. He then discussed the three charge questions that EPA asked the PM Centers Panel to advise upon. The questions include:

- a) Charge Question 1 asks, **“How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA’s mission?”**
- b) Charge Question 2 asks, **“What advice does the panel have on how to move to a multi-pollutant approach in the PM Centers program?”**
- c) Charge Question 3 asks, **“What strengths and weaknesses does the panel see in different structural options for a future Centers Research Program?”**

Panel members' comments were focused on the following issues and areas:

- a) Whether EPA believes it would receive the same value from its PM research without the Centers – to which Dr. Costa stated that ORD believes overwhelmingly that the Centers have added value as well as provides flexibility for the program.
- b) Whether STAR grants distributed at large was more or less productive as grants given to Centers – EPA believes that both mechanisms have had comparable results so far and EPA believes that both mechanisms provide greater results than a program that does not employ grants at all.
- c) The extent to which Centers' work should be tied to near term needs to support regulations.

- d) The extent to which the PM focus should move toward EPA’s new one-air, multi-pollutant focus versus the previous fragmented approach – for now the multi-pollutant work will be more based on opportunities that arise. Over time the tension will be how to do more of the mandated work on PM and also work into a broadened multi-pollutant focus.
  - e) Integration will be important in the future and it is the case that many problems already involve multiple pollutants (e.g., PM usually involves ozone as well). In addition, PM is not just one pollutant, but a variety. To advance on problems in the future, the research will need to be broadened beyond “individual” pollutants.
  - f) PM Centers funding should be seeking funding from other agencies as well.
- 6. Discussion:** Panel Members then discussed each charge question and the comments that would be appropriate to make in the report to the Administrator. For question 1, issues raised for consideration in this regard included: the need for EPA to work and partner with other agencies in getting the most out of the program; the possibility of having matching fund requirements for universities having centers; the value of on-site collaboration; the need for EPA to identify what Centers uniquely contribute that is not available through other research approaches in order to hold program cuts at bay; the possibility of having more directed requests for application in contrast to open-ended RFAs that might not so directly address EPA’s mission; the need for EPA to be clear in how the research has supported its mission; the long-term nature of doing research from a multi-pollutant perspective; the importance of Centers as a complement to EPA’s other research mechanisms; the importance of some metric for program success; the difficulty in deriving meaningful metrics for research.

For question 2, members noted again the importance of multi-pollutant research; the need to give ideas to EPA on how they might approach multi-pollutant research; the vast array of pollutant combinations that are possible and their relationship to the types of sources in proximity to one another; the importance of atmospheric transformation to mixtures that are presented; the need for control strategies that target various mixtures; and the value in asking those who propose centers for funding to be creative in identifying how they might explore the multi-pollutant issue.

For question 3, Members discussed the value of small centers vs. larger ones; the pros and cons of each type; the breadth of topics that can be covered by large centers as contrasted with small centers; the ability of specific centers to focus on region-specific PM issues; the influence on center size on attracting talented researchers; and the possibility of having a mix of small and large centers.

- 7. Day 2: Members Continued Discussion:** Panel Members reconvened and prior to breaking into teams to draft responses to the charge questions discussed a number of issues. They noted the unevenness across centers in that some have very strong areas, but that the same center may also have less robust programs in other areas. They suggested that EPA should devise mechanisms to address the unevenness that exists and to react to it as appropriate. The importance of program reviews for centers in doing this was noted.
- 8. Members Drafting Sessions:** Following their brief discussion at the beginning of day 2, Panelists then broke into groups to draft responses to the three charge questions. The results of those sessions are contained in Attachment J.

- 9. Action:** Panelists then agreed to the following actions in order to complete the report drafting:
- a) Revised drafts to each charge question are to be sent to the DFO by October 3
  - b) The DFO will compile the revised responses into a draft report with the other background sections that are normally a part of an SAB report and send it to the Chair, Dr. Allen for comment by October 14
  - c) The Chairs revised draft will be sent to the Panel Members for Comment on October 20
  - d) The Panel will hold a teleconference to discuss any difficult issues that arise on November 6
  - e) The Panel will be provided a revised draft for concurrence as soon as possible after the teleconference
  - f) The Panel Draft will be sent to the Chartered SAB for quality review during its December 16, 2008 meeting.

The meeting was adjourned at 11:30 a.m.

Respectfully submitted:

*/ Signed /*

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Thomas O. Miller  
Designated Federal Officer  
SAB Particulate Matter Research Centers Program Advisory Panel

Certified as true:

*/ Signed /*

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Dr. David T. Allen  
Chair  
SAB Particulate Matter Research Centers Program Advisory Panel

Attachments

**ATTACHMENT A**  
**U.S. Environmental Protection Agency**  
**EPA Science Advisory Board (SAB)**  
**SAB *Ad Hoc* Particulate Matter (PM) Research Centers Program Advisory Panel**

**Public Advisory Meeting**

Wednesday, October 1, 2008 – 8:30 a.m. to 5:30 p.m. Eastern Time, and  
Thursday, October 2, 2008 – 8:30 a.m. to 1:00 p.m. Eastern Time

SAB Conference Center, 1025 F Street, N.W., Suite 3700, Washington, DC 20004

**Advisory Meeting to Comment on EPA's Current Particulate Matter (PM)  
Research Centers Program and Provide Advice to the Agency Concerning Future  
Structures and Strategic Direction for the Program**

**Final Meeting Agenda**

**Wednesday, October 1, 2008**

8:30 a.m.	<b>Convene Meeting; Call Attendance; Introductions and Administration</b>	Mr. Tom Miller, SAB Designated Federal Officer, SAB Staff
8:40 a.m.	<b>Welcome</b>	Dr. Vanessa Vu, Staff Director, Science Advisory Board
8:45 a.m.	<b>Purpose of Meeting and Review of Agenda</b>	Dr. David T. Allen, Chair
8:50 a.m.	<b>Overview of EPA's Extramural Research Grants Program, National Center for Environmental Research (NCER)</b>	Dr. William Sanders, Director, NCER, Office of Research and Development (ORD)
9:10 a.m.	<b>Overview of EPA's Air Research Program and Role of Agency's Particulate Matter (PM) Research Centers</b>	Dr. Dan Costa, EPA's National Program Director for Air Research, ORD
9:55 a.m.	<b>Perspective from EPA's Office of Air Quality Planning and Standards (OAQPS)</b>	Ms. Lydia Wegman, Director, Health and Environmental Impacts Division, OAQPS
10:25 a.m.	<b>Break*</b>	
10:40 a.m.	<b>Public Comment Period</b>	Mr. Miller (Moderator)
11:10 a.m.	<b>Future Directions for EPA's Air Research Program; Review Charge to SAB Panel</b>	Dr. Costa
12:00 p.m.	<b>Lunch</b>	
1:00 p.m.	<b>SAB Panel Questions-&amp;-Answers and Discussions with EPA Personnel</b>	Chair & SAB Panel members, EPA (ORD, OAQPS)

\*Note: Periodic breaks will be taken as necessary and at the call of the Chair.

**Wednesday, October 1, 2008 (continued)**

1:15 p.m.	<b>Panel Discussions and Deliberations in Response to Agency Charge Question #1: <i>PM Centers' Contribution to Advancing EPA Research on Relevant and Key PM Issues</i></b>	Panel members
2:00 p.m.	<b>Panel Discussions and Deliberations in Response to Agency Charge Question #2: <i>SAB Panel's Advice to EPA on a Multi-Pollutant Approach in the PM Research Centers Program</i></b>	Panel members
2:30 p.m.	<b>Break</b>	
2:45 p.m.	<b>Panel Discussions and Deliberations in Response to Agency Charge Question #3: <i>SAB Panel's Evaluation of Different Structural Options for a Future Centers Research Program</i></b>	Panel members
4:00 p.m.	<b>Break</b>	
4:15 p.m.	<b>Panel Discussions and Deliberations in Response to Agency Charge Questions #2 &amp; #3 (continued)</b>	Panel members
5:15 a.m.	<b>Summary and Wrap-Up for the Day</b>	Dr. Allen
5:30 p.m.	<b>Adjourn meeting for the day</b>	Mr. Miller

**Thursday, October 2, 2008**

8:30 a.m.	<b>Reconvene Meeting</b>	Mr. Miller
8:35 a.m.	<b>Remarks from Panel Chair</b>	Dr. Allen
8:40 a.m.	<b>Additional Agency Comments</b>	ORD, OAQPS representatives
8:45 a.m.	<b>Panel Members Break into Workgroups to Draft Sections of Panel's Report</b>	Panel members
10:00 a.m.	<b>Panel Reconvenes</b>	Mr. Miller
10:05 a.m.	<b>Compile SAB Panel Workgroup Reports; Discuss Panel's Draft Report</b>	Panel members
12:15 p.m.	<b>Summary, Wrap-Up and Next Steps</b>	Dr. Allen
12:30 p.m.	<b>Adjourn Meeting</b>	Mr. Miller

## Attachment B

### Science Advisory Board Staff Office; Notification of Upcoming Meeting of the Science Advisory Board Particulate Matter Research Centers Program Advisory Panel

[PDF Version](#) (2 pp, 74K, [About PDF](#))

[Federal Register: July 15, 2008 (Volume 73, Number 136)]

[Notices]

[Page 40576-40577]

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[DOCID:fr15jy08-46]

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ENVIRONMENTAL PROTECTION AGENCY  
[FRL-8692-3]

Science Advisory Board Staff Office; Notification of Upcoming Meeting of the Science Advisory Board Particulate Matter Research Centers Program Advisory Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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SUMMARY: The Environmental Protection Agency (EPA or Agency) Science Advisory Board (SAB) Staff Office announces a public meeting of the SAB Particulate Matter (PM) Research Centers Program Advisory Panel to comment on the Agency's current PM research centers program and provide advice to EPA concerning future structures and strategic direction for the program.

DATES: The meeting dates are Wednesday, October 1, 2008, from 8:30 a.m. to 5:30 p.m. through Thursday, October 2, 2008, from 8:30 a.m. to 3 p.m. (Eastern Time).

ADDRESSES: The meeting will be held in the SAB Conference Center located at: 1025 F Street, NW., Room 3705, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain further information about this meeting must contact Mr. Fred Butterfield, Designated Federal Officer (DFO). Mr. Butterfield may be contacted at the EPA Science Advisory Board (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; or via telephone/voice mail: 202-343-9994; fax 202-233-0643; or e-mail at [butterfield.fred@epa.gov](mailto:butterfield.fred@epa.gov). General information about the EPA SAB, as well as any updates concerning the meeting announced in this notice, may be found on the SAB Web site at <http://www.epa.gov/sab>.

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SUPPLEMENTARY INFORMATION: The SAB was established by 42 U.S.C. 4365 to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. This SAB Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: In 1998, the Congress directed EPA to establish as many as five university-based PM research centers as part of the Agency's expanded Office of Research and Development (ORD) PM research program. The first PM Research Centers were funded from 1999 to 2005 with a total program budget of \$8 million annually (see: <http://es.epa.gov/ncer/science/pm/centers.html>). In the original Request for Applications (RFA), prospective centers were asked to propose an integrated research program on the health effects of PM, including exposure, dosimetry, toxicology and epidemiology. ORD's PM Research Centers program was initially shaped by recommendations from the National Research Council.

In 2002, ORD requested that the Science Advisory Board conduct an interim review of EPA's PM Research Centers program, the report from which is found at [http://yosemite.epa.gov/sab/sabproduct.nsf/6374FD2B32EFE730852570CA007415FE/\\$File/ec02008.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/6374FD2B32EFE730852570CA007415FE/$File/ec02008.pdf). This review was instrumental in providing additional guidance to ORD for the second phase of the program (2005-2010). In 2004, ORD held a second competition for the PM Research Centers program. This RFA asked respondents to address the central theme of ``linking health effects to PM sources and components,' ' and to focus on the research priorities of susceptibility, biological mechanisms, exposure-response relationships, and source linkages. From this RFA, five current centers are funded for 2005-2010 with the total program budget at \$40 million (see: [http://cfpub.epa.gov/ncer\\_abstracts/index.cfm/fuseaction/outlinks.centers/centerGroup/19](http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/outlinks.centers/centerGroup/19)).

EPA's National Center for Environmental Research (NCER), within ORD, requested that the SAB Staff Office form an expert panel to comment on the Agency's current PM Research Centers program and to advise EPA concerning the possible structures and strategic direction for the program as ORD considers funding a third round of air pollution research centers into the future, i.e., from 2010 to 2015. Therefore, in response to this request from NCER, the SAB Staff Office published a notice in the Federal Register ([73 FR 5838](#)) on January 31, 2008, which announced the formation of an SAB ad hoc panel for this advisory activity and requested public nominations of qualified experts to serve on this panel.

The SAB Staff Office has established the SAB PM Research Centers Program Advisory Panel. This ad hoc Panel is comprised of nationally- and internationally-recognized, non-EPA scientists with extensive research program management expertise and experience related to airborne pollution (including PM) and the application of research results in reducing air pollution in protection of human health and the environment. Furthermore, these experts have had direct research experience related to airborne particulate matter. The roster and biosketches of this SAB Panel are posted on the SAB Web site at <http://www.epa.gov/sab>.

Technical Contacts: Any programmatic or technical questions concerning EPA's Airborne Particulate Matter Research Centers Program can be directed to Ms. Stacey Katz, NCER, at phone: 202-343-9855, or e-mail: [katz.stacey@epa.gov](mailto:katz.stacey@epa.gov); Ms. Gail Robarge, NCER, at phone: 202-343-

9857, or e-mail: [robarge.gail@epa.gov](mailto:robarge.gail@epa.gov); or to Mr. Dan Costa, ORD's National Program Director for Air Research, at phone: 919-541-2532, or e-mail: [costa.dan@epa.gov](mailto:costa.dan@epa.gov).

Availability of Meeting Materials: All Agency documents to be discussed during this advisory activity will be available on EPA's ``Airborne Particulate Matter Research Centers--New (2005)'' Web page at: [http://cfpub.epa.gov/ncer\\_abstracts/index.cfm/fuseaction/outlinks.centers/centerGroup/19](http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/outlinks.centers/centerGroup/19).

The SAB meeting agenda and any other materials for this upcoming public advisory meeting will be available on the EPA Web site at <http://www.epa.gov/casac> in advance of the meeting.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information for the SAB Panel to consider on the topics included in this advisory activity and/or group conducting the activity. Oral Statements: In general, individuals or groups requesting an oral presentation at a public meeting will be limited to five minutes per speaker, with no more than a total of one hour for all speakers. Interested parties should contact Mr. Butterfield, DFO, in writing (preferably via e-mail) at the contact information noted above, by September 24, 2008, to be placed on a list of public speakers for the meeting. Written Statements: Written statements should be received in the SAB Staff Office by September 24, 2008, so that the information may be made available to the SAB Panel members for their consideration. Written statements should be supplied to the DFO electronically via e-mail (acceptable file formats: Adobe PDF, MS Word, WordPerfect, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format).

Accessibility: For information on access or services for individuals with disabilities, please contact Mr. Butterfield at the phone number or e-mail address noted above, preferably at least ten days prior to the meeting to give EPA as much time as possible to process your request.

Dated: July 8, 2008.  
Anthony F. Maciorowski,  
Deputy Director, EPA Science Advisory Board Staff Office.  
[FR Doc. E8-16118 Filed 7-14-08; 8:45 am]  
BILLING CODE 6560-50-P

## ATTACHMENT C

### **U.S. Environmental Protection Agency Science Advisory Board (SAB) Staff Office SAB Particulate Matter (PM) Research Centers Program Advisory Panel**

#### **CHAIR**

**Dr. David T. Allen**, Gertz Regents Professor of Chemical Engineering, Department of Chemical Engineering, and Director, Center for Energy and Environmental Resources, University of Texas, Austin, TX

#### **MEMBERS**

**Mr. Bart Croes**, Chief, Research Division, California Air Resources Board, Sacramento, CA

**Dr. Bruce Fowler**, Assistant Director for Science, Division of Toxicology and Environmental Medicine, Office of the Director, Agency for Toxic Substances and Disease Registry, U.S. Centers for Disease Control and Prevention, Chamblee, GA

**Dr. Terry Gordon**, Professor, Environmental Medicine, NYU School of Medicine, Tuxedo, NY

**Mr. Daniel Greenbaum**, President, Health Effects Institute, Charlestown Navy Yard, Boston, MA

**Dr. Steven Kleeberger**, Professor and Lab Chief, Laboratory of Respiratory Biology, National Institute of Environmental Health Sciences, National Institutes of Health (NIH/NIEHS), Research Triangle Park, NC

**Dr. George Lambert [M.D.]**, Associate Professor of Pediatrics, Director, Center for Childhood Neurotoxicology, Robert Wood Johnson Medical School-UMDNJ, Belle Meade, NJ 08502)

**Dr. Frederick J. Miller**, Independent consultant, Cary, NC

**Dr. Peter Scheff**, Professor, Environmental and Occupational Health Sciences, School of Public Health, University of Illinois at Chicago, Chicago, IL

**Dr. Bryan Shaw**, Commissioner, Texas Commission on Environmental Quality, Austin, TX

**Dr. Barbara Zielinska**, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

#### **SCIENCE ADVISORY BOARD STAFF**

**Mr. Thomas Miller**, Designated Federal Officer, 1200 Pennsylvania Avenue, N.W., Washington, DC

## **EPA Particulate Matter Research Centers Program**

### **SAB Advisory Panel Meeting**

**October 1-2, 2008**

### **Charge to the SAB PM Research Centers Program Advisory Panel**

The Agency seeks advice from the SAB regarding the effectiveness of the current Particulate Matter Research Centers Program and suggestions for an improved future Centers Program, and requests that the Panel focus on the following charge questions during its review of the PM Research Centers Program:

#### **Overall Charge Question**

In the context of the current state-of-the-science and the priorities for the EPA Air research program, ORD seeks advice on the possible structures and strategic direction of an Air Research Centers program for 2010 – 2015.

#### **Specific Charge Questions**

- 1. How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA's mission?**
- 2. What advice does the panel have on how to move to multi-pollutant approach in the PM Centers program?**

One prominent theme of EPA's multi-year research plan for Air is the need to better understand air pollution effects within the context of the entire ambient mixture. What advice does the panel have regarding the appropriate balance between single-pollutant and multi-pollutant research? What additional broad strategic directions should EPA consider for a future Centers Research Program?

- 3. What strengths and weaknesses does the panel see in different structural options for a future Centers Research Program?**

Given the strategic directions discussed above, please comment on various approaches EPA could consider for the *structure* of a future air pollution Centers program. For example, a future Centers program might continue with a common theme for all Centers, or might seek Centers that specialize in different research areas. In addition, some Centers might address a broad research portfolio while others have a more targeted focus. EPA may consider funding fewer Centers in order to maintain appropriate program balance with the individual STAR grants and intramural research programs. EPA is seeking the panel's views on the strengths and weaknesses of different approaches for the structure of the program.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20004

September 10, 2008

**MEMORANDUM**

**SUBJECT:** Particulate Matter Research Centers Program SAB Advisory Panel Meeting

**FROM:** William H. Sanders III, Dr. P.H.   
Director  
National Center for Environmental Research, Washington, DC  
Office of Research and Development

**TO:** Fred Butterfield  
Designated Federal Officer  
SAB Advisory Panel  
EPA Science Advisory Board Staff Office (1400F)

This memorandum provides background information and transmits charge questions for the upcoming meeting of the **EPA Science Advisory Board (SAB) Particulate Matter Research Centers Program Advisory Panel**. The Panel is scheduled to meet on **October 1-2, 2008** in Washington, DC, to advise the Office of Research and Development (ORD) on the **Particulate Matter (PM) Research Centers Program** and, subsequently, to provide the EPA Administrator with its advice and recommendations on the future directions of this program. Please forward this memorandum to the members of the SAB Advisory Panel in preparation for this review.

Attached to this memorandum is a twelve-page "Explanation of the Charge and Supporting Materials." This document explains the rationale behind ORD's request for this advisory panel and information to assist the panelists in addressing the charge questions. In addition to this memorandum, all members of the SAB Advisory Panel will receive a CD-ROM containing supporting documents referenced in the following pages. Hard-copies of these documents can be provided upon request. These supporting materials are also posted on the EPA-NCER Web site at the following URL: <http://es.epa.gov/ncer/science/pm/2008sab/index.html>.

We appreciate the efforts of the SAB Advisory Panel in preparing for this upcoming meeting, and we look forward to discussing the PM Research Centers Program with the Panel in detail on October 1-2. Should you have any questions regarding the attached explanatory document or the CD-ROM of supporting documents, please contact Stacey Katz, NCER, at phone: 202-343-9855, or email: [katz.stacey@epa.gov](mailto:katz.stacey@epa.gov), or Gail Robarge, NCER, at phone 202-343-9857, or email: [Robarge.gail@epa.gov](mailto:Robarge.gail@epa.gov).

Attachment

## Science Advisory Board Advisory Panel Meeting Particulate Matter Research Centers Program

### Explanation of the Charge and Supporting Materials

#### Overall Charge Question

In the context of the current state-of-the-science and the priorities for the EPA Air research program, the Office of Research and Development (ORD) seeks advice on the possible structures and strategic direction of an Air Research Centers program for 2010 – 2015.

#### Background

##### Particulate Matter Research Centers

EPA established new air quality standards for particulate matter (PM) smaller than 2.5 $\mu$ m in 1997 based on findings relating exposure to these fine particles with adverse health effects, including increased hospitalizations and premature deaths. In the 1998 EPA Appropriations bill, Congress augmented the President's recommended EPA budget by over \$22 million to address uncertainties in the evidence on PM health effects. A part of the expanded ORD research program was a directive to EPA to establish as many as five university-based particulate matter research centers (Tab 4-K). In addition, EPA was directed to provide support to the National Academy of Sciences National Research Council to develop priorities for a comprehensive PM research program and review of research progress over the next five years. The recommendations in the NRC Committee's first report, *Research Priorities for Airborne Particulate Matter*<sup>1</sup>, were used as a major source of guidance for the PM Centers Request for Applications (RFA). Prospective Centers were asked to propose an integrated research program on the health effects of PM, addressing a set of research needs in the areas of exposure, dosimetry, toxicology and epidemiology (Tab 4-L). The first research Centers were funded from 1999 – 2005, with a total program budget of \$8 million annually (Tab 4-M). Although the initial funding was awarded for five years, the Centers were funded for a sixth year, so that the final NAS report could be considered in the next solicitation.

In 2002, with the first PM Centers grants at a midway point, the EPA Science Advisory Board (SAB) conducted an interim review that recommended continuing the Centers program, while maintaining a balance of Centers and individual grants (Tab 4-N). Subsequent to the positive SAB review and the issuance of the 2004 NRC report<sup>1</sup>, a second PM Centers competition was held. The recommendations and conclusions in the interim SAB review and the final NRC report were highly influential in the development

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<sup>1</sup> <http://search.nap.edu/nap-cgi/de2007.cgi?term=Research+Priorities+for+Airborne>

of the second PM Centers solicitation. The 2004 RFA focused on understanding which sources and components in the particle mixture, as well as which size fractions or other physical attributes are most responsible for observed adverse effects (Tab 4-O). The RFA asked respondents to address the central theme of “linking health effects to PM sources and components,” and to focus on the research priorities of susceptibility, biological mechanisms, exposure-response relationships, and source linkages (although applicants were not required to address all four topics). While the 2004 RFA did not require specific scientific disciplines to be included in the proposal, the RFA emphasized the need for integration, focusing on research strengths, partnering with others who have complementary strengths, and showing how integration would occur. From the second competition, five current Centers are funded for 2005-2010 (program budget of \$8 million annually).

### **Original and Current PM Research Centers**

<b>Harvard University PM Research Center</b> (Director: Petros Koutrakis), 1999-2005 and 2005-2010
<b>Johns Hopkins PM Research Center</b> (Director: Jonathan Samet), 2005-2010
<b>Northwest Research Center for Particulate Air Pollution and Health</b> (Director: Jane Koenig) 1999-2005
<b>New York University PM Center</b> (Director: Morton Lippmann) 1999-2005
<b>San Joaquin Valley Aerosol Health Effects Center at UC Davis</b> (Director: Anthony Wexler) 2005-2010
<b>Southern California Particle Center</b> (Director: John Froines) 1999-2005 and 2005-2010
<b>University of Rochester PM Research Center</b> (Director: Gunter Oberdorster) 1999-2005 and 2005-2010

EPA is now seeking the advice of the SAB before announcing a third competition. Current plans are for an RFA to be issued in 2009, in anticipation of funding Centers for 2010 – 2015.

### ORD Multi-Year Plan for Clean Air Research

ORD’s National Program Director for Clean Air Research led the recent revision of the plan that explains goals and priorities in air research. The program is now guided by the Clean Air Research Multi-Year Plan<sup>2</sup> (MYP), 2008-2012 (see inside pocket of notebook). It addresses research in the areas of PM, ozone, and air toxics, combined into a single, comprehensive plan, and emphasizes the need to move from a single-pollutant focus to a multi-pollutant approach. The plan was reviewed by a panel of external scientists through ORD’s Board of Scientific Counselors. The two long-term goals (LTGs) of this plan are:

<sup>2</sup> <http://www.epa.gov/ord/npd/pdfs/Air-MYP-narrative-final.pdf>

LTG 1: Reduce uncertainties in standard setting and air quality management decisions due to advances in air pollution science

LTG 2: Reduce uncertainties in linking health and environmental effects to air pollution sources.

The MYP envisions a coordinated program of air research, describing goals and objectives to be addressed jointly by the EPA intramural research laboratories and the extramural research grants program. The current PM Centers are conducting work that will contribute to many of the annual performance goals and measures in the plan.

The intramural and extramural air research programs are highly integrated and complement each other throughout the MYP. In certain areas, such as epidemiology, the extramural program provides the bulk of research, whereas other areas, such as combustion engineering, are primarily the focus of the intramural program. Significant research efforts in areas such as toxicology, exposure, controlled human exposure and atmospheric science are actively supported in both the intra- and extramural programs and carefully coordinated to achieve the long-term and annual performance goals specified in the MYP.

#### Coordination with Other Air Research Programs

As ORD considers future strategic directions, ORD is cognizant that other agencies also fund highly relevant research. For ORD, critical considerations are EPA's unique research niche and its mission as a regulatory agency. In research areas where other large funders, such as the National Institutes of Health or the National Science Foundation, have major initiatives, EPA involvement makes sense if the focus is more related to the Agency's mission. For example, the NIEHS strategic plan (2006-2011)<sup>3</sup> emphasizes gene-environment interactions; cross cutting problems in human biology and human disease; improved community-linked research; and sensitive markers of environmental exposure. In this context, EPA is only likely to fund research on gene-environment interactions that is very targeted to specific research questions of interest to EPA. EPA also coordinates with other sponsors of air pollution research, including the California Air Resources Board<sup>4</sup> and the Health Effects Institute (HEI)<sup>5</sup> – interaction takes various forms, such as providing input to strategic plans and research solicitations, participating in review of applications, and collaborating on workshops.

#### EPA's Extramural Air Research Grants Program

EPA's National Center for Environmental Research (NCER)'s extramural research is conducted principally through the Science to Achieve Results (STAR) program. STAR is a competitive, rigorously peer-reviewed program of research grants that solicits proposals

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<sup>3</sup> NIEHS strategic plan: <http://www.niehs.nih.gov/about/od/strategicplan/index.cfm>

<sup>4</sup> California Air Resources Board strategic plan: <http://www.arb.ca.gov/research/apr/apr.htm>

<sup>5</sup> HEI strategic plan: <http://www.healtheffects.org/Pubs/StrategicPlan2005-2010.pdf>

from scientists at universities and nonprofit institutions in response to targeted Requests for Applications (RFAs) issued by NCER. The RFAs address research priorities in ORD's multi-year research plan. They are developed in conjunction with the National Program Director and scientific staff from ORD laboratories, regions, and the EPA Office of Air and Radiation, considering input from external scientific advisory panels and workshops. In recent years, the NCER Air Research program has funded \$15-18 million in air grants annually, out of the total STAR budget of approximately \$55-65 million (Tab 4-P). Each year, \$8 million of the NCER Air budget funds the inter-disciplinary PM Research Centers.

#### STAR Individual Research Grants

Each year, \$6-8 million from NCER Air budget is awarded through RFAs for individual grants. In contrast to Centers, these RFAs can be targeted to very specific research topics that require a particular focus. Given the complexity of air research Centers, funding for a five year period is needed to accomplish all of the Centers objectives, many of which are cross-discipline. Individual grants tend to be three years in duration and allow EPA to solicit proposals in response to quickly emerging issues and targeted needs for research methods development. In addition, individual grants provide ORD with the ability to address a single topic, such as effects of long-term exposures to PM or assessing the potential toxicity of coarse PM, with single, dedicated grants. Recent RFAs for individual STAR grants have addressed high priority, focused research needs, for example:

- **A prospective epidemiological study** to examine the health effects of long-term exposure to PM. The investigators are studying the effects of exposure to air pollution on 8700 people aged 50-89 prospectively for ten years. This is the largest research grant ever funded by EPA, and it is a joint effort with the National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI). The majority of the study population recruitment and medical examinations are conducted through the NHLBI Multi-Ethnic Study of Atherosclerosis. The air pollution study, known as MESA-Air<sup>6</sup>, will provide new and critically important information on the role of PM and other air pollutants in cardiovascular disease and mortality.
- **Atmospheric science** studies focused on measurement and modeling methods, with a special emphasis on understanding the sources of carbonaceous particulate matter.
- Research to understand the sources, composition and effects of **coarse particulate matter**, including research by both atmospheric and health scientists.
- **Innovative approaches** to using advanced measurement and modeling techniques that can strengthen the air quality and exposure aspects of

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<sup>6</sup> MESA-Air fact sheet [http://es.epa.gov/ncer/publications/factsheets/mesa\\_air.pdf](http://es.epa.gov/ncer/publications/factsheets/mesa_air.pdf)

epidemiologic studies.

A complete list of STAR RFAs in the Air Program and a description of the process through which RFAs are developed and grants awarded can be found in Section 4-Q.

## Specific Charge Questions

### **Charge Question 1. How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA's mission?**

#### Advancing Research Most Relevant to EPA's mission

EPA believes the PM Centers have contributed significantly to the scientific literature on exposure to and effects of airborne PM. To support this conclusion, a range of evidence is provided in section 2 of the SAB panel notebook and described briefly here.

From a scientific perspective, the Centers have made major contributions in many areas of PM research. At the SAB panel meeting, Dr. Dan Costa, EPA's National Program Director for Clean Air Research, will present some key examples of how the PM Centers have played a role in advancing air pollution research, selected from the Centers' integrated summaries of accomplishments and progress reports. Additionally, Dr. Costa will provide an EPA scientific perspective on the benefits that have resulted from the Centers program, for example:

- Recognized as world leaders in investigating the health effects associated with exposure to ultrafine particles and in characterizing the chemical composition, sources, and atmospheric processing of ultrafine particles;
- Advanced the theory of oxidative stress as a key mechanism by which PM causes adverse health effects, including elucidating the role of reactive oxygen species;
- Developed cutting edge technologies for PM research, e.g., size-specific particle concentrators, personal exposure monitors, single particle analyzers;
- Produced unique contributions in epidemiology and biostatistics, areas which complement the EPA intramural program;
- Played a key role in research to link health effects of PM to sources, e.g., demonstrating that emissions near roadways are of special concern;
- Participated in cooperative efforts among Centers and with EPA, including advances in controlled human exposure studies.

A discussion of these and other outcomes is provided in a brief report by senior EPA scientist Dr. Robert Devlin (Tab 1-A).

#### Summary Report from Original Centers

The major scientific findings of the original PM Centers (1999-2005) are summarized in a final report to EPA (Tab 1-B)<sup>7</sup>. This summary report was drawn from three technical reports which were prepared by working groups from across the five PM Centers and

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<sup>7</sup> A manuscript integrating and summarizing the Centers findings is under review for publication in Environmental Health Perspectives.

address the following topics: PM health effects including epidemiology and toxicology, mechanisms of PM toxicity, and PM characterization and exposure; all contain extensive references to previously published findings (Tab 4-R, and <http://es.epa.gov/ncer/science/pm/centers.html>).

#### Current Center Progress Reports

The productivity of the current Centers is presented in progress reports prepared by each Center. Rather than provide only the annual update for this past year, the Centers summarized their progress over the last three years, highlighting preliminary findings and their significance (Tab 1-C). These reports illustrate the extent to which the PM Centers conduct multi-disciplinary research. In addition, the multiple authors of many PM Center publications illustrate the multi-disciplinary cooperation within the Centers.

#### Research Impacts

At the SAB panel meeting, the Office of Air Quality, Planning and Standards' (OAQPS) Director of the Health and Environmental Impacts Division, Lydia Wegman, will discuss the National Ambient Air Quality Standards (NAAQS) setting process, and how the PM Center science supports air quality regulation and decision-making (Tab 4-S). Of note, PM Center publications play prominently in the review of the PM NAAQS and in the development of state, local, and public health and air quality policies (Tab 1-D). The Centers' work contributed to the 2007 PM NAAQS review and will certainly impact the upcoming EPA Integrated Science Assessment (ISA) for PM. As part of the 2007 review, ORD prepared a "provisional assessment" of research studies published between 2002 and 2006 that were of potentially greatest relevance to assessing the health effects of PM. Of the 215 national and international citations in this PM provisional assessment, 71 (or 33%) were PM Center papers.

Also, the Centers' work has been cited in policy statements from the American Heart Association and the American Academy of Pediatrics. For example, the American Heart Association issued a scientific statement on air pollution and cardiovascular disease, reviewing the literature and addressing the public health indications for clinicians and policy implications for regulators. Of the statement's 108 recent citations (since 2000), which include international sources, 18 (or 17%) were PM Center papers. PM Center work also influences state and local policy decisions – for example, the California state law specifying that schools must be sited at least 500 feet away from freeways.

Beyond air pollution, the Centers' work is significantly influencing new directions in science. For example, toxicological work by the Southern California Particle Center has been cited in a recent NAS report on "Toxicology in the 21<sup>st</sup> Century" as contributing to "a revolution taking place in biology." Also, studies of ultrafine particles by the University of Rochester and Southern California PM Centers are providing a foundation for studying the health effects of nanoparticles (Tab 1-D).

### Bibliographic Analyses

As one aspect of assessing productivity of research programs, ORD has begun analyzing publications data. The original PM Centers collectively authored over 500 publications. An analysis of these papers with respect to citation rates, publication in high impact journals, and other features demonstrates that this program is highly productive and far exceeds expectations. For example, when the frequency of citation of PM Center publications was compared to that of all publications in their field, 37% of PM Center publications ranked in the top 10% (3.7 times as many as expected), and 5.5% of PM Center publications ranked in the top 1% (5.5 times as many as expected). As explained in the brief report (Tab 1-E), this analysis primarily focuses on publications from the original Centers, since the current Centers have not yet reached a critical mass of publications. Although the publications analyses show that publication counts do not peak until the last year of a Center, the current Centers have published over 100 papers to date.

### External Review of PM Research Program

The PM Centers program is an integral part of the EPA Air Research Program and as such has been included in the reviews of the Air Research Program by ORD's external Board of Scientific Counselors (BOSC). Conclusions from the 2005 review relating to the high quality of the air research program and integration between the intramural and extramural programs (Tab 1-F) include:

“The ORD PM & O<sub>3</sub> Research Program has resulted in significant reductions in scientific uncertainty in critical areas.”

“The Subcommittee finds a high degree of integration in the conduct of intramural and extramural research across the various laboratories, centers, and scientific disciplines.”

“The Subcommittee finds the overall science being conducted by the ORD PM & O<sub>3</sub> Research Program in both intramural and extramural research laboratories to be of high quality as indicated by: (a) scholarship and scientific publications; (b) credentials of participating investigators; (c) integrative and outcome-oriented program design; and (d) building of a knowledge and information database.”

In September 2007, the Clean Air program underwent a “mid-cycle review” by the BOSC and was rated as “exceeds expectations” in the context of performance categories established by the Office of Management and Budget. The quality and impact of the Air program publications, weighted heavily by Center publications, were specifically cited by the BOSC in its report.

### Interactions, Scientific Training, and External Advice

In assessing the success of the PM Centers, several other factors are relevant including evidence such as: 1) examples of interaction among the Centers, with EPA scientists and the broader scientific community and the subsequent benefits of those activities; 2) scientific training provided by the five Centers to almost 90 post-doctoral students and over 50 graduate students in an interdisciplinary environment, inspiring the next generation of air pollution researchers; and 3) guidance and oversight by external scientific advisory committees, comprised of highly-respected scientists, including senior scientists from other PM Centers and EPA (Tab 1-G).

### **Charge Question 2. What advice does the panel have on how to move to a multi-pollutant approach in the PM Centers program?**

#### ORD's Multi-year Plan for Clean Air Research: Moving Towards Multi-Pollutant Research

EPA's Multi-year Plan (MYP) for Air research recognizes the importance of providing research to support the single-pollutant regulatory program at EPA, while moving the program toward a multi-pollutant focus that better reflects the complexity of real-world air pollution exposures (excerpts, Tab 2-H).<sup>8</sup> As noted above, the plan includes two major long-term goals (LTGs):

LTG 1: Reduce uncertainties in standard setting and air quality management decisions due to advances in air pollution science

LTG 2: Reduce uncertainties in linking health and environmental effects to air pollution sources.

The first LTG (LTG 1) supports the following priorities/themes:

- 1) Developing the NAAQS and other air quality regulations – includes research on health effects of PM size fractions, PM components, effects of long-term exposure, biological mechanisms, and susceptibility
- 2) Implementing air quality regulations – includes measurement methods, emissions factors, modeling, source apportionment, and air quality forecasting

The second LTG (LTG 2) is more multi-pollutant in nature and is oriented toward three research themes

- 1) Launching a multi-pollutant research program

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<sup>8</sup> EPA is cognizant that air pollution conditions in the future will need to be understood in the context of changing global conditions. ORD's Clean Air MYP does not focus on how climate change will affect air quality, as that is currently one of the main focus areas for EPA's Global Change research program (<http://www.epa.gov/ord/npd/globalresearch-intro.htm>).

- 2) Identifying specific source-to-health linkages, with initial emphasis on “near roadway” impacts
- 3) Assessing the health and environmental improvements due to past regulatory actions

#### External Advice on Moving Toward a Multi-Pollutant Focus

Multiple external advisory committees have encouraged EPA to move to a multi-pollutant approach to researching, assessing and managing air pollution risks

- “There is an opportunity and a critical need to shift the focus of the EPA program from a single pollutant, PM, to a multipollutant orientation. Because of the momentum that the PM research program has generated over the past 6 years, now is an opportune time to begin orienting EPA’s air quality research program toward a broader scope that specifically considers all components of the atmosphere – PM and the other criteria pollutants, hazardous pollutants, and the other nonclassified components of the atmosphere. The committee envisions a transformation from a PM-focused research program to a multiple air pollutant program (MAPP).” (NRC. *Research Priorities for Airborne Particulate Matter, IV: Continuing Research Progress*. 2004, [http://www.nap.edu/catalog.php?record\\_id=10957](http://www.nap.edu/catalog.php?record_id=10957); See Executive Summary in Tab 2-J)
- “Air quality management should...strive to take an integrated multipollutant approach to controlling emissions of pollutants posing the most significant risks.” (National Research Council. *Air Quality Management in the United States*. 2004, [http://www.nap.edu/catalog.php?record\\_id=10728](http://www.nap.edu/catalog.php?record_id=10728))
- “For the SIPs States are required to submit over the next several years, EPA and S/L/T should promote the consideration of multipollutant impacts, including the impacts of air toxics, and where there is discretion, select regulatory approaches that maximize benefits from controlling key air toxics, as well as ozone, PM<sub>2.5</sub>, and regional haze. The SIP process provides an opportunity for many urban areas to include key toxic air pollutants in a comprehensive, multipollutant air quality plan.” (Air Quality Management Work Group. *Recommendations to the Clean Air Act Advisory Committee*. January 2005, <http://www.epa.gov/air/caaac/aqm/report1-17-05.pdf>)

EPA’s own regulatory Office of Air Quality Planning and Standards (OAQPS) has reorganized to encourage a multi-pollutant focus, rather than its former “stove-piped” split between criteria pollutants and air toxics (Tab 2-I). It also is designed to develop expertise and leadership in multi-pollutant, sector-based approaches.

#### Current PM Center Research Focus

Currently, the PM Research Centers’ primary goal is to link PM sources and components to health effects, emphasizing the following general research areas:

- susceptibility to the adverse effects of exposure to PM of different composition or from different sources
- biological mechanisms by which PM and/or PM components cause adverse effects

- exposure-response relationships for biologically important constituents/sizes of PM and PM from different sources
- relationships between emissions sources and ambient concentrations of PM, its components and size fractions.

### The Challenge

As ORD contemplates the next round of research centers, the challenge is moving from PM-focused Centers to broader “air pollution” Centers that will address source-to-health effects questions from a multi-pollutant perspective. Yet understanding about PM sources and components is just beginning. For example, monitoring data have only recently become available to begin assessing the effects of exposure to PM components. ORD has just begun to support research specifically on coarse particles, and studies on ultrafine particles are still relatively new. Thus, ORD expects to continue PM research for the next several years. However, considering the next competition for research centers, ORD would like to emphasize moving toward a multi-pollutant program that reflects a more realistic view of air pollution science.

### Request for SAB Panel Advice

Recognizing the importance of anticipating future research priorities, while continuing to address the research needs of EPA’s current regulatory program, ORD asks the panel for advice on how to address these competing priorities in the future by providing insights on strategic directions for the Centers. ORD asks the panel for advice on how to move the Centers toward a multi-pollutant program.

The emphasis on linking health effects to PM sources and components is relatively recent. Does it make sense to continue on this path in some capacity? Similarly, as research on effects from exposure to specific components and size fractions of PM gets underway, do questions of biological mechanisms and susceptibility continue to be top priorities?

If ORD continues some Center work on single pollutant themes, how should the program address the growing scientific and technical challenges of complying with new national ambient air quality standards?

Given a multi-pollutant strategic direction, how can Air Research Centers best contribute to moving the air pollution science forward using this approach? Are the primary questions health-related, compliance-related or both? How should ORD approach multi-pollutant research? Is it a combination of a few air pollutants that often track together, or must it be a large, complex mixture consisting of multiple criteria and hazardous air pollutants? What is the appropriate balance of health, exposure and atmospheric science research in multi-pollutant Centers?

ORD believes that the panel's insights on the questions above will be invaluable in charting future directions for the PM Centers program as it evolves into an Air Research Centers program.

**Charge Question 3: What strengths and weaknesses does the panel see in different structural options for a future Centers Research Program?**

EPA would like to think broadly about how the structure of Research Centers would affect the research program. As ORD contemplates changes in strategic direction for the program, and in light of declining resources, ORD would also like to consider whether the Centers program structure used for the past 10 years should be continued or could be improved. In the context of the strategic directions discussed in the second charge question, we request the SAB panel discuss and articulate strengths and weaknesses of each option below – and as needed, strengths and weaknesses of any additional scenarios the Panel suggests.

Given the different perspectives of panel members, this charge question intentionally asks the panel to illuminate the strengths and weaknesses of **each** option below. ORD is **not** requesting that one preferred structural option be recommended. The panel brings a breadth of perspectives that could shed light on implications of each option that ORD may not anticipate when moving forward with developing the next Research Centers RFA. ORD plans to incorporate the feedback received from the panel regarding structural options into the RFA writing team's discussions. All of these perspectives will be considered collectively to determine which structure will best meet the objectives of the RFA.

In the current budget climate, ORD is expecting to reduce the size of the Centers program. Current Centers are funded at approximately \$1.6 million each, or \$8 million total annually. Given resource projections, a balanced program between the Centers and other extramural research would be in the \$6-7 million dollar range which would fund four Centers of the current size. This would allow ORD to maintain the STAR individual grants program in the range of \$6-7 million, as well as continuing to provide funding for the intramural air research program. ORD will consider whether to continue to fund five Centers at a reduced funding level (e.g. \$1-1.2 million per year per Center) or whether to reduce to four Centers in order to maintain approximately the current funding level. ORD welcomes the SAB panel's views on this issue.

Research topics mentioned in the options below refer to a general research area, e.g., in the last RFA – susceptibility, biological mechanisms, source linkages. Within each topic in the RFA, specific science questions are given for the applicant to address.

## Structural Options For Research Centers Program (Tab 3)

### 1. Same research topics for all applicants – large Centers

This RFA would continue with the structure that EPA has used to date. It would include several research topics, listing specific science questions within each. All applicants would propose interdisciplinary research in response. Usually, each applicant addresses most of the questions listed in the RFA.

#### Strengths

- When multiple Centers address the same questions using different approaches, they produce a rich set of results that can be analyzed and compared at multiple levels. Examples include: statistical methods, technological innovations, and biological and atmospheric insights.
- Easier to foster collaboration among the Centers as they all would be addressing similar issues with different approaches.

#### Weaknesses

- With limited resources it may not be most efficient to have all Centers addressing the same set of questions.
- Most Centers will not have strong efforts in all areas.

### 2. Regional Centers

This type of RFA would require Centers to have a regional focus, reflecting the understanding that air pollution exposures and effects may vary by region of the country depending on predominant sources, land use, and atmospheric conditions. The RFA would also require specific ties to state and local air quality decision makers and public health officials in that region. The topic areas could be loosely defined, in order to allow freedom for Centers to choose the air pollution research questions of most importance to their regions. The intent would be to develop strong links between health and atmospheric science researchers. The assumption with this option is that there could be more than one Center in any given region. There would be no pre-determined regions for the RFA. Selection of Centers would be based on a combination of scientific excellence and regional representation.

#### Strengths

- Would promote research on effective implementation strategies to achieve air quality goals.
- Ties to state and local air quality decision makers and public health officials in the regions will enhance the relevance and outcomes of the research.

#### Weaknesses

- Studies addressing national problems or impacts would be less likely to be proposed under this option.

- More difficult to promote collaborations across Centers.

### 3. Big and small Centers

This RFA would solicit a certain number of large and small Centers. One example could be 2 large, multi-disciplinary Centers at current size and 3 or 4 smaller Centers at half size. The smaller Centers have the option of being multi-disciplinary, but smaller in scope. The topics for each size would be defined in the RFA.

#### Strengths

- Would make possible both large Centers modeled after the current ones that can address broad multi-disciplinary questions, as well as smaller Centers that could be targeted to specific areas.
- Would expand the range of applicants to include groups that are excellent in limited areas but not large enough to compete for a large Center.

#### Weaknesses

- Cross-Center efforts would be more challenging.

### 4. Choice of one topic – large Centers

This RFA would fund large, multi-disciplinary Centers. The RFA would include two research topics and applicants would be required to respond to only one. The RFA would describe the scientific uncertainties of interest within each topic and present scientific questions under each. As an example, EPA might fund one Center studying the first topic and three Centers studying another topic (or 2 and 2).

#### Strengths

- Would allow applicants to focus the application on areas of strength and expertise instead of trying to cover multiple or too broad topics.
- Promotes more focus within a given Center and advances the science in two distinct areas.

#### Weaknesses

- May not receive strong scientific applications in both areas, resulting in a limited scope of the program.
- Cross-Center efforts would be less likely across Centers addressing different topics.

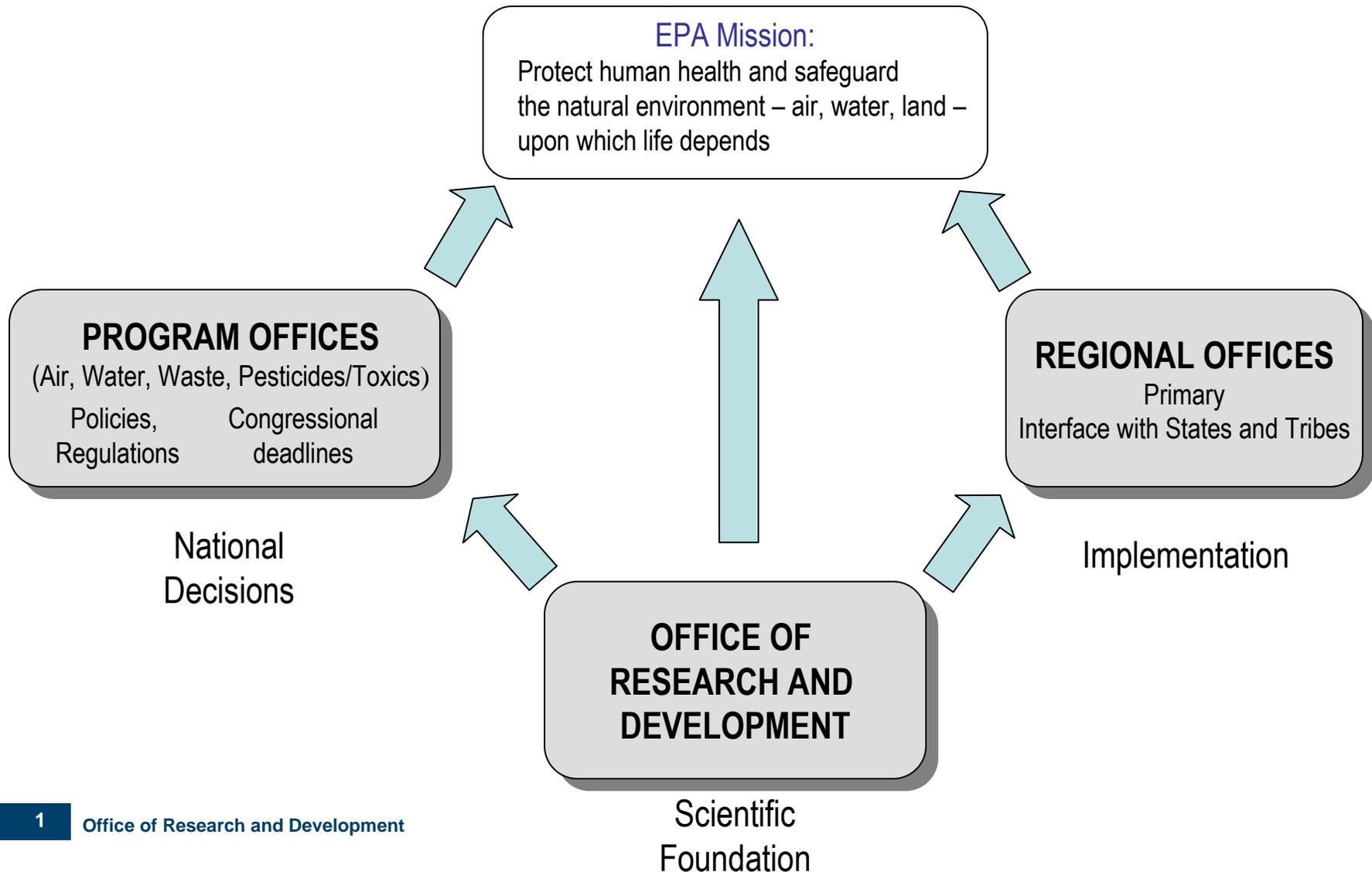
### 5. Other – Such as a hybrid of any options above

# Overview of EPA's Extramural Research Grants Program

*Christopher Zarba, Deputy Director  
National Center for Environmental Research  
Office of Research and Development, U.S. EPA*



# Support for EPA's Mission

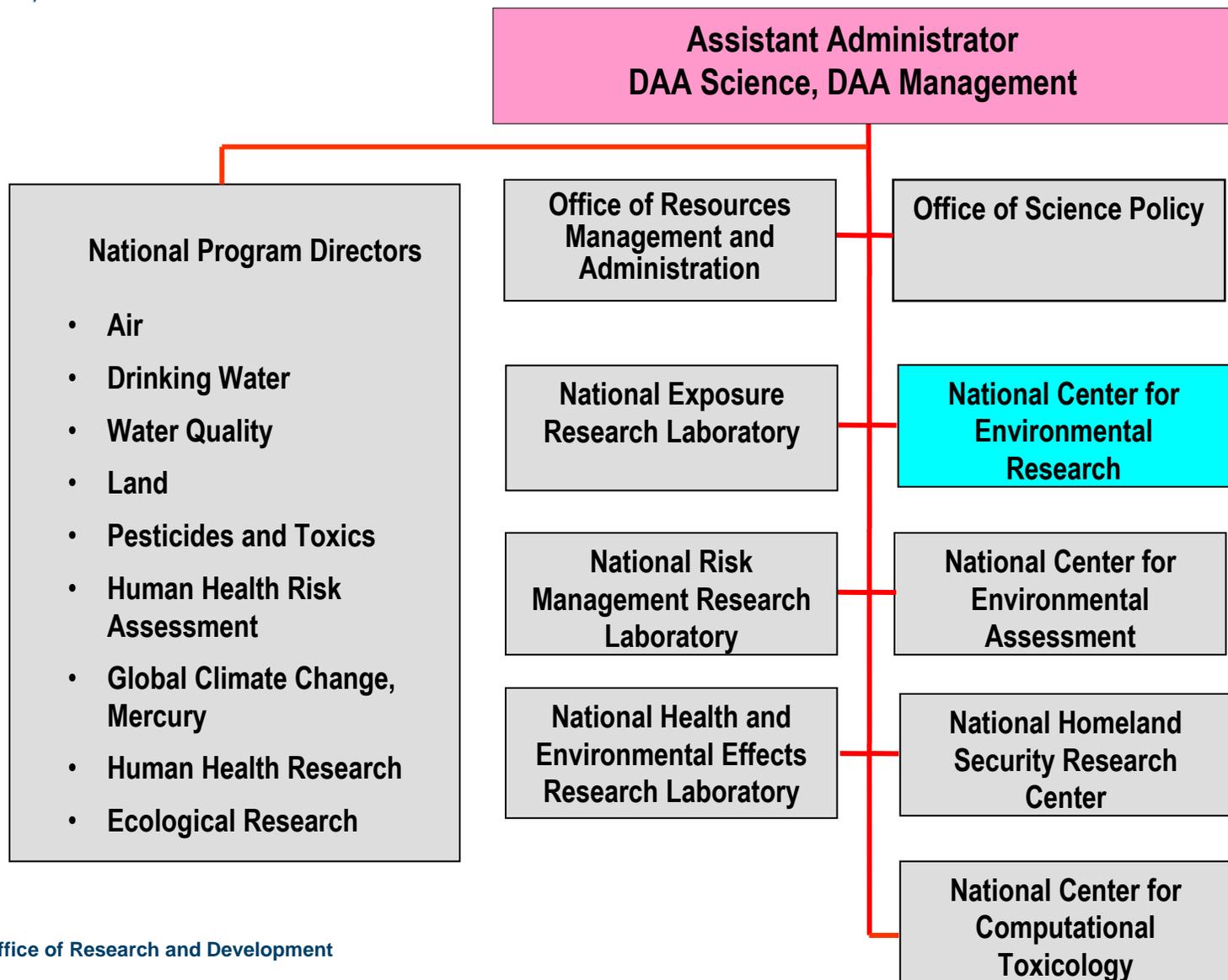


# Research and Development

- 1,800 employees
- \$500 million budget
- \$65 million extramural research grant and fellowship program
- 13 lab or research facilities across the U.S.
- Credible, relevant and timely research results and technical support that inform EPA policy decisions



# How ORD is Organized



# NCER's Extramural Programs

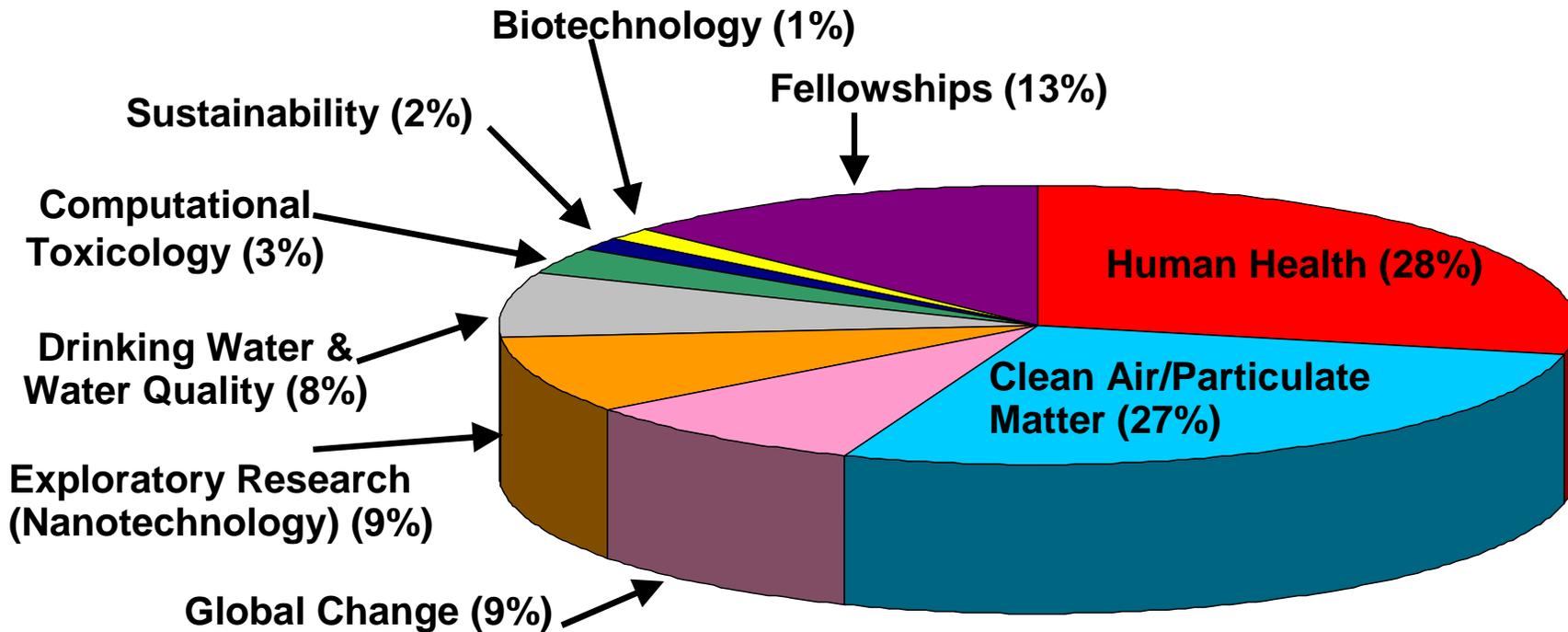


- STAR Grants
  - Established in 1995 to include universities and non-profit centers in EPA's research program and to ensure the best possible quality of science in areas of highest risk and greatest importance to the agency
  - FY08 budget: \$65 million
  - Manages ~1000 active research grants and fellowships
  - People, Prosperity and the Planet (P3)
- Small Business Innovation Research Program
- Earmarked Centers



# STAR's Research Programs

ORD in cooperation with other EPA offices (using the ORD Strategic Plan, national environmental research needs, relevance to Agency mission, and research being done in ORD's intramural program) selects topics for the STAR program.

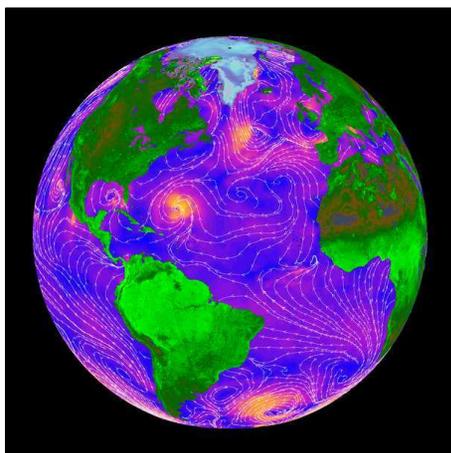


**NCER Budget FY08 ~\$65 million**

- Ecological Services
- Endocrine Disrupting Chemicals

## Please Note:

- NCER's air and global change programs are separate, with separate budgets
- A good portion of the global change research investigates impacts of global change on air quality
- **The air program will be the focus of our discussions**



# Research Planning and RFA Development Process

- ORD research programs are guided by NPDs, working with representatives from the intramural labs and NCER
- A multi-year research plan identifies priority research needs
  - Developed by the NPD working with EPA client offices, labs, and regional staff with input from external scientific advisory committees
  - Considers research supported by other agencies and funders
- RFA topics selected to address Multi-Year Plan priorities and complement EPA's intramural research program
- Air RFA writing teams represent different offices in OAR (policy), EPA intramural scientists, and EPA Regions



# RFA Review Process

1. Applications are peer-reviewed by a panel of external scientific experts
2. Applications that pass peer review are reviewed internally by a panel of EPA scientists, including client offices
3. Application(s) are selected for funding based on combined ratings from internal and peer review panels and past performance of applicants

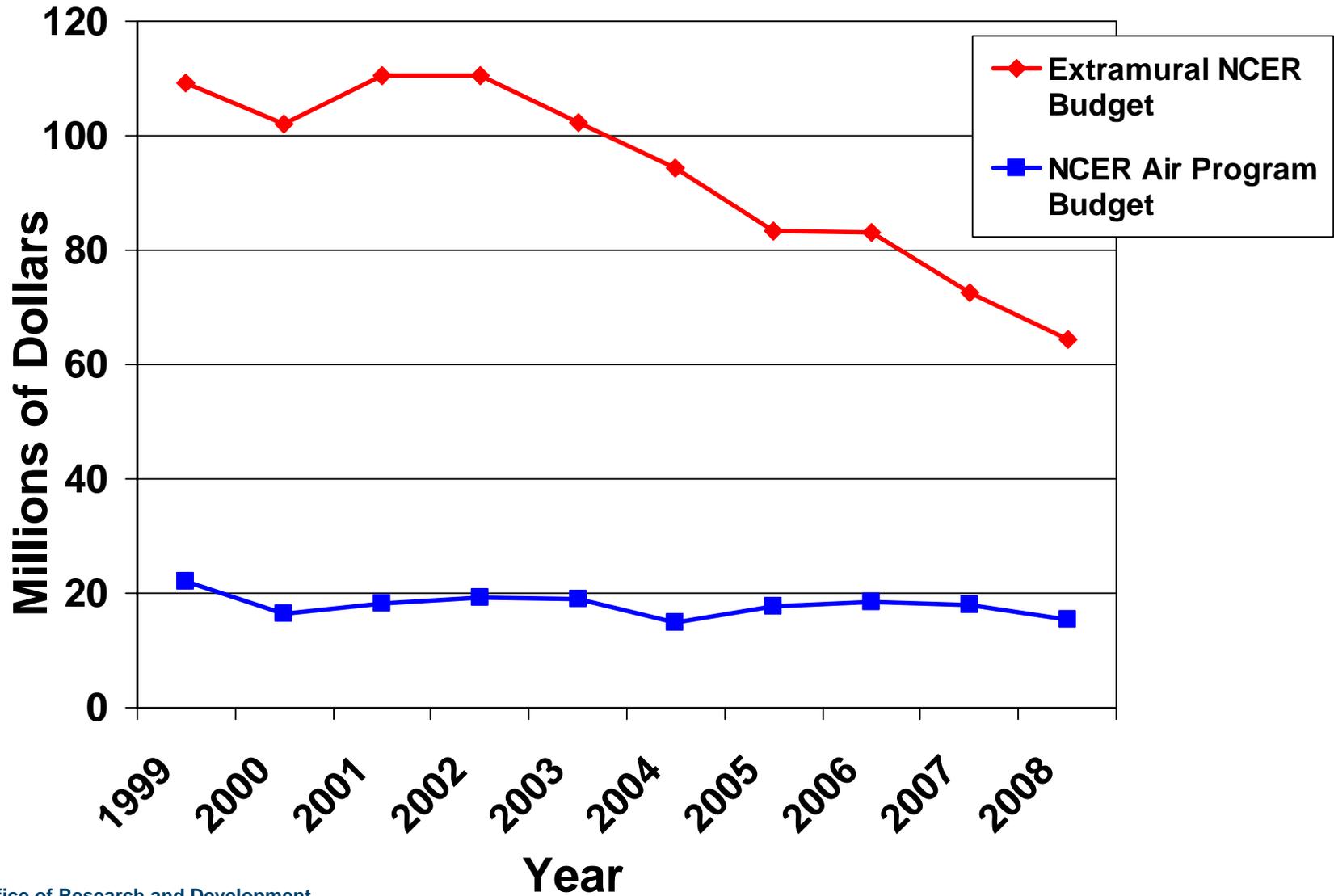


## NCER's Air Research Program

- \$15-18 million per year
- 2002 SAB review panel advised NCER to keep balance between Centers and individual grants
- May want to consider funding fewer Centers than the current five:
  - Shrinking NCER budget
  - Inflation and rising costs of research: \$8 million in 2008 only buys the equivalent of \$6 million dollars in 1999, which is a 25% cut



# NCER Extramural Grants Budget: Total Grants and Air Grants



## Recent Air Research Topics

<b>Years</b>	<b><i>PM Center Research Topics</i></b>	<b><i>STAR Grant Research Topics</i></b>
1999-2005	Exposure Dosimetry Modeling Toxicology Epidemiology	Health effects of PM Mechanisms of PM cardiovascular effects Epidemiologic research on health effects of long-term exposure to PM & other air pollutants Measurement, modeling, and analysis methods for airborne carbonaceous fine PM Source apportionment of PM
2005-present	Link health effects of PM with PM components and sources	Continuous measurement methods for PM composition Sources, composition and health effects of coarse PM Sources and formation of organic PM Health effects of near-roadway exposures to air pollution (cooperative agreement) Innovative approaches to PM health, composition and source questions

# PM Center Selection Process

- Five Centers selected in 1999
- Three original Centers were renewed and two new Centers were awarded under second RFA in 2005

<u>Original Centers</u>	<u>Current Centers</u>
Harvard University	Harvard University
Rochester University	Rochester University
Southern California Particle Center (UCLA, USC)	Southern California Particle Center (UCLA, USC)
New York University	Johns Hopkins University
Northwest Research Center (University of Washington)	San Joaquin Valley Aerosol Health Effects Research Center (UC-Davis)

Truly competitive process

- International and highly renowned scientists on peer review panel

## PM Centers Have Been Highly Successful

- Proud of PM Centers program – an important part of NCER’s Air Program
- 500+ publications from original Centers
- Citation rates of publications higher than expected
  - 3.7 times more publications than expected rank in the top 10% of publications
  - 5.5 times more publications than expected rank in the top 1% of publications
- Over 100 publications from current Centers
- High caliber of science, for example
  - In the recent NAS report, *Toxicity Testing in the 21st Century: A Vision and a Strategy*, SCPC research was prominently cited in the Vision chapter, describing a

“revolution taking place in biology”

with progress being made in the elucidation of cellular-response networks  
(Nel et al., *Science*, 2006)

## Closing Thoughts

- NCER integral part of ORD Air Program
- In the face of decreasing resources across ORD, we want the strongest program possible
- We look forward to the SAB panel's discussion to guide us as we move forward
- We thank you in advance for your assistance



Great Smoky Mountains, Hazy Day



Great Smoky Mountains, Clear Day



# CLEAN AIR RESEARCH PROGRAM

BUILDING A SCIENTIFIC FOUNDATION FOR SOUND ENVIRONMENTAL DECISIONS

www.epa.gov/ord

## Overview of EPA's Air Research Program and Role of EPA's Particulate Matter (PM) Research Centers

SAB PM Center Advisory Panel  
October 1-2 2008



**Dan Costa, Sc.D., DABT**  
Office of Research & Development  
USEPA

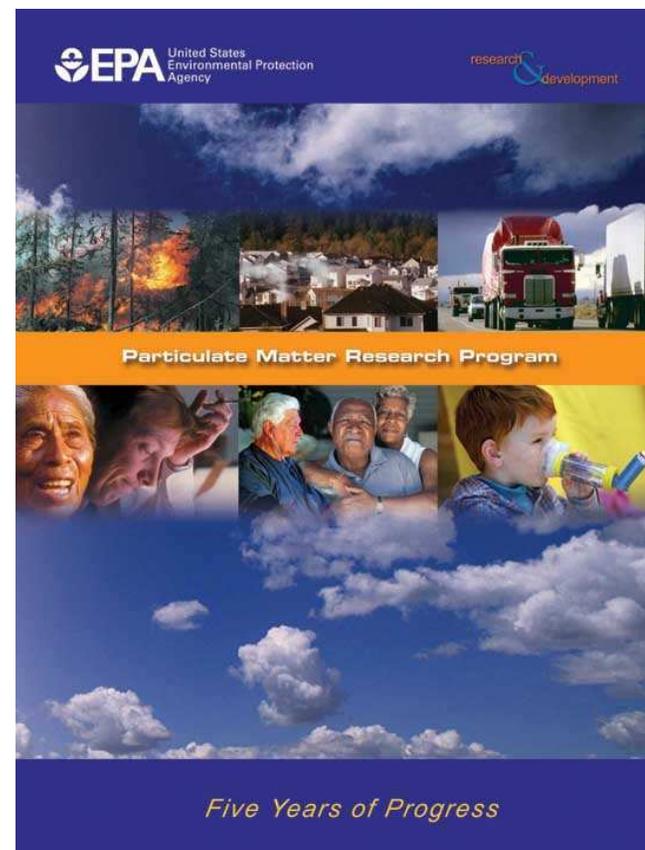


U.S. Environmental Protection Agency  
Office of Research and Development

costa.dan@epa.gov

# Overview

- Background
  - Brief history of the Air (PM) program & Centers
  - Air program structure & coordination
- Value of Centers to EPA Research Program
  - Complements intramural program
  - Cutting edge science
- Making a difference
  - Science highlights
  - Enhancing public health
- Conclusion



# *ORD Clean Air Research Program*

The Clean Air research program utilizes interdisciplinary, problem-oriented approaches that are coordinated and leveraged to better understand and reduce the risks associated with air pollution.



## ***1998: New Emphasis on PM***

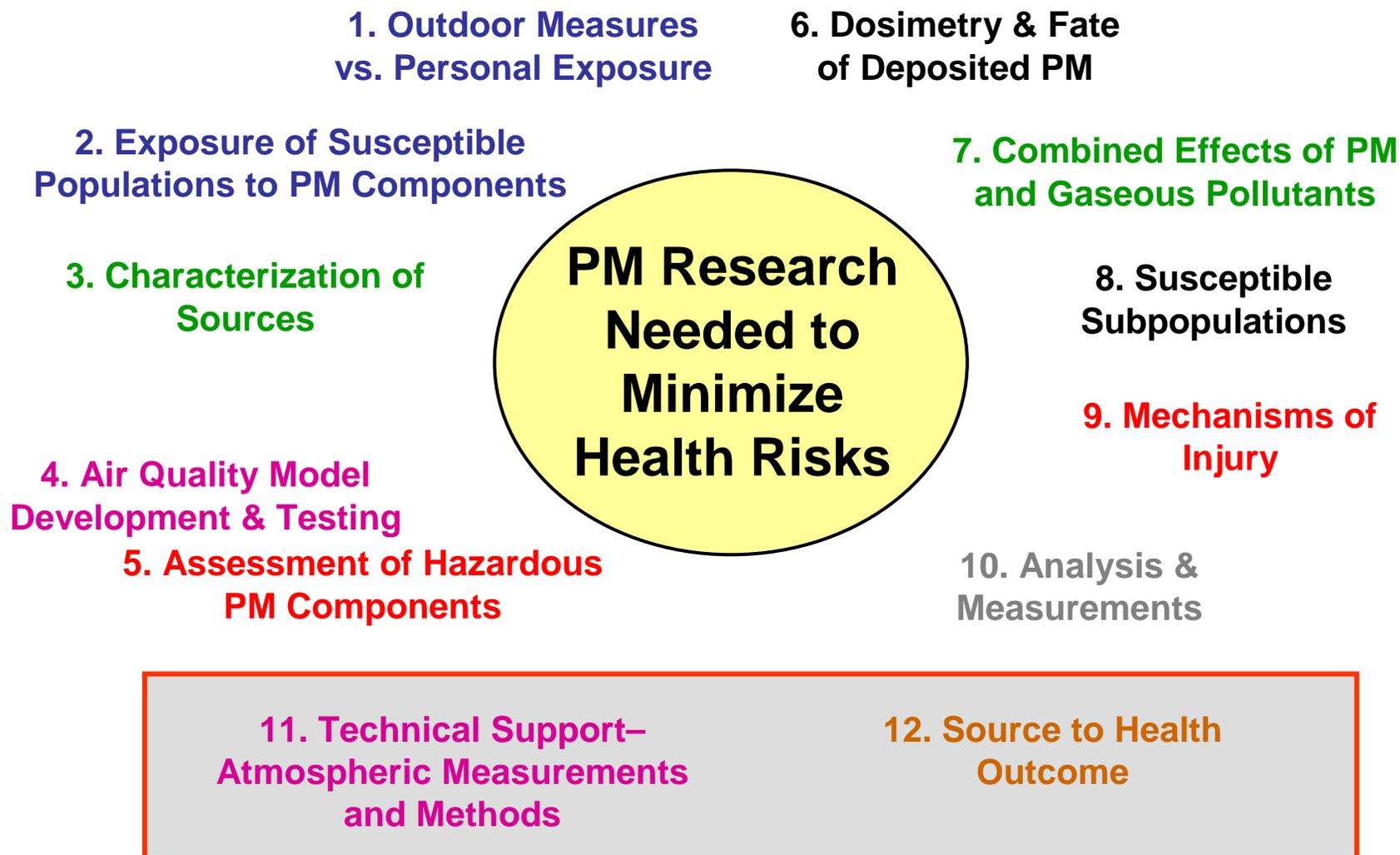
- **Congress increased the EPA PM Research Program budget by \$22.4 million per year with mandates:**
  - Redirect & expand intramural program
  - Establish NAS / NRC expert panel on research priorities
  - Expand STAR PM Grants Program
    - Up to 5 PM Centers
    - Develop RFA's on pressing science issues
  - Coordination across federal agencies

# NRC Reports: Research Priorities for Airborne Particulate Matter

- Important research needs identified
- Recommended a multi-year portfolio of the highest priority research topics



# ***NRC PM Research Priorities***





# The Clean Air Research Program



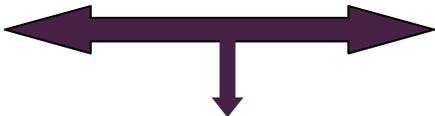
Epidemiology



Molecular

Clinical and Animal Toxicology Studies

Intramural Program



EPA STAR Program (PM Centers)

- EPA Partners:
- Other Federal/State Agencies
  - Health Effects Institute
  - Academia
  - Industry laboratories

Emission Source Characterization



Exposure, Atmospheric Measurement and Models



EPA Monitoring Network

## 2008 Revised Multi-Year Plan

- PM, ozone and air toxics integrated into one *Clean Air MYP*
- Emphasis on program coordination and leveraging
- Emphasis on interdisciplinary science
- Gradual shift to a multi-pollutant research theme
- Regulatory support with public health outcome



# Long Term Goals

## ***LTG 1* - Reduce uncertainty in the science that supports standard setting and air quality management decisions.**

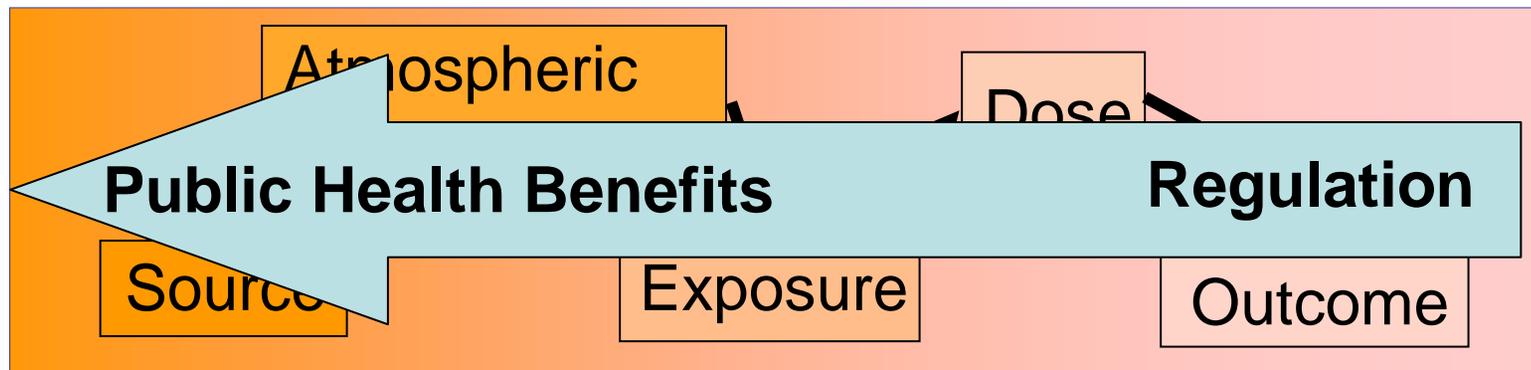
- Inform regulatory decision-making (NAAQS, AT)
- Support implementation of regulations with tools (methods and models) and information to OAR, Regions, States, tribes.

## ***LTG 2* - Reduce uncertainties in linking health and environmental outcomes to air pollution sources.**

- Launch a multi-pollutant research program
- Identify specific source-to-health linkages, with initial emphasis on “near roadway” impacts
- Demonstrate effectiveness of the science and its

# Source to Health Outcomes

Source to Health Outcome approach recognizes health outcomes are linked to sources via interconnected biological, chemical, and physical behaviors



- Greater degree of integration across disciplines
- Improved understanding of entire problem
- Yield efficient and effective regulation
- Link to public health outcomes

## *Timeline of PM Centers Program*

- 1999 – First PM Centers funded
  - Harvard; NYU; Southern California; Rochester; Northwest
- 2002 – SAB interim review of PM Centers Program
- 2005 – Current PM Centers funded
  - Harvard; Johns Hopkins; Southern California; UC Davis; Rochester
- 2005 – ORD Air (PM/O<sub>3</sub>) Program Review by:
  - Board of Scientific Counselors (BOSC)
  - Performance Assessment Rating Tool (PART)
- 2007 – ORD Mid-cycle BOSC
- 2008 – SAB advice on future Air Centers Program
- 2009 – Scheduled ORD Air Program BOSC
- 2009 – Release new Air Research Centers RFA

## *First PM Center Directors*



**Petros  
Koutrakis**

Harvard  
University  
PM Research  
Center



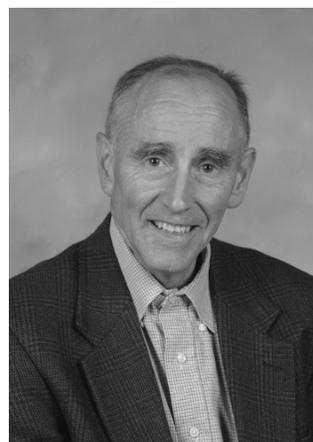
**John Froines**

Southern  
California  
Particle Center



**Jane Koenig**

Northwest  
Research  
Center for  
Particulate Air  
Pollution and  
Health



**Günter  
Oberdörster**

University of  
Rochester PM  
Research  
Center



**Morton  
Lippmann**

New York  
University PM  
Center



# *Major Conclusions of 2002 SAB PM Center Report*

- The Centers Program has produced benefits beyond those normally found in individual investigator-initiated grants and is likely to continue to provide such benefits
- Overall the PM Centers & individual grants programs should be maintained in roughly the same proportion
- There are clear advantages to maintaining a diverse research portfolio
  - Ensures that the widest range of investigators contribute ideas to the PM program
  - Provides opportunities for cross-fertilization within the science community
- The Agency should continue to support both intramural and extramural components of an overall PM research effort

## *Current PM Center Directors*



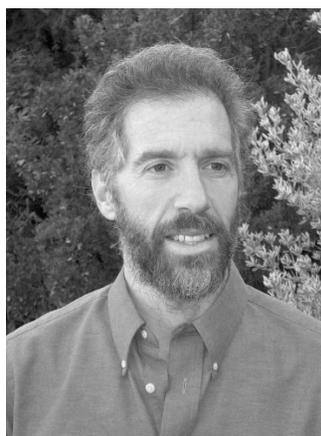
**Petros  
Koutrakis**

Harvard  
University  
PM Research  
Center



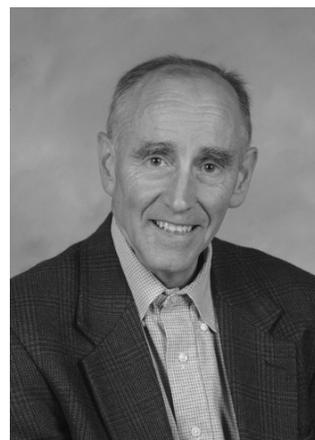
**John Froines**

Southern  
California  
Particle Center



**Tony Wexler**

San Joaquin  
Valley Aerosol  
Health Effects  
Center at UC  
Davis

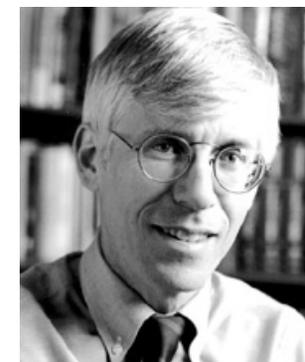


**Günter  
Oberdörster**

University of  
Rochester PM  
Research  
Center



**Francesca  
Dominici**



**Jonathan  
Samet**

Johns Hopkins  
University PM  
Research Center

## ***Why EPA Values the PM Centers Program***

- Complements Intramural Program
- Cutting Edge Science in Multitude of Disciplines

### **◆ Science that Makes a Difference ◆**

- Important Science Advances from 1998 to 2008
- Implications of the Science Extend Beyond “Regulations”
  - New directions in science and public health practice

## *Complements Intramural Program*

- Provides the core of ORD's air pollution epidemiology program – EPA has one intramural air epidemiologist
- Possesses the intellectual and institutional flexibility to respond and expand as the science evolves (leveraging)
- Provides a balanced rationale for EPA's intramural program to target highly programmatic needs
- Attracts investigators with needed ["new"] expertise (notably cardiovascular but also oxidant biochemistry, engineering)

## ***Complements Intramural Program*** ***(continued)***

- Expands ORD's capacity to do science that is fundamentally strong yet programmatically relevant
- Yields synergies with STAR grants and intramural PIs and projects
- Develops novel technologies – e.g., to allow controlled exposures of humans & animals to ultrafine, fine, and coarse PM
- Moves the focus toward identifying and understanding the sources and composition of PM as these relate to health outcomes

## *Cutting Edge Science*

- Many highly cited publications
  - Original Centers have produced over 500 publications
  - Current Centers over 100 publications so far
  - Peak in publications not until ~5 years after initial funding
  - Published in high impact scientific and medical journals, e.g. *NEJM*, *Science*, *Lancet*, *Circulation*, *JAMA*
- Paper of the Year
  - EHP 2008 “Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles”

# *Scientific Leadership*

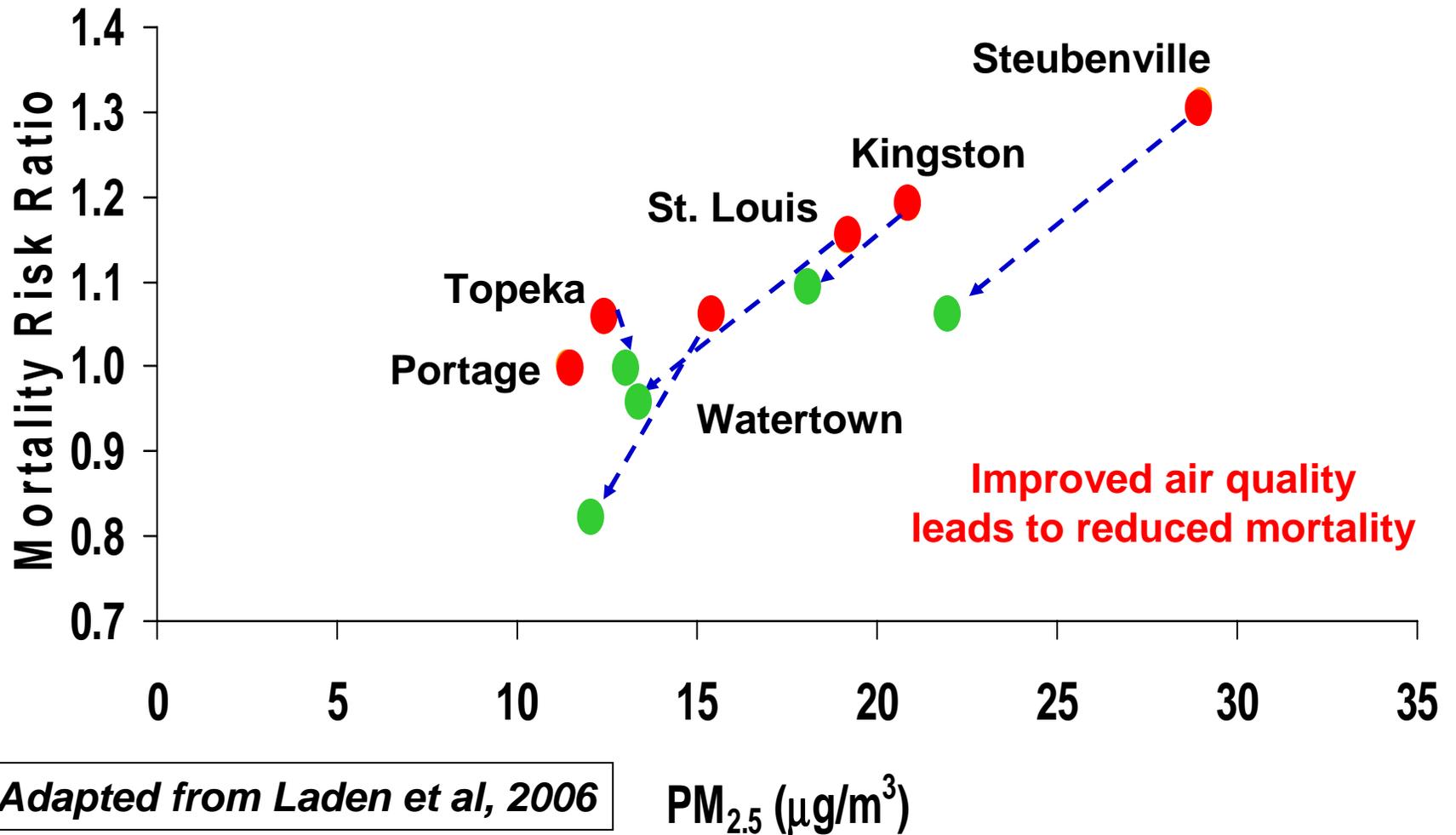
- **Chair/Membership on national scientific advisory committees**
  - NRC Committee on Research Priorities for Airborne Particulate Matter
  - Science Advisory Board for the U.S. EPA
  - Clean Air Scientific Advisory Committee
  - Board of Scientific Counselors of the National Toxicology Program
  - Health Effects Institute Research Committee
- **Editorial boards of leading scientific journals**
  - Journal of the Air & Waste Management Association
  - Atmospheric Environment
  - Aerosol Science and Technology
  - Environmental Health Perspectives
  - Inhalation Toxicology
- **Awards/honors received**
  - Surgeon General's Medallion
  - Prince Mahidol Award, from the King of Thailand, for work on air pollution
  - Outstanding contributions in Aerosols in Medicine (AAAR and ISAM)
  - Named among Top 1% Authors Worldwide in Engineering (ISI)
- **Leadership positions in professional societies**
  - American Chemistry Council
  - American Thoracic Society
  - American Association for Aerosol Research
- **Collectively hold more than 20 U.S. patents in the field of aerosol instrumentation**

## *Epidemiology / Human Studies*

- Ambient fine PM concentrations provide “reasonable” estimates of exposure in time-series analyses - *Sarnat et al. 2000, 2002*
- No apparent threshold for PM effects - *Schwartz et al., 2002*
- “Harvesting” unlikely - *Schwartz, 2001*
- East – West coast differences in PM hospitalization seems to reflect composition - *Bell et al., in press*
- Long-term PM linked to cardiovascular events, lung cancer, and cardiovascular mortality - *Pope et al, 2002, 2004; Miller et al., 2007*
- Cardiovascular effects and mortality linked to PM and select components - *Peters et al., 2001; Franklin et al., 2008; Peng et al., 2008*
- Vascular dysfunction tied to PM - *Delfino et al., 2008*
- Some evidence that intervention can mitigate responses -  
*Schwartz et al., 2005*

# Reductions in PM Reduces Risk

(Six Cities Cohort Follow-up)

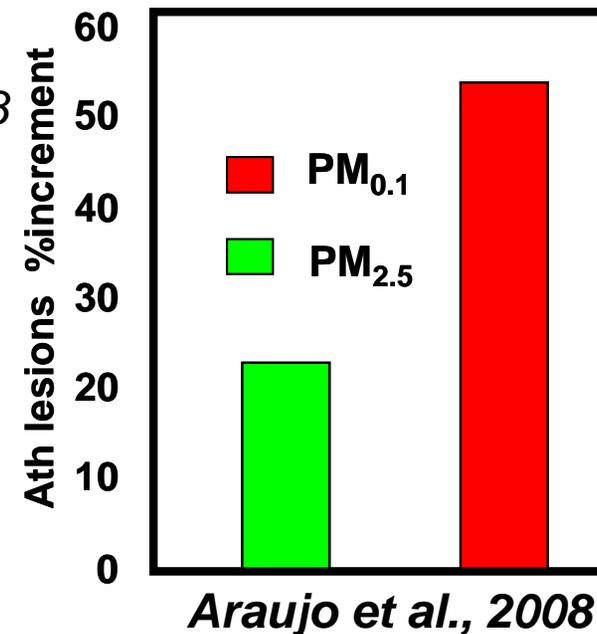


# Environmental Cardiology

- *Workshop on Cardiovascular Effects Associated with Air Pollution*, Rochester, March 2001 - *Utell et al., 2002*
  - AHA recognition – *Circulation* (Brook et al., 2004)
- HRV changes (humans & animals)  
*Adar et al., 2007; Nadziejko et al. 2002; Chen et al., 2005*
- Cardiac function (ECG) changes – *Godleski et al., 2006*
- Systemic Inflammation – *Frampton et al., 2006; Delfino et al., 2005*
- Atherosclerosis – *Lippmann et al., 2005; Corey et al., 2006; Araujo et al., 2008*

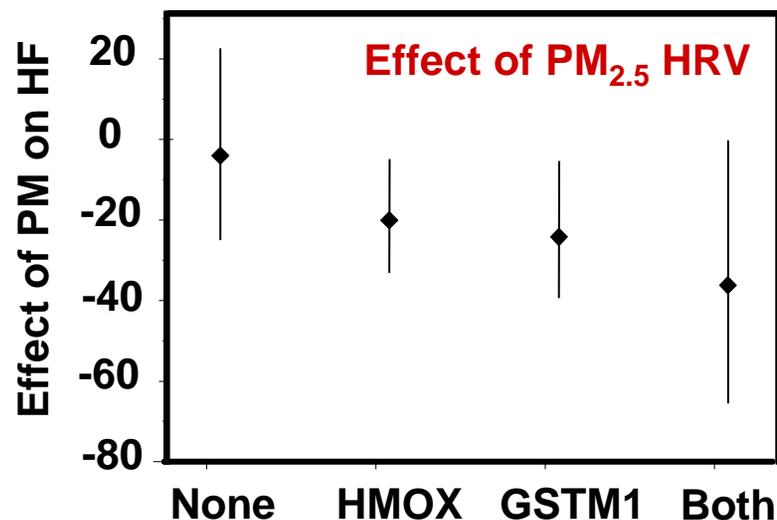
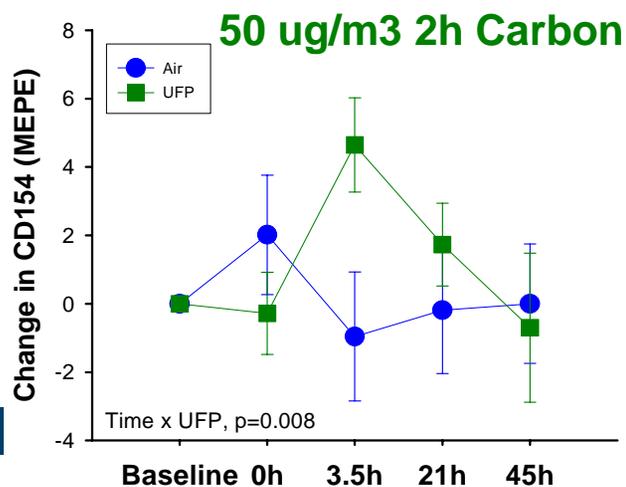


*Chen and Nadziejko, 2005*



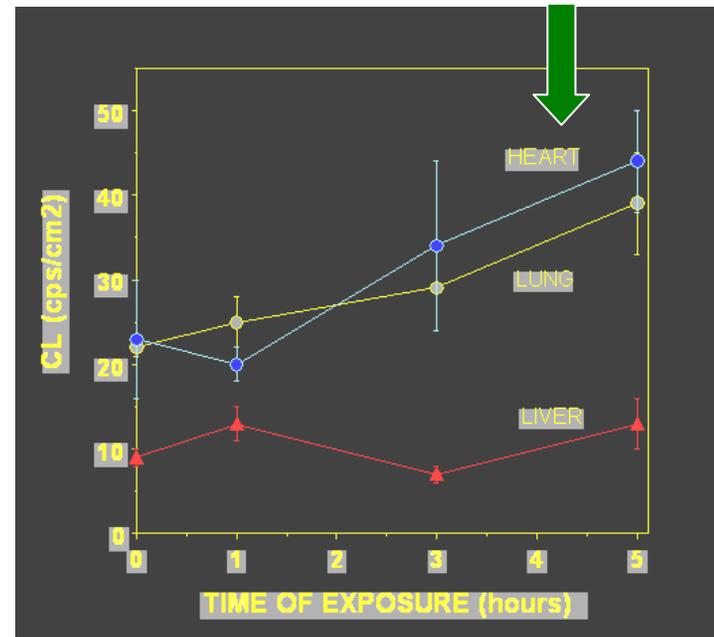
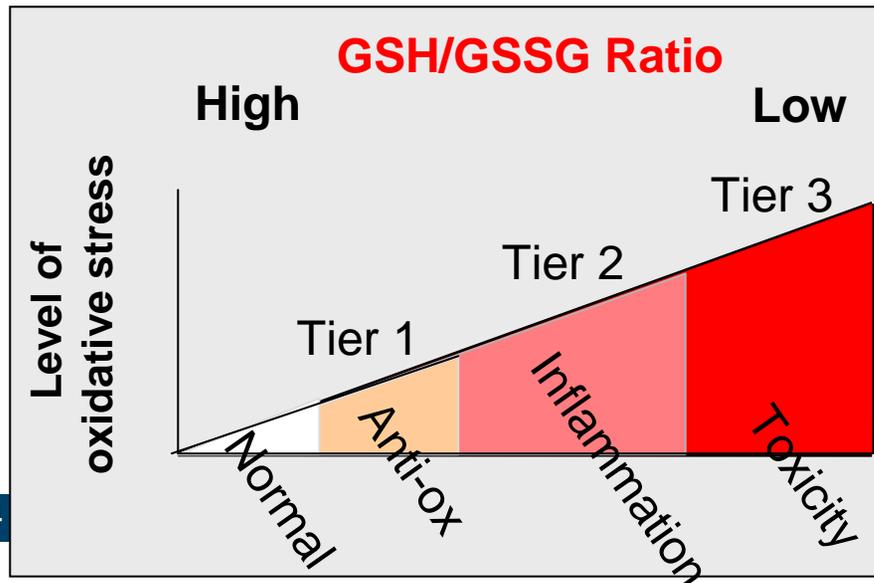
# Mechanisms and Susceptibility

- Children – *Delfino et al., 2008; Koenig et al., 2005 (many)*
- Elderly – *Park et al, 2008; Baccarelli et al., 2008*
- Cardiopulmonary disease – *Liu et al., 2003; Wellenius et al., 2005; Jansen et al., 2005*
- Diabetes – *Zanobetti & Schwartz, 2001; Frampton et al., 2008*
- Animal Models – *Elder et al, 2000, 2002, 2004; Kleinman et al., 2005; Last et al., 2004*
- Gene-Environment – *Schwartz et al., 2005; Gong et al., 2007; Chahine et al., 2007*



# Mechanisms/Oxidative Stress

- Particles contain pro-oxidant components (cross-over with uF) – *Cho et al., 2005; Zhou et al., 2003*
- Stratified Oxidative Stress Hypothesis – **Nel et al 2006**
- Oxidant pathways (*in vitro*) – *Hatzis et al., 2006*
- Oxidant pathways (*in vivo*) – **Gurgueira et al., 2002**; *Delfino et al., 2005*
- Mitochondrial mediation – *Li, et al, 2003*
- Systemic oxidants and inflammation – *Delfino et al., 2008*



# Ultrafine Particles

- Major sources include: vehicular emissions and secondary photochemical formation – *Kim et al., 2002*
- High organic and metal content may confer higher toxicity (Surface area / oxidant) – *Li et al., 2003; Zhou et al., 2003*
- High spatial heterogeneity / dispersion with distance from roadways – *Zhu et al., 2002*

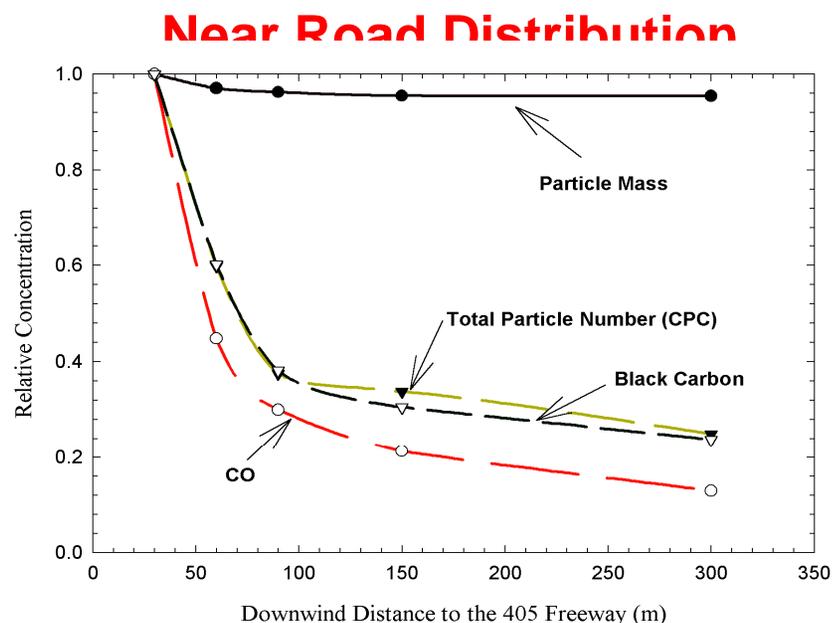


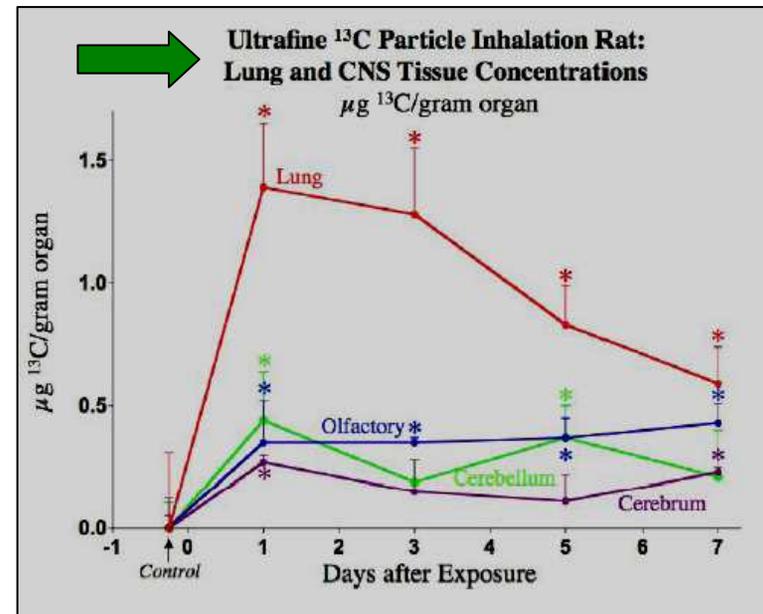
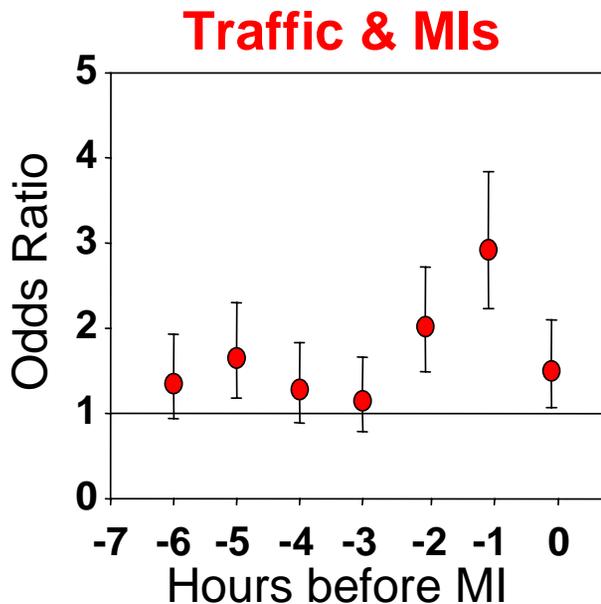
Table 5  
Contrasting features of coarse, fine, and ultrafine particles<sup>a</sup>

Parameters	Particle mode		
	Coarse (PM <sub>10</sub> )	Fine (PM <sub>2.5</sub> )	Ultrafine
Size	2.5–10 μm	2.5–0.15 μm	<0.15 μm
Organic carbon content	+	++	+++
Elemental carbon content	+	++	+++
Metals as % of total elements	+++	++	+
PAH content	+	+	+++
Redox activity (DTT assay)	+	++	+++
HO-1 induction	+	++	+++
GSH depletion	+	+++	+++
Mitochondrial damage	None	Some	Extensive

<sup>a</sup> [85].

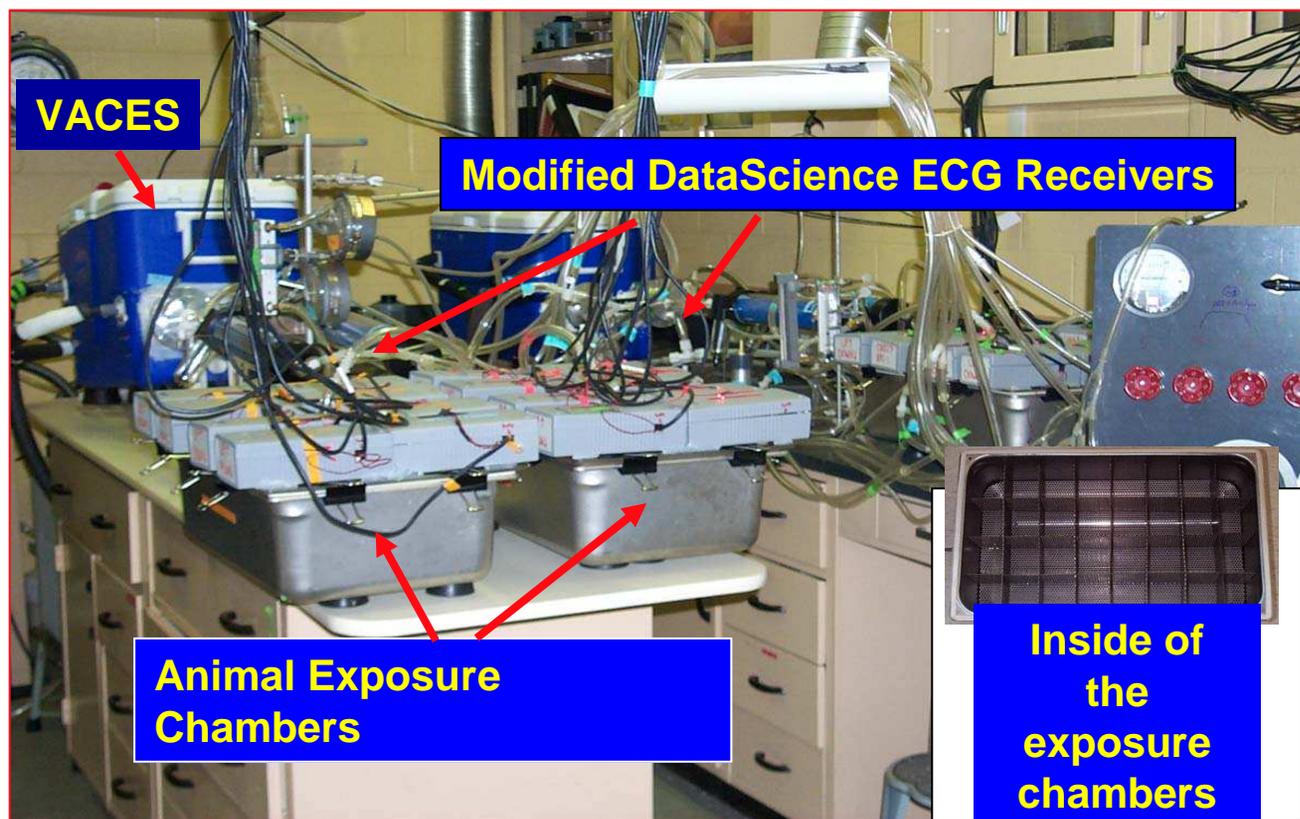
# Ultrafine Particles (continued)

- Traffic impacts on health – *Peters et al., 2004; Gauderman et al., 2005, 2007; Elder et al. 2004, 2006; Kleinman et al., 2005*
- Translocation to CNS – *Elder et al, 2007; Oberdörster 2004*
- Effects on CNS – *Veronesi et al., 2005; Kleinman et al., 2008*
- Systemic inflammation – *Frampton et al., 2006; Elder et al., 2004; Araujo et al., 2008*



## Advances in New Technology

- Coarse Concentrator – *Demokritou et al., 2002a*
- Ultrafine Concentrator – *Kim et al., 2000; Gupta et al., 2004*
- Chem Vol (sampler) – *Demokritou et al., 2004*
- Personal PM sampler – *Misra et al., 2002; Demokritou et al., 2002b*



## *Health Effects of PM Sources*

- Source apportionment workshop (2004) – *Thurston et al., 2005*
- Source apportionment / health linkage – *Ito et al., 2006; Mar et al., 2006*
- Traffic / near road studies – throughout centers
- Agricultural PM – *Smith et al., 2003*
- On-road exposures of rats in a mobile emissions laboratory (MEL) – *Elder et al., 2004, 2007*
- Power plants (TERESA), tunnels, shipping ports, airports – *Ruiz et al., 2007; Geller et al., 2005; Arhami et al., in press; Westerdahl et al., 2008*



# *What We Knew About PM Exposure & Human Health Effects in 1997*

- Growing data base showing adverse health effects, including premature death associated with PM
- Correlations appeared stronger with PM<sub>2.5</sub> (fine)
- Some groups appeared to be at unusual risk
- Long-term exposure associated with shortened life-span
- Controversy: ‘Biologic Plausibility’ uncertainty with major questions about personal exposures and effects
- Yet - The Findings were Compelling: EPA revised the PM National Ambient Air Quality Standards (NAAQS)
  - New PM<sub>2.5</sub> standards

## *Epidemiological Perspective\**

### 1997: Top 9 Reasons Not to Regulate PM<sub>2.5</sub>

- Time Series Associations confounded
- Exposure uncorrelated with ambient
- All Harvesting
- Thresholds
- No Mechanism/Biological Plausibility
- Only due to Some Particles, will Regulate Wrong Ones
- Don't know who is Susceptible
- Only 2 Cohort Studies/Faked
- Don't know if lower PM<sub>2.5</sub> means fewer deaths

## *Ten Years of Progress (2008)*

- Research strengthened confidence that PM causes adverse health effects – “biologic plausibility”
- Supported use of ambient fine PM concentrations to evaluate exposure in time-series epidemiologic analyses
- Greater recognition that PM hazardous components (physical and chemical) are key to impacts on human health
- Better understanding of source and PM formation processes, especially for the organic fraction
- Size matters – all modes seem to have “unique” properties and associated toxicities
- Broadened the focus of PM effects beyond the lungs, effects on CV system perhaps of greatest concern; also CNS, birth outcomes
- New insights on susceptibility issues (launching G-E)
- Supported revisions of NAAQS and has moved air pollution into the realm of public health practice

## *Entry into Public Health Practice*

- Air pollution is not just a respiratory issue, impacts have been identified systemically – notably cardiovascular but also potentially CNS and birth outcomes
- Clinicians alerted to the risks of air pollution via the:
  - AHA Scientific Statement: *Air Pollution and Cardiovascular Disease - A Statement for Healthcare Professionals From the Expert Panel on Population and Prevention Science of the American Heart Association, Circulation, 2004*
  - *American Academy of Pediatrics Policy Statement, Ambient Air Pollution: Health Hazards to Children, Pediatrics, 2004*
  - AIRNow emphasizes cardiac risk as well as pulmonary cautions
  - AHA video news release on cardiovascular responses to air pollution
    - EPA abstract (Detroit studies) 1 of 2 selected from 1800

## ***Entry into Public Health Practice*** ***(continued)***

- Public Health Literature: “*Preventing Chronic Disease: Public Health Research, Practice and Policy*” 2008, CDC authors, citing air pollution as a top-6 risk factor for cardiovascular disease
- National Heart Lung and Blood Institute contacts EPA to help assess the feasibility of an air pollution intervention study to reduce cardiovascular deaths.

# *Evolving Air Pollution Landscape*

- **Multipollutant assessment**
  - OAQPS - Broad-based and source (sector)-targeted regulation
  - Source to Health-Outcome Paradigm – more effective regs?
  - Less studied (diffuse) sources – ports, airports, CAFOs, fires
  - “Post-Sulfur” air environment – C / N dominance
  - Biofuels – new chemistry / nitrogen
  - Urbanization
  - Complexities of exposure (potential for remote technologies?)
  - Host factors and susceptibility – ‘omic technologies?
  - Accountability – ‘quantifying’ that we are making a difference?
- **Air Pollution – Climate interactions**
  - Influence of Climate (global issues)
  - How will CO<sub>2</sub> be regulated?

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# PM Centers' Research in EPA's NAAQS Program

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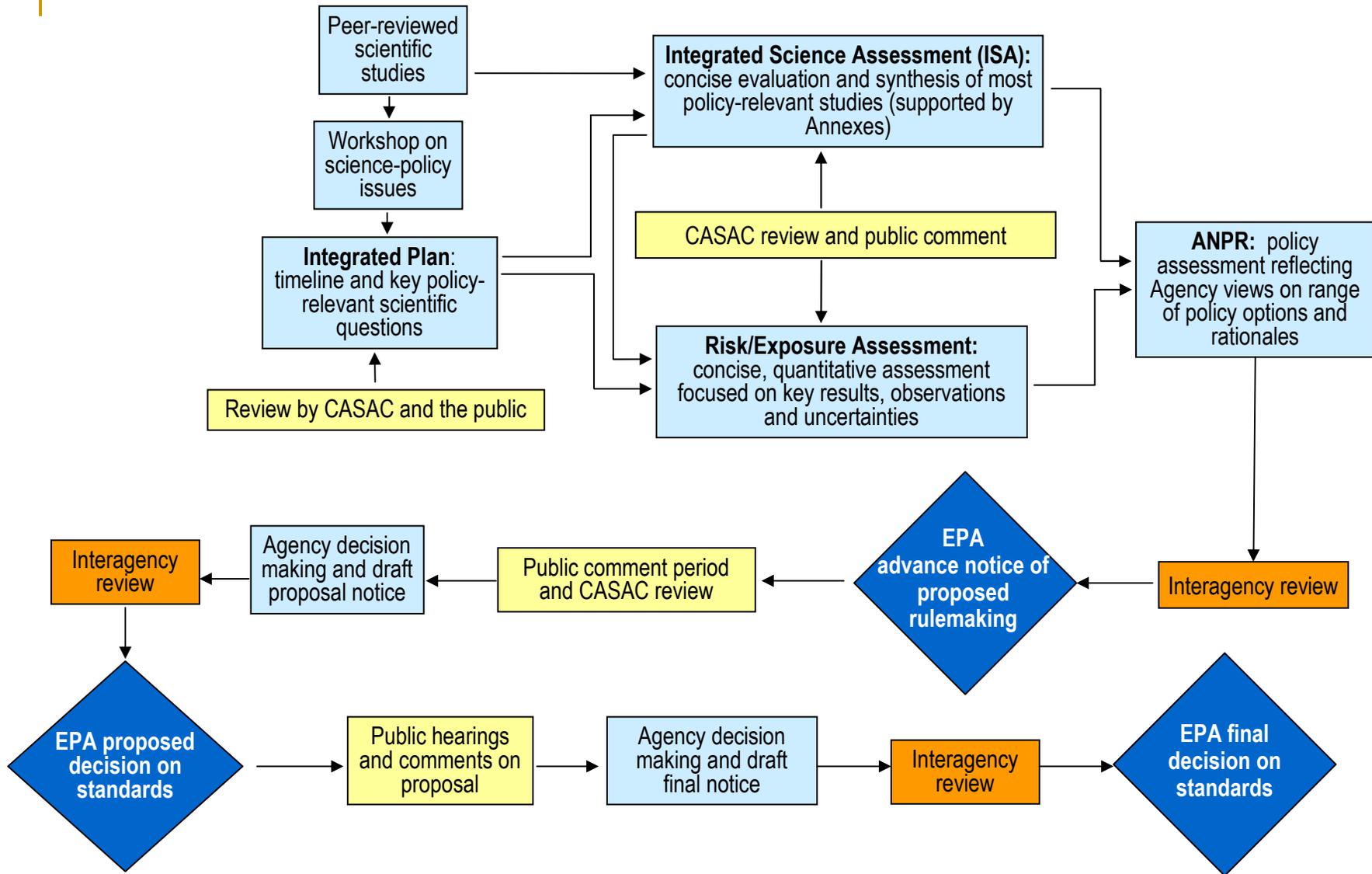
Lydia Wegman, Director  
Health and Environmental Impacts Division  
Office of Air Quality Planning and Standards  
US EPA

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## High Quality Research is the Backbone of Credible and Defensible Program Office Decision-Making

- ORD Air research is used in virtually every facet of the review process of the NAAQS as well as in support of standard implementation
- The integration of the intramural and extramural programs ensures the strongest database and science quality needed to move policy decisions forward

# Overview of NAAQS Standard-Setting Process



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# Scientific Research in the NAAQS Review Process

- **Integrated Science Assessment (ISA)**
  - Concise evaluation and synthesis of the most policy-relevant science
  
- **Risk/Exposure Assessment (REA)**
  - Scientific evidence contained in the ISA provides the foundation to inform the analyses in the REA including...
    - Critical health/welfare endpoints
    - Concentration-response functions
    - Study populations including consideration of sensitive subpopulations
    - Study areas on which to focus
    - Evidence-based identification of potential alternative standards for consideration
  
- **Sources of scientific research relevant for NAAQS standard-setting include...**
  - PM Research Centers
  - EPA STAR grants program
  - EPA intramural research program
  - National Institute of Environmental Health Sciences (NIEHS) grants programs
  - Health Effects Institute (HEI)
  - California Air Resources Board (CARB)
  - Electric Power Research Institute (EPRI)

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# PM Centers Research in Recent NAAQS Reviews

- **Notable studies cited in the 2004 Criteria Document and/or 2005 Staff Paper**

- ❑ ACS Study – extended analyses (Pope et al, 2002)
- ❑ Reanalyses of time-series studies due to GAM (HEI special report) (Ito 2003; Mar et al, 2003; Schwartz 2003; Sheppard 2003)
- ❑ Association of PM components with daily mortality as published in an HEI report (Lippmann et al, 2000)
- ❑ Evidence of myocardial infarction (Peters et al, 2001)
- ❑ Evaluation of the relationship between ambient and personal exposure levels (Sarnat et al, 2000/2001)

# PM Centers Research in Recent NAAQS Reviews (cont.)

- **2006 Provisional Science Assessment**
  - Completed between proposal & final rule
  - Reviewed significant “new” studies not included in the CD
  - 34% (71 of 211) of studies cited were from PM Centers
  
- **Notable studies that were cited in the Provisional Science Assessment include:**
  - Follow-up to the Six Cities study (Laden et al, 2006)
    - Reductions in PM<sub>2.5</sub> resulted in reduced long-term mortality risk
  - Subchronic animal study (Lippmann et al. 2005 and related articles)
    - PM<sub>2.5</sub> caused cardiovascular effects in mice susceptible to atherosclerosis
  - Source apportionment / health (Hopke et al 2006; Ito et al, 2006; Mar et al 2006)
    - Contribution of sources to total/CV mortality was estimated in Wash. DC and Phoenix
  - Controlled human exposure study of coarse PM (Gong et al, 2004)
    - Increased heart rate & decreased HRV following exposure to coarse CAPS
  - National Medicare cohort (Dominici et al, 2006)
    - Acute exposure to PM<sub>2.5</sub> was associated with hospitalization for cardiovascular and respiratory diseases
    - Suggests differential cardiovascular effects in eastern v. western U.S. locations
  - Cystic Fibrosis cohort (Goss et al, 2004)
    - Significant association between long-term PM<sub>2.5</sub> exposure & pulmonary exacerbations

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# PM Centers Research in Current NAAQS Reviews

- PM Center publications are expected to be influential in current review of the PM NAAQS
  - Almost 200 PM Centers' papers (from the original Centers) are cited in the current version of the 1<sup>st</sup> draft ISA
    - Citations from current PM Centers have not yet been analyzed
  - PM Centers' publications span a variety of policy-relevant topics including...
    - Cardiovascular effects associated with long-term PM exposure
    - Evidence for PM-associated health effects in susceptible subpopulations
    - Understanding the linkages between PM sources, ambient levels, exposures, and health effects
  
- PM Centers' papers are also cited in the current ISAs for NO<sub>x</sub> and SO<sub>x</sub>

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# Broader Impacts of PM Center Research

- PM Center publications cited in documents from State, local, and international agencies, including:
  - Numerous Regional, State, and local air agencies, for example:
    - South Coast Air Quality Management District
    - California Air Resources Board
  - World Health Organization
  - United Nations Environmental Programme
  
- Examples of State and local impacts
  - Southern California PM Center research influential in the development of a new California state law prohibiting the construction of new schools within 500 feet of freeways
  - NYU PM Center characterized exposures and health risks resulting from the collapse of the World Trade Center Buildings on September 11, 2001
  - Rochester PM Center working with NY Dept. of Environmental Conservation on ultrafine particle monitoring

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## Additional Contributions of PM Centers from the Program Office Perspective

- Centers support a large number of extremely high-caliber investigators and serve to focus those investigators on the scientific issues that are of greatest importance to NAAQS decision-making
- Centers provide a source of authoritative input to the Agency at critical steps in the NAAQS review process
  - Investigators participate in Agency-sponsored workshops and advisory activities (e.g., CASAC)
  - Serve as authors for some sections of the Integrated Science Assessments (ISAs)

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## Important Science-Policy Issues for Future NAAQS that PM Centers Research Can Help Inform Program

### ■ **Particulate Matter**

- Defining PM - evaluating components, sources, environments
  - Current NAAQS and implementation approach is based on particle mass; however, it is theoretically possible that regulatory efforts could focus on the sources that make the largest contribution to PM-associated health effects by considering linkages between PM sources, PM composition, and health effects
  - Existing scientific evidence is not sufficient to support such an approach
  - Key Issue: To what extent does the newly available information support consideration of alternative indicators for fine and thoracic coarse particles?
- Improving our understanding of the health impacts of long-term PM exposures, including impacts in sensitive subpopulations

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## Important Science Policy Issues for Future NAAQS that PM Centers Research Can Help Inform Program (cont.)

### ■ **Multi-pollutant**

- ❑ Agency science advisory bodies (i.e., CASAC) advocate consideration of entire ambient mix of pollutants in our standard-setting and implementation efforts
- ❑ Existing scientific evidence is not sufficient to support a comprehensive, multi-pollutant approach to standard setting and implementation

### ■ **Improving ability to estimate/model exposure**

- ❑ Epidemiology studies, which form an important part of the evidence base that is considered in setting standards, often rely on ambient monitoring data to provide estimates of exposure
- ❑ Research is needed to address uncertainties (particularly important for PM components, sources, and PM size fractions and other pollutants that have received less attention from researchers) and also to improve our ability to estimate exposures for purposes of informing the standard-setting process



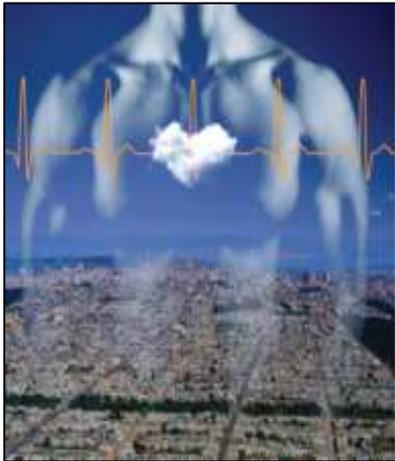
## CLEAN AIR RESEARCH PROGRAM

BUILDING A SCIENTIFIC FOUNDATION FOR SOUND ENVIRONMENTAL DECISIONS

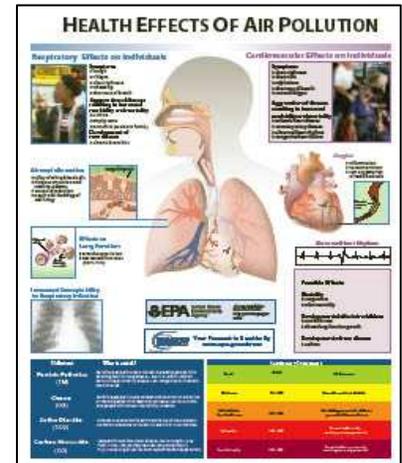
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# Future Research Directions and Charge to SAB Panel

SAB PM Center Advisory Panel  
October 1-2, 2008

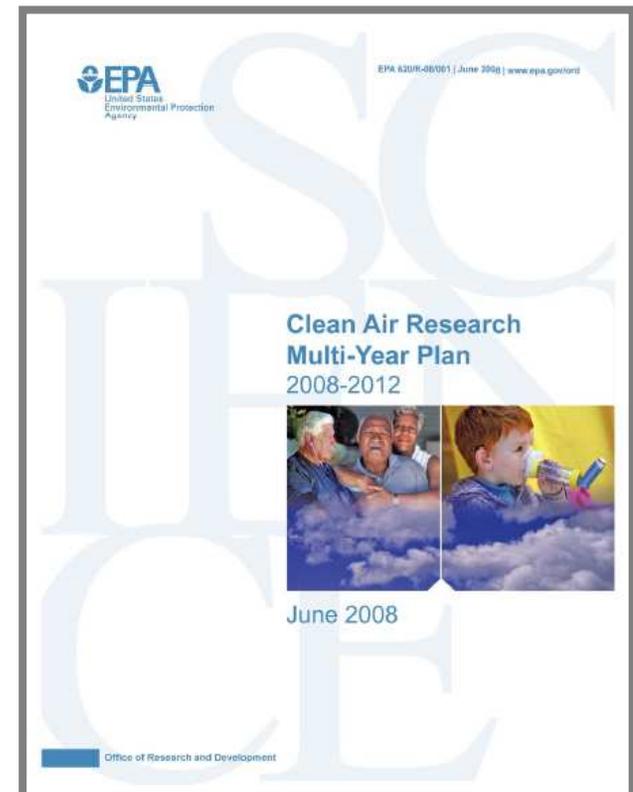


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USEPA



# Future Directions for EPA's Air Research Program

- **Clean Air Multi-Year Plan - Goals**
  - **Supporting EPA's Clean Air regulations**
    - review of health-based standards
    - information and tools to help states and locals achieve standards
  - **Improving science linking health and environmental effects to air pollution sources**
    - launching a multi-pollutant research program
    - investigating specific source-to-health linkages, starting with near-road
    - assessing health and environmental improvements due to past regulatory actions



## Implementing the Clean Air Multi-Year Plan

- The Clean Air Multi-Year Research Plan emphasizes an integrated intramural and extramural research program
- Successful program integration noted in 2005 Review of Air Research Program by ORD's Board of Scientific Counselors (BOSC):

“The Subcommittee finds a high degree of integration in the conduct of intramural and extramural research across the various laboratories, centers and scientific disciplines”





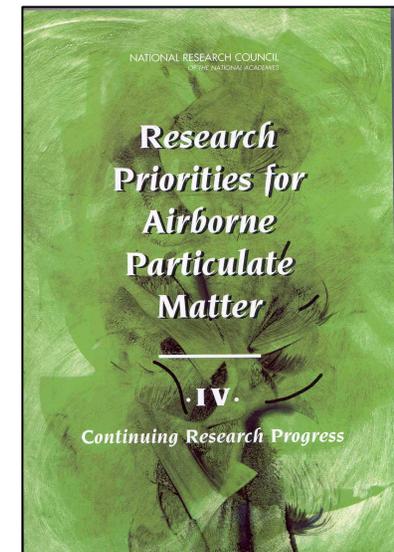
## Charge Question One

- Question 1 asks the Panel's view of the PM Centers' contributions
- How well have the PM Centers continued to contribute to advancing the science on key PM issues most relevant to EPA's mission?
  - As described earlier, EPA believes the PM Centers have been significant contributors to the EPA air research program



## Charge Question Two

- What advice does the panel have on how to move to a multi-pollutant approach in the Centers program?
  - What is meant by “multi-pollutant”?
  - Current Centers are focusing on PM, especially components, size fractions and sources
  - Envision the new Centers as “air research” centers
    - could address PM and precursors
    - PM, ozone, and precursors, or
    - Any/all pollutants in the air pollution mixture



The NRC said, “....now is an opportune time to begin orienting EPA’s air quality research program toward a broader scope that specifically considers all components of the atmosphere—PM and the other criteria pollutants, hazardous pollutants, and the other nonclassified components of the atmosphere.”

## Charge Question Two (continued)

- How to address competing priorities or balance of single and multi-pollutant air research?
  - EPA still operates under the Clean Air Amendments that call for single pollutant standards and compliance
  - There is still a lot to be learned about each of these pollutants, independent of their role in a more complex mixture
    - PM components/sources research still in early stages
    - continue focus on susceptibility, mechanisms, exposure/response?
  - Outside experts calling for new review of ozone atmospheric science
- Should we consider other general strategic directions?



## Charge Question Two (continued)

- Were we to move toward a multi-pollutant program, how to go about it?
  - Phased in, starting with a few pollutants, or all components of the atmosphere?
  - What is the appropriate balance between health and atmospheric science/air quality research in multi-pollutant research?
  - How have other researchers succeeded in conducting multi-pollutant research?
  - Is the source-based approach most pragmatic? Relevant?



## Charge Question Three

- Given the strategic directions discussed in Question 2, how would the panel characterize the strengths and weaknesses of different Center structural options?
- EPA is not asking for a single recommended approach—rather what are the strengths we may not have considered with various approaches and similarly, what are the unanticipated limitations? What other options might we consider?
- Resources are diminishing
  - \$8 million per year reduced in value to \$6 or \$7 million/year
  - Fewer centers or reduce funding per center?
  - Adopt a new Center design?



## Charge Question Three (continued)

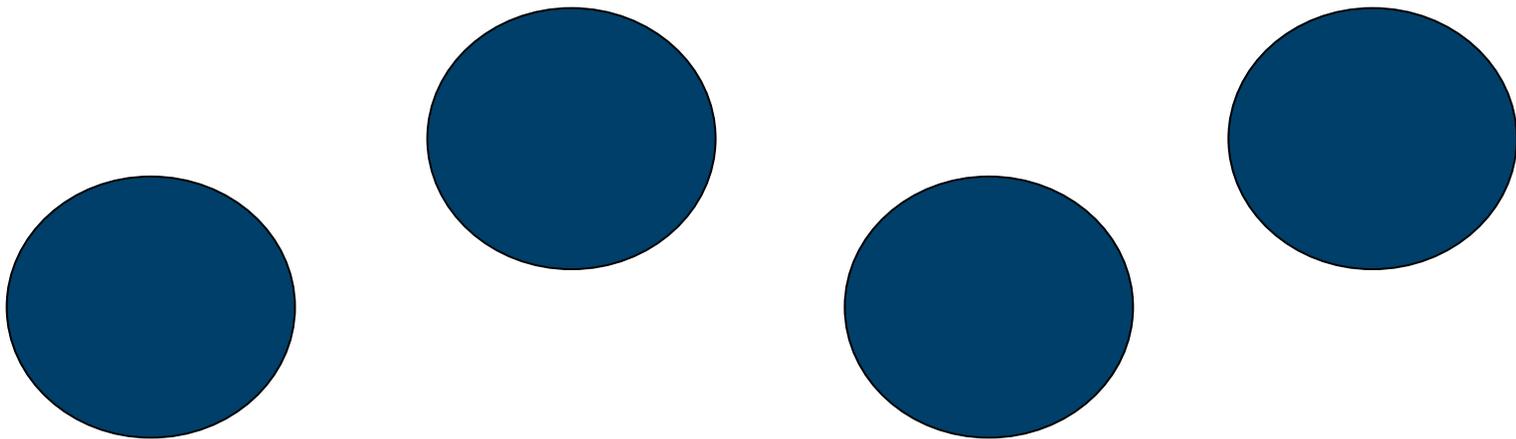
How might the structure of research centers affect the research program?

1. Same research topics for all applicants
2. Regional centers
3. Big and small centers
4. Choice of one topic – large centers
5. Other (hybrid?)



## Same Research Topics for All Applicants

- Continue with same structure of past Center RFAs
- All applicants propose interdisciplinary research in response to research topics in RFA

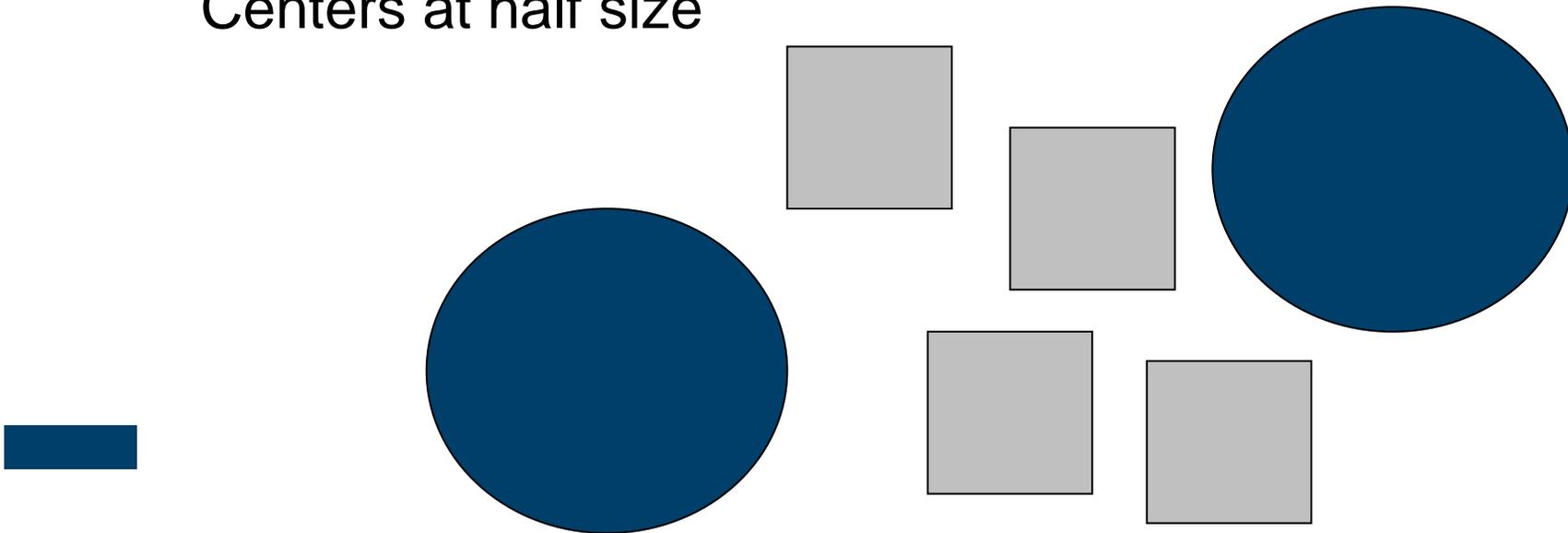


## Regional Centers

- 
- Center must have a regional focus
  - Specific ties to state and local air quality decision makers and public health officials
  - Topics loosely defined, applicants focus on highest priority for region
  - No predetermined regions
    - Could be more than one Center per region
    - Selection based on scientific excellence and regional representation

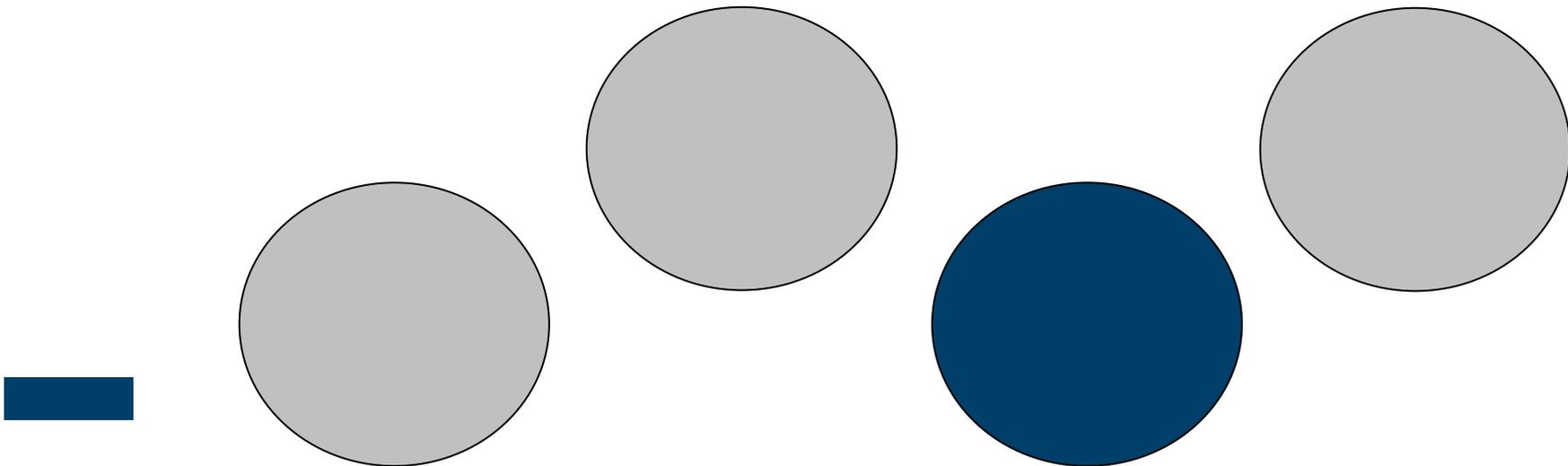
## Big and Small Centers

- Allows both large Centers addressing broad questions and smaller Centers targeted to specific areas
- Smaller Centers may also be multidisciplinary, but smaller in scope
- For example, could support 2 large Centers and 3-4 Centers at half size



## Choice of One Topic – Large Centers

- Large, multidisciplinary Centers
- RFA includes two research topics; applicant only responds to one topic
- For example, may fund one Center studying first topic and three others studying the second



## Next Steps

- EPA looks forward to panel's advice – both the discussion today and the written report
  - Subsequently, ORD will work with EPA offices to develop the next Centers RFA
- Plan to release a new Centers RFA by next summer



## Attachment J

### SUMMARY PARAGRAPHS

#### **Charge Question 1. How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA's mission?**

The PM Centers continue to advance research on key issues relevant to EPA's mission. The Centers have made critical advances in improving the scientific understanding of and reducing and characterizing scientific uncertainty in atmospheric particle composition, transformation, exposure and health impacts. The advances have been extensively cited in EPA documents supporting policy decisions, and have been influential in the scientific community. The panel recommends that the EPA continue to use a variety of performance indicators to assess Center performance, and recommends additional measures be added to those already used in the Center evaluations. Additional measures should characterize the extent to which Center resources are augmented by other research support. They should also broaden the range of measures that assess Center impacts on the scientific community, and that document the extent to which Center work is used in support of Agency decisions.

The panel also concluded that the use of a Center Program produced benefits over those that would be expected in traditional STAR grant mechanisms. These benefits included flexibility and adaptability in research programs, the creation of large inter-disciplinary teams, the development of unique research infrastructures, and the ability to support high risk pilot research. The panel recommends that a substantial fraction of the EPA's extramural research efforts continue to be funded through Centers that are regularly evaluated and re-competed.

## FULL TEXT

### **Charge Question 1. How well have the PM Centers continued to contribute to advancing research on key PM issues most relevant to EPA's mission?**

The PM Centers continue to advance research on key issues relevant to EPA's mission. The Centers have made critical advances in improving the scientific understanding of and reducing and characterizing scientific uncertainty in atmospheric particle composition, transformation, exposure and health impacts. The documentation reviewed by the panel demonstrated that PM Center investigators:

- are recognized as world leaders in PM health effects research
- have improved understanding of the epidemiology and toxicology of particulate matter
- have identified mechanisms for PM health effects
- have improved our understanding of the populations most susceptible to PM health risks
- have identified new micro-environments (e.g., roadways) that lead to ultra-fine particle exposures
- have developed new technologies and instruments for PM research
- have advanced the understanding of source specific health impacts
- have enhanced the range of expertise available to the EPA in assessing PM health impacts

The first set of Centers, funded from 1999-2005, have produced more than 500 publications, a rate of publications per dollar of funding that is 20% higher than the publication rate per dollar of funding for comparable STAR grants. These publications have been influential, as evidenced by citation rates that are higher than average citation rates in the fields covered by the publications. For example, a 2007 analysis of ORD Air Program publications indicated that about 37% of PM Center papers are in the top 10% in overall citation rate, 6% of PM Center papers are in the top 1%, and 3% are in the top 0.1%.

The assessments of a variety of expert panels have provided additional endorsements of the scientific impact and the relevance of the work of the PM Centers. These have included assessments by BOSC, an SAB panel, National Research Council panels and professional organizations such as the American Heart Association, and the American Academy of Pediatrics.

The work of the Centers has also been extensively cited in EPA documents supporting policy decisions. The Centers' work contributed to the 2007 PM NAAQS review, and the Integrated Science Assessment (ISA) for PM. PM Center work has also influenced policy decisions in regulatory organizations beyond EPA, such as the California law requiring that schools must be at least 500 feet from freeways.

The panel recommends that the EPA continue to use a variety of performance indicators to assess Center performance, and recommends additional measures be added to those already used in the Center evaluations.

One set of additional measures should characterize the extent to which Center resources are augmented by other research support. Augmentation of EPA funding should not become a requirement of the Centers program, but the extent of augmentation can serve as an indicator of the interest by organizations outside of EPA in the work of the Centers.

A second set of additional measures should broaden the range of indicators that assess Center impacts on the scientific community. Current measures are focused on numbers of journal publications, citations, and students trained. The Centers could also begin to track the impact that program graduates are having on the field after they leave the Centers.

A third set of additional measures should broaden the range of indicators that document the extent to which Center work is used in support of Agency decisions. Current measures focus on documents developed in support of setting National Ambient Air Quality Standards. The Center's work has also been used in Regulatory Impact Assessments, in assessing the costs and benefits of the Clean Air Act (Section 812 analysis), and in other documents developed by EPA in support of its regulatory mission. These uses of the Centers' work should be tracked.

Finally, the panel concluded that the use of a Center Program produced benefits over those that would be expected in traditional STAR grant mechanisms. These benefits included flexibility and adaptability in research programs, the creation of large interdisciplinary teams, the development of unique research infrastructures, and the ability to support high risk pilot research. The advantages of Center programs, as compared to traditional STAR grant funding mechanisms, will be expanded on in response to charge question 3. The panel recommends that a substantial fraction of the EPA's extramural research efforts continue to be funded through Centers that are regularly evaluated and re-competed.

**2. What advice does the panel have on how to move to multi-pollutant approach in the PM Centers program?**

One prominent theme of EPA's multi-year research plan for Air is the need to better understand air pollution effects within the context of the entire ambient mixture. What advice does the panel have regarding the appropriate balance between single-pollutant and multipollutant research? What additional broad strategic directions should EPA consider for a future Centers Research Program?

***The Panel's Reply:***

In reviewing the PM Centers progress to date, and the potential for the future, the Panel found that the Centers have already begun to make contributions in efforts to address the broader set of pollutants that contribute to exposure and health effects and agreed with the agency that more could be done to enhance multipollutant approaches in the next round of centers. The Panel also found that the next round of Centers could usefully address another important and broad direction: the regional differences in pollutant mixtures, and potential differences in health effects.

**Enhancing Multipollutant Approaches in the Centers Program:** In 2004, the NRC's Committees on *Research Priorities for Airborne Particulate Matter* and *Air Quality Management in the United States* recommended that the nation's efforts to improve air quality should move from its historical single-pollutant-at-a-time regulatory approach to a multipollutant approach that provides both the science and the regulatory programs to allow for the most cost-effective interventions to reduce exposure and improve public health. In response, the EPA has over the past several years made a commitment to trying to move both its research programs and air quality management programs to a more multipollutant perspective. Although the setting of multipollutant ambient air quality standards is likely well in the future, the agency is working with states to develop multipollutant air quality management plans, and seeking to move its air quality research program to a multi-pollutant perspective that can increasingly identify the effects of the simultaneous co-exposure to many different pollutants that humans and the ecosystem face.

There are hundreds of compounds in the ambient mix of pollutants; the agency has begun to focus on the subset of these which have been the main targets of the Clean Air Act: the so-called criteria pollutants (especially PM and ozone) and air toxics. The Panel agreed that this subset is useful, but also noted that there are significant “multipollutant” challenges within some pollutant classes, especially PM (with its diverse sources and particle characteristics as well as the variations in gas/particle phase distribution) and ozone and the other photochemical oxidants. Some of the same new methods that would be useful in broader multipollutant approaches across classes of pollutants (i.e. PM, ozone, and air toxics) would also be useful in addressing these significant mixture issues within one class of pollutants.

The Panel agrees that the Agency should find ways to re-direct the PM Centers program so that it is better able to address the broader multi-pollutant context. The development of a more robust set of atmospheric chemistry, exposure, toxicology and epidemiology research methods will be essential to building the evidence necessary to support both nearer term decisions by states and localities about the best integrated intervention strategies, and to laying the foundation for the development of multipollutant ambient standards in the future.

Specifically, the Panel found:

- Multi-pollutant approaches should be strongly encouraged by EPA, with a clear indication that innovative efforts to develop methods and implement multipollutant atmospheric transformation, exposure, toxicology, and epidemiology research will enhance the applicant’s chances of being selected. These new methods could include a range of innovative approaches, from computational toxicology and genomics to enhanced statistical methods for identifying principal components or factors, to novel analytic chemistry.

- The Panel felt that while the Agency should provide a strong incentive for multipollutant approaches, it should not mandate them, but rely on the skills and innovation of the research community to propose new approaches
- The Panel generally agreed that the Agency's suggestion that it should try to organize its multipollutant efforts around sources could be useful, but cautioned that an over-emphasis only on near-roadway exposures in such efforts could substantially under-represent the importance of other sources and the atmospheric transformation of their emissions that are also significant contributors to exposure.
- Finally, it will be important to balance the interest in a multipollutant approach with the need to continue answering an increasingly focused set of decision-relevant single pollutant questions that can inform nearer term decisions critical to the Agency's mission to improve public health. This should include science to inform standard setting (e.g. better understanding PM exposure-response and the relative toxicity of PM Components). It also should inform implementation (e.g. better tools for source apportionment). But even in these instances, the Centers program should emphasize the need to produce such pollutant-specific evidence as much as possible in a multi-pollutant context to enhance its interpretation.

**Addressing Regional Differences:** The panel noted the well-known differences in pollutant sources and mixtures in different regions, and emerging evidence of differences in health effects, and found that exploring, characterizing, and understanding these regional differences in exposure and effect should also be a broader direction to be encouraged in a new round of Center awards.

- As with multi-pollutant approaches the Panel felt that systematic approaches to addressing regional differences should be strongly encouraged by EPA, with a clear indication that such efforts will enhance the applicant's chances

of being selected. Here too, the Panel felt that while the Agency should provide a strong incentive for addressing regional differences, it should not mandate them, but rely on the skills and innovation of the research community to propose new approaches.

- The Panel further found that addressing these regional differences could take two forms:
  - o First, individual centers that could demonstrate a systematic approach to exploring and understanding differences in exposure and health in two or more regions should be encouraged;
  - o Second, once centers are selected, and to the extent that they represent geographical differences in their location and focus, EPA should foster enhanced collaboration and coordination among the relevant centers on regional differences.

Charge Question 3: What strengths and weaknesses does the panel see in different options for a future Centers Research Program?

The PM Centers panel recognizes the successes of the PM Centers program over the last 8 years as discussed in Change question 1. Since the Program is so successful, some members questioned the need to make major changes “if it is not broke, do not fix it.” Despite these successes the Panel was asked to evaluate structural changes to the Program, both raised by the EPA and others brought up by the Panel.

#### EPA structural options

1. Same Research topics for all applicants/choice of one topic.

The panel did not support the concept that all applicants should study the same research topic. The RFA should describe the range of desired air research and let the applicants decide on the exact research topics and approaches. It is then up to the EPA funders to decide what they select to fund into their active research portfolio. These decisions should be effected not only by quality of the but also by what research the EPA needs to have and also what would be best in complementing the Intramural and Extramural EPA research program.

2. Regional Centers

The consensus of the Panel was that the requirement of funding Centers based on their regional locations would not be a structurally beneficial alteration to the Program, despite some regulatory benefits as described above.

There are important regional differences in atmospheric contaminants and health outcomes that need to be studied and understood. The development of regional centers may help delineate these differences however other scientific approaches may be scientifically and fiscally better. For example, one study could be to have one or more Centers address these air and outcome regional differences in a more comprehensive and cost effective manner. The establishment of Regional Centers would, however, provide closer links to regional, state, and local officials and facilitate identification of regional issues.

3. Big and Small Centers

There are advantages and disadvantages to having only the classical big Centers or a mixture of Big and Small Centers. The funding of small and big Centers was favored by a minority of the panel. The main concern of most of the group would be that funding limited or small Centers would diminish the impact of the program and not afford the “The Big Centers benefits stated in Charge question 1.

The funding of small Centers would allow Research Centers that are not as comprehensive or developed as the large Centers to be funded and develop their research program in depth and breathe. It also provides the agency to select research programs that may fill a very specific research need in the Program or the Agency itself. While the funding of small centers have advantages the loss of

the Center effect and use of critical funds requiring the decrease in Big Centers is not supported by the majority of the Panel members.

4. Leveraging/partnership to enhance and augment the Centers Program

Other potential structural elements that the Agency is encouraged to entertain is the potential use of Core laboratories shared among the Centers; and the need of each Center to leverage their science and funding to increase scientific output and funding of the Centers research. The Centers are encouraged to develop research partnership to maximize research output. The Centers are also encouraged to identify if their University or Institutes or research partners can provide additional scientific or fiscal support to the Center if it is funded.

The Panel also recommends that the EPA search to find research partners that may help fund this Program. NIEHS, NIIHL, NIGMS, ALA, AHA, ATS would be just some of the federal and non federal programs that may help fund this research. Other Centers programs of the EPA have been successful in developing outside EPA funding to cover 50% of the total costs of the program. The EPA is encourage to see if partners in funding can be found.

5. Ongoing Center Evaluation and scientific flexibility

The Centers must have a process of periodic evaluation at least annually. The Centers have done a very good job in this to date. The Centers should have the flexibility to alter specific projects within the Center that has completed its research, the research is not being productive or new findings are taking the project or Center in an expanded or new pathway. This will of course be done in consultation with the Center oversight committees and the Agency.

6. Centers internal integration and integration with the agency

The Centers should be complemented on their previous and ongoing integration of science, data, and methodology allowing rapid progress of the state of the art in science and methods throughout the Centers and synergistic activity. The Panel did not see integration of the Centers at the same level with the Agency and this interaction would be beneficial to the Centers, Agency, and research of both. The plans for integration of each applicant could be asked in the RFA. This could be at many levels (epidemiology, statistical, method development and others). The integration of the Centers is a strong overall component of the entire Centers Program

7. External Advisory Panels

The Centers and RFA must be complemented on the structure and use of the external advisory Panels. It may be helpful if the Centers involve research in a community, the EAP should have a member of the community on their Panel to facilitate communication between the community and Center and visa versa.