



Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties Report of a Workshop

Science, Technology, and Law Panel, National Research Council

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**ACCESS TO RESEARCH DATA
IN THE 21ST CENTURY**
An Ongoing Dialogue
Among Interested Parties

Report of a Workshop

Science, Technology, and Law Panel
Policy and Global Affairs
National Research Council

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SCIENCE, TECHNOLOGY, AND LAW PANEL

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- DAVID L. GOODSTEIN**, Vice Provost and Professor of Physics and Applied Physics, California Institute of Technology, Pasadena, Calif.
- BARBARA S. HULKA**, (IOM), Kenan Professor, Department of Epidemiology, School of Public Health, University of North Carolina, Chapel Hill, N.C.
- SHEILA JASANOFF**, Professor of Science and Public Policy at Harvard University's John F. Kennedy School of Government and the School of Public Health, Cambridge, Mass.
- ROBERT KAHN**, (NAE), Chairman, CEO, and President of the Corporation for National Research Initiatives, Reston, Va.
- DANIEL J. KEVLES**, Stanley Woodward Professor of History, Yale University, New Haven, Conn.
- DAVID KORN**, (IOM), Senior Vice President for Biomedical and Health Sciences Research, Association of American Medical Colleges, Washington, D.C.
- ERIC S. LANDER**, (NAS/IOM), Member, Whitehead Institute for Biomedical Research, Professor of Biology, MIT, Director, Whitehead Institute/MIT Center for Genome Research, and Geneticist, Massachusetts General Hospital, Massachusetts Institute of Technology, Cambridge, Mass.

PATRICK A. MALONE, Partner, Stein, Mitchell & Mezines,
Washington, D.C.
RICHARD A. MESERVE, Chairman, Nuclear Regulatory Commission,
Washington, D.C.
ALAN B. MORRISON, Director, Public Citizen Litigation Group,
Washington, D.C.
HARRY J. PEARCE, Chairman, Hughes Electronics Corporation, El
Segundo, Calif.
HENRY PETROSKI, (NAE), A.S. Vesic Professor of Civil Engineering
and Professor of History, Duke University, Durham, N.C.
CHANNING R. ROBERTSON, Ruth G. and William K. Bowes
Professor, School of Engineering, and Professor, Department of
Chemical Engineering, Stanford University, Palo Alto, Calif.
PAMELA ANN RYMER, Circuit Judge, U.S. Court of Appeals for the
Ninth Circuit, Pasadena, Calif.

STAFF OF THE SCIENCE, TECHNOLOGY, AND LAW PROGRAM

ANNE-MARIE MAZZA, Director
SUSIE BACHTEL, Staff Associate
KIRSTEN A. MOFFATT, Christine Mizrayan Intern
ALAN H. ANDERSON, Consultant

Preface

In 1997, the Environmental Protection Agency (EPA) announced new regulatory standards for airborne particulate matter. These standards were based in large part upon two bodies of scientific evidence. The first was a series of epidemiological studies led by John Dockery of the Harvard School of Public Health that tracked approximately 8,000 individuals from six mid-size cities over a period of 20 years (referred to generally as the Harvard Six Cities Study). Numerous peer-reviewed papers and presentations resulted from these studies. The second was an epidemiological study led by C. Arden Pope of Brigham Young University that reviewed a large body of data of the American Cancer Society (ACS). Both studies showed a correlation between levels of airborne particulate matter and death rates. In developing the standards, the EPA undertook its own assessment of these studies and oversaw peer review of the results by the external Scientific Advisory Board.

EPA then developed proposed new regulatory standards that would limit the release of airborne particulates. Critics of the proposed standards claimed that implementing the new standards would be unreasonably costly, with estimates reaching billions of dollars. They argued further that the standards were not scientifically justified, and they called for access to all of the underlying data so that the results could be verified by other scientists. The Harvard researchers, who had been funded by the National Institutes of Health (NIH) and not the EPA, declined to provide the underlying data. They took this position in large part because of their concern that releasing all data would violate the privacy agreements they

had made with the patients who participated in the study as part of the informed consent process. However, Harvard did indicate a willingness to provide the data to other qualified researchers for confidential analysis and requested that the Health Effects Institute (HEI) conduct an independent review of the data.

The researchers' refusal to make all their data available led to calls from Congress, industry, and others, requesting access to the data, and was one of the causes of the enactment of a rider, known as the Shelby Amendment, that was attached to the Omnibus Appropriations Act for FY1999, P.L. 105-277. The rider directed the Office of Management and Budget (OMB) to amend Circular A-110 so as to require federal agencies to ensure that "all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act (FOIA)."¹ The amendment itself was not discussed in public hearings, however, so that it has virtually no legislative history.²

Enactment of the Shelby Amendment caused a stir in the academic research community as well as among other groups. The academic community, including The National Academies, raised a number of issues and objections: (1) What are data? (2) How will the privacy of human research subjects and the confidentiality of trade secrets that might one day be patentable or publishable be protected? (3) Who will bear the costs? (4) How will agencies handle research data generated with funding from both federal and non-federal sources? (5) How will researchers be protected from groups that try to gain access to data as a way to harass investigators and their institutions in order to hinder or deter the pursuit of specific research topics? and (6) Is FOIA the appropriate mechanism for providing public access to large bodies of complex research information? Defenders of the Shelby Amendment argued that it provided the public with both accountability (taxpayers fund the research—therefore they should be able to see its basis) and transparency (the public should be able to review research data produced with federal funds that is used to support regulatory decisions that affect the public).

The OMB issued proposed revisions to Circular A-110 in February

¹OMB Circulars are instructions or information issued by OMB to federal agencies. Circular A-110 sets forth standards for obtaining consistency and uniformity among federal agencies in the administration of grants to and agreements with institutions of higher education, hospitals, and other non-profit organizations.

²The Shelby Amendment was published in the Federal Register as 64 FR 5684 on February 4, 1999. Clarifying changes were issued by OMB the following summer and made available in the August 11 edition of the Federal Register at 64 F.R. 43786-43791. Public Law 105-277 was enacted on Oct. 21, 1998.

and August 1999, and issued final revisions in September 1999. The revisions took effect on November 8, 1999. Two years later agencies are still in the process of developing their implementation strategies.

In the years since the Shelby Amendment, scientists, industry, and policy makers have struggled over how the public's new right of access should be applied to scientific data. There is loose agreement that research data should be accessible, but wide disagreement over the "depth" to which the public has such a right. There is now a new level of demand for data, as more stakeholders claim the right to challenge the basic science that supports regulatory decisions.

The National Academies' Science, Technology, and Law Program held a one-day workshop to explore the mounting tensions in the federal regulatory process between the need to provide access to research data and the need to protect the integrity of the research process. The workshop provided a picture of the debate arising from passage of the Shelby Amendment and the resulting OMB revisions of Circular A-110. It also took a broad look at the competing interests seeking access to research data by providing various groups with an opportunity to voice their views on public access to research data. In addition, the workshop explored alternative approaches that might be used to improve public access to research data.

The goal of the workshop was not to reach conclusions or recommendations; nor could it address other pressing issues beyond the regulatory process, such as protection of intellectual property, the influence of broader access on scientific competition, the potential for increased administrative burdens and changes in the research process, and the challenge of providing data access in an increasingly electronic world. The STL Panel may address some of these issues in the future. For the present, this report attempts to be faithful to the workshop's original goal of airing all viewpoints from both legal and scientific leaders. It summarizes the proceedings and organizes them by topic, without drawing conclusions or making recommendations.

Acknowledgments

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Bruce Alberts, President, National Academy of Sciences
Frederick R. Anderson, Jr., Partner, Cadwalader, Wickersham & Taft
Wendy Baldwin, Deputy Director for Extramural Research, National Institutes of Health
Joel Cohen, Abby Rockefeller Mauze Professor and Head, Laboratory of Populations, The Rockefeller University and Professor of Populations, Columbia University
E. William Colglazier, Executive Officer, National Research Council
Douglas W. Dockery, Professor of Environmental Epidemiology and Professor of Medicine, Department of Environmental Health, Harvard Medical School
William H. Farland, Acting Deputy Assistant Administrator for Science, Office of Research and Development, U.S. Environmental Protection Agency
Steven Goodman, Associate Professor, Department of Biostatistics, The Johns Hopkins University
Kenneth W. Harris, Acting Director, Research Data Center, National Center for Health Statistics
David G. Hawkins, Director, Air and Energy Program, Natural Resources Defense Council

David Korn, Senior Vice President for Biomedical and Health Sciences
Research, American Association of Medical Colleges
William L. Kovacs, Vice President, Environment, Technology, and
Regulatory Affairs, U.S. Chamber of Commerce
Barry S. Kramer, Director, Office of Medical Applications of Research,
National Institutes of Health
Alan Morrison, Director, Public Citizen Litigation Group
Robert O'Keefe, Vice President, Health Effects Institute
Jim J. Tozzi, Member, Board of Advisors, Center for Regulatory
Effectiveness
The Honorable Jack B. Weinstein, Senior Judge, United States District
Court for the Eastern District of New York

This workshop report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for quality, objectivity, and responsiveness to the charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this report: Cynthia M. Beall, Case Western University; Martin Blume, American Physical Society; Anita K. Jones, University of Virginia; Sylvia K. Kraemer, National Aeronautics and Space Administration; Norine E. Noonan, National Space Science and Technology Center; Sheldon L. Trubatch, Foley & Lardner; and Patrick Windham, Independent Consultant.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the content of the report, nor did they see the final draft before its release. The review of this report was overseen by Robert M. Hauser, University of Wisconsin-Madison, and R. Stephen Berry, University of Chicago. Appointed by the National Research Council, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring panel and the institution.

We wish to thank the staff of the STL Program: Anne-Marie Mazza, Susie Bachtel, Kirsten Moffatt, and consultant writer, Alan Anderson.

Donald Kennedy and Richard Merrill
Cochairs

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1

Historical Perspective

A Washington attorney, Frederick R. Anderson, provided the workshop participants with a brief overview of the events leading up to the Shelby Amendment.³

Important precedents. The Shelby Amendment has several important precedents, including the Freedom of Information Act (FOIA) and the Supreme Court's decision in *Forsham v. Harris*. FOIA broadly guarantees citizens access to information gathered by the federal government, including the records of federal agencies. FOIA is subject to exceptions for the purposes of protecting such interests as personal privacy, trade secrets, national security, personnel records, and privileged communications.

The law underlying FOIA-based public access to research data is reflected in the Supreme Court's 1980 decision in *Forsham v. Harris*. In this decision, a physician's group was denied access to physical data that had been gathered by persons working under a grant from the federal government in the course of research on diabetes treatment. The decision excluded from FOIA access to any material that was not physically in the sponsoring agency's hands.

As explained during Panel I by Dr. David Korn of the American Association of Medical Colleges, much of the science that supports regu-

³This chapter essentially summarizes the points made by Mr. Anderson, with additional documentary material that is identified as such.

latory action involves research on human beings. Since at least the early 1970s, he said, when the code of federal regulations to protect human participants in research was adopted by the Department of Health, Education, and Welfare, issues of protection, privacy, and confidentiality of participants' medical information have been paramount. The issue of individual privacy remains a controversial issue nationally, and the DHHS has recently issued a final rule on the privacy of medical information—a long, complicated, and hotly contested rule. Basically, said Dr. Korn, our society continues to place a very high premium on the protection of individuals' medical information, and this desire stands opposed to unlimited access to information used in research.

The wording of the Shelby Amendment. The Shelby Amendment took the form of a two-sentence rider to the Omnibus Appropriations Act for FY1999, Public Law 105-277, which reads as follows:

Provided further that the Director of OMB amends Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act.⁴

This amendment, which takes its name from its sponsor, Senator Richard Shelby of Alabama, precipitated a highly charged public debate, but only after it became law. Industry and regulated communities supported the measure as a fair way to challenge scientific studies that support costly regulations, tort suits, and dubious/questionable risk estimates. The scientific community opposed the amendment on the grounds that it would invite intellectual property searches by industry and scientific competitors, jeopardize the privacy of research subjects, decrease the willingness of research subjects to participate in studies, expose researchers to deliberate harassment, and increase costs and paperwork.

Revised OMB guidelines. The Shelby Amendment required OMB to modify OMB Circular A-110 so that it became the regulatory expression of the amendment. That section is titled "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations."

The OMB, as instructed, in early 1999 proposed guidelines for applying the amendment. These stimulated over 9,000 comments from the public to the OMB, which revised the guidelines twice. When the final guidelines were issued in late 1999, the OMB received 3,000 additional comments.

⁴The revised Circular became effective November 6, 1999.

The wording of the relevant section of the final version is as follows:

(d) (1) In addition, in response to a FOIA request for research data relating to published research findings under an award that were used by the federal government in developing an agency action that has the force and effect of law, the federal awarding agency shall request, and the recipient will provide within a reasonable amount of time, the research data so that they can be made available to the public under FOIA.

Three additional sentences repeated the guideline's order to permit an agency to recover any costs associated with compliance.

Because Circular A-110 applied only to non-profit institutions, the amendment targeted only universities, teaching hospitals, and non-profit research centers, and did not apply to federally funded research undertaken by for-profit entities.

OMB's final guidelines acknowledged FOIA's protections—the protection of confidential commercial information and trade secrets, and of personnel and medical information, the disclosure of which would constitute, in the words of the circular, “clearly unwarranted invasion of personal privacy such as information that could be used to identify a particular person in a research study.”

The wording of OMB's guidelines qualified the Shelby Amendment in several ways. First, it limited the data that must be divulged to published or cited research that has been used by the federal government to develop legally binding agency actions. Also, it defined “published” as an appearance in a peer-reviewed scientific or technical journal, and/or use by an agency in support of an action that has the force of law. The OMB also added the provision for a “reasonable amount of time” to assemble and provide the data. In an earlier version the OMB limited the rule to actions with an economic impact of \$100 million or more, but this limitation was dropped in the final version.

The OMB further defined research data as the factual material commonly accepted by the scientific community as necessary to validate research findings. This definition excluded preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. It did not specifically include laboratory samples or biopsy materials, and left open the question of audio and video tapes of interviews with research subjects. The OMB gave some discretion to the researcher to decide which materials should be provided to a requesting party. No process was specified to resolve disagreements between the principal investigator and the research institution, the federal agency, or the requesting party.

The OMB further interpreted the amendment as applying only to new and continuation awards. Some parties, including the U.S. Chamber of

Commerce and Public Citizen, disagreed with this interpretation. However, the OMB did not limit the requirement to research that is supported wholly by federal funds. Even if a project has only a relatively small amount of federal funding, all data must still be produced. Notably, OMB did not require access to data produced by privately funded research, even if that research was used by a federal agency as the basis for a legal ruling.

The revised guidelines received qualified praise from the research community, but some industry critics contended that the OMB construed the Shelby Amendment too narrowly. The U.S. Chamber of Commerce announced an intention to bring suit to challenge the OMB's interpretation, but had not yet done so. Thus, the controversy and uncertainty surrounding the Shelby Amendment continues, although reportedly only a few Shelby requests had reached the agencies. Out of almost 20,000 total FOIA requests filed each year, at the time of the workshop the EPA and the NIH had each received only a handful of requests under the Shelby Amendment; of seven such requests to the NIH, the agency had granted four and denied three.

The issues of access and reliability. The Shelby Amendment directs our attention to the nature of the science that supports regulation and other policy making: how it is done, who does it, and how reliable it is.

Opponents of the Shelby Amendment agreed that, in principle, the more open the science, the more reliable the regulations based on it will be, and the less likely are government regulators, industry, non-profit advocacy groups, and perhaps other stakeholders to obscure the facts and distort the data to serve their interests. Thus, the announced goal of the Shelby Amendment to provide openness was appealing to both sides of the debate. Furthermore, even opponents of the amendment acknowledged that society has interests that legitimately may sometimes counterbalance researchers' freedom to perform research and handle the data as they see fit, and that the public does deserve access to reliable facts relevant to policy making and dispute resolution. Nonetheless, some participants argued that the Shelby Amendment was too blunt and cursory to fully address an issue as complex as that of data access. One lawyer stated, ". . . many have argued, and I think persuasively, that there must be a better way to provide such access than a two-sentence amendment that simply requires that all data produced be made available under FOIA."

2

The Scientific Process and the Universe of Data

In order to understand the complexities underlying the issue of data access, it is necessary to first examine some of the foundations and processes of science. It is important to note that few people outside the business or practice of science are likely to be familiar with these foundations or processes. Accordingly, the first panel discussion of the workshop sought to clarify some fundamental scientific issues: What is the universe of scientific data? What is scientific publication? How are scientific claims validated? The panel, moderated by David Korn, included Steven Goodman and Douglas W. Dockery.

At the outset, Dr. Goodman noted that a fundamental feature of scientific claims is that they are not “binary”; that is, they are rarely proven or disproven for all time. Instead, all scientific claims fall in the category of being uncertain to various degrees. He likened these claims to “shades of gray, with truth and falsity just beyond the bounds of what we can absolutely know.” Furthermore, no particular statistical formula exists that can put a number on how certain one can be on the basis of any scientific evidence. Therefore, although specific scientific research may support the hypothesis that a particular claim is true or false, it is important to realize that the researcher’s original hypothesis is subject to revision over time.

The scientific process itself, he said, is made up of several phases, including development, execution, inference, communication, and response/revision. Fundamental to this process is an indirect and circuitous feedback loop between the final response and revision of results

and the development of new questions and new studies. Scientists assemble and weigh evidence in its totality. This weighing requires an understanding of how to assess the strength of experimental design and execution, the strength of statistical methods and results, and the importance of multiple sources of related evidence.

What are data? One way to imagine the scientific method, said Dr. Goodman, is to visualize a single scientist toiling with a few students at the laboratory bench. Once a pertinent question has been studied, the activities, observations, calculations, and conclusions of such a scientist would be assembled, distilled, and published. Other researchers interested in the topic then would use the publication and perhaps ask for some of the scientist's original materials to further their own studies of the topic. Bench scientists understand that if they do not report accurately and honestly their methods, results, and conclusions, their reputation within the scientific community could be jeopardized. This reality has always been a powerful force for integrity.

That information, as data, may then move through many levels during preparation of a study report: raw data, abstracted data, coded data, computerized data, cleaned or edited data, analyzable data, and, finally, analyzed data. It is important to realize that as data flows from one level to the next, researchers often have to evaluate or "clean" the particular items of data. For example, cleaned data often must be purged of "outlier" data that are interpreted as unlikely to be accurate or likely to distort the results. Only when the data are cleaned or edited are they brought into the analysis module of a statistical program and organized. This module typically is thus a very small subset of the total data, and it is organized to focus on one particular question. In complicated data sets, many questions are typically asked of the data over some years by multiple investigators. It is these analyzed data that appear in published form, highly compressed and processed, and often presented in graphs or tables. Although many choices are made in deciding which data enter the final analysis, these decisions are determined by trained scientists who have spent years understanding the limits of their methods and deciphering the particular research question.

What is peer review? One way to answer this question is by discerning what peer review is not. Peer review does not detect fraud, validate factual findings, dictate publication decisions, or substitute for the judgments of the scientific community as a whole. What it does do is provide a mechanism of independent outside advice to a journal editor about the importance of a paper's findings, its strengths and weaknesses, and any modifications necessary to make the author's claims match the strength of the reported evidence. Since it is those claims that are often what the

media and the lay public pay the most attention to, assessing their strengths and weaknesses is one of the main purposes of peer review.

What is publication? The Shelby Amendment calls for the release of data whose results have been published. Publication, said Dr. Goodman, is a highly compressed summary of the main study findings. The primary purpose of a scientific publication is to communicate to other scientists. It should not be considered the establishment of scientific “truth” or the final resolution of a question, but rather an addition to or clarification of an ongoing conversation about the state of knowledge. Publication should be considered part of a continuing process of discussion of a particular topic by the scientific community of evidence and claims.⁵

How reliable is a scientific finding? Since one cannot expect a simple true-or-false answer from most scientific studies, noted the speaker, a more useful question is: Was the study reliable enough to support an action as important as a policy decision or regulatory action? There are several ways to evaluate the soundness of a scientific study. First, one examines the strength of the design, the methods, and the statistical results. Next, one asks whether there is consistency within the data (pertaining to mechanisms of effect or related outcomes) and with other studies and scientific theories. Then, the robustness of the findings is evaluated through the use of different analytical approaches. Ultimately, the reliability of findings rests on trust and in believing that the investigators did what they said they did. This trust forms the bedrock of the scientific conversation, and its violation can damage or end a scientific career.

The ability to replicate a study is typically the gold standard by which the reliability of scientific claims are judged. In some types of experimental studies, it is possible to manipulate or exactly replicate the original study. For large epidemiological studies, however, repeating a study is seldom either possible or desirable. Preferable are studies examining the same hypothesis in other places, in other populations, and/or in other ways. In general, then, “replication” might involve any of the following:

- Additional analyses done on the data set by the original or collaborating investigators;

⁵It is worth noting that the traditional understanding of publication is being stretched in the present era of electronic communication. Today, articles posted on web sites (often including extensive data), as well as conference proceedings and other unreviewed materials, are widely used by the scientific community to communicate results. Similarly, many conference proceedings are not peer reviewed. Whether, and how, such materials should be used in the setting of regulations has not been established.

- New results generated from older data sets;
- New studies addressing the same hypothesis;
- Independent analysis of the same data set by different people;
- Monitoring of the results of actions taken on the basis of the findings.

An additional layer of replication is *meta-analysis*, which is a systematic strategy for comprehensively describing and summarizing a body of research evidence from two or more studies. The goal is to produce a quantitative synthesis of the evidence presented in multiple studies that relate to a research question. In a typical meta-analysis, all the data used have been published in the public domain and are easy to inspect and analyze.

Although scientific studies and their replication generate results that fall into a range of shades of gray, there exist long established and proven mechanisms within the scientific community, such as peer review and publication, for judging scientific merit. It is due to the uncertain nature of science itself that scientific claims will always be subject to questioning, challenge, and refinement as additional questions are asked and newer data are generated.

THE SIX CITIES STUDY

History of the Study. Douglas Doherty, an epidemiologist associated with the Harvard Six Cities Study, provided an overview of the research project. In 1973, the OMB requested that the National Institute of Environmental Health Sciences (NIEHS), one of the institutes of the National Institutes of Health (NIH), review the health effects of sulfur oxides and propose a longitudinal study of the health effects of fossil fuel air pollution. Two researchers at the Harvard University School of Public Health, Ben Ferris and Frank Speizer, submitted a proposal in 1974 for a study of children and adults in six cities in the midwestern and eastern United States to evaluate the effects of the anticipated degradation in air quality. The study was approved and received funding for 20 years; the Electric Power Research Institute provided additional funding after the study began. Also, the EPA provided technical assistance, information from air monitors, equipment, and limited input into the conduct of the study.

The project studied areas around the major coal-fired power plants in the Midwest and looked at the health effects of the air pollution as it was transported northeastward by prevailing winds. To achieve a range of exposures, the researchers chose the cities of Watertown, Mass.; Steubenville, Ohio; Kingston, Tenn.; St. Louis, Mo.; Topeka, Kan.; and Portage, Ind. These communities ranged from rural areas upwind of the

power plants to downwind communities with more polluted air. The core studies measured air pollution in those communities and the health of a sample of the population. The Six Cities Study was not a single study but a constellation of studies tied together in their focus on these six communities. One study, for example, was a random sample of children enrolled as first graders and followed through high school graduation. Ultimately, different groups of investigators produced at least 15 identifiable data sets; new findings then fed back into new studies. During the course of the 20-year period, more than 100 publications emerged as a result of these studies.⁶

One of the studies monitored the effects of air pollution on mortality rates, using a random selection of adults aged 25 to 74 in each community, selected from census lists and city directories. Study participants took a pulmonary function test every 3 years and filled out a questionnaire, answering the same set of questions each time. The study kept track of which participants died in the interval.

Two of the goals of this study were to determine how long study participants lived and to identify predictors of survival. The study used the Social Security System and the National Death Index to determine information. The Index allowed the researchers to search through all the death certificates in the U.S. for matches with people on the Six Cities list. Although the matches were not perfect, and each name had to be validated by Social Security number, age, gender, and other factors, it saved the investigators from having to visit all the participants each year.

To validate that the people who died were in fact the same individuals as those in the studies, and to determine the cause of death, the investigators had to obtain the original death certificates and compare the information on the certificates with the original records. The study took into account several known predictors of survival: age, sex, personal habits (such as smoking), socioeconomic status, and occupation (including exposure to chemicals).

After adjusting for all known variables, the study found that people who lived in areas with higher air pollution, as determined by fine-particle concentration, had a shorter life expectancy than people living in the cleaner cities. According to Doherty, the investigators were surprised by

⁶Probably the most widely noted of these is the following: Dockery, D.W., Pope, C. A. III, Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E, Ferris, B.G., Jr., and Speizer, F.E. "An association between air pollution and mortality in six U.S. cities," *New England Journal of Medicine*, 1993, 329:1753-1759.

the magnitude of this effect because the concentrations of air pollutants seemed low.⁷

Impact of the study. Since the EPA first set standards for particulate matter in 1970, several hundred epidemiological studies of the effects of air pollution have been published. During the year when the Six Cities Study was released, it was one of several (12-15) published studies that examined the effects of particulate air pollution. While none of these studies was by itself able to capture the whole “truth” about air pollution, their cumulative power persuaded the American Lung Association (ALA) to sue the EPA to tighten the 1970 particulate standards. In 1997 a federal court found in favor of the ALA and mandated that the EPA set a new standard.

Rule making as a result of the study. The EPA evaluated the results of the mortality study, approved the basic performance of the methodology and the standards of publication, and used the study’s findings in setting its ambient air quality standards. Due to the strong interest in the research, the agency encouraged the researchers to allow interested scientists and agencies the opportunity to understand fully the basis of their work. The investigators understood this to mean discussions with other scientists regarding the approach, methodology, and results of the study. The EPA did not call for a release of all the underlying data. Indeed, as mentioned above, the data were encumbered by several types of confidentiality constraints. The investigators had assured the participants in the studies that their identity and their relationship to any information obtained would be kept confidential. Specific agreements were signed by each participant, the study director, and a witness. Assurances of confidentiality are typical in studies of this kind.⁸

⁷Although the Six Cities Study was the most visible impetus for the Shelby Amendment another large epidemiological study led by C. Arden Pope of Brigham Young University with data from the American Cancer Society (ACS) was also fundamental to the EPA’s standard setting. The data used in the Pope study were actually owned by the ACS, introducing a new complexity to the call for access to data. At issue is the question of access to large databases used for research that influence federal rule making but whose collection and maintenance involve no federal funds. (See Arden C. Pope III et. al., “Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults,” *American Journal of Respiratory Critical Care Medicine*, Vol. 151:669-674, 1995.)

⁸Formal protections of privacy and confidentiality are described by the Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects. For example, one of seven mandatory requirements for federally funded research on human subjects is that “When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data” (46.111-a-7). The code also requires “a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained” (46.116-a-5).

In an experiment to discover whether confidentiality could be preserved while opening the data for public review, the study investigators attempted to disguise the identity of the study participants. They deleted as many features as possible from the questionnaires, such as the name, the state file number, the mother's maiden name, and the name of the person providing the information. However, they needed to retain a minimum set of features if other scientists were to be able to replicate the basic findings of the study. They needed the place of death, because they were investigating the possibility of a link to air pollution exposure; they needed the date of death because the study concerned survival; and they needed both the age at death and gender in order to adjust for both factors. They found that even this minimum set of features could allow for identification of research participants. For example, Dr. Dockery performed a simple test of confidentiality by using the minimal information that a male of a certain age had died on a certain day in one of his six cities. On the Internet he was easily able to find newspaper obituaries of those who had died in that city on that day. From that relatively short list of descriptions he quickly identified one of his subjects simply by the facts of age and gender, added to the place and date of death.

In addition to the confidentiality agreements with the individual study participants, the investigators had had to sign certain statements in order to obtain death certificates from the states. They had had to agree that they would (1) limit access to the records to only the members of the research staff, (2) destroy records upon the completion of the study, and (3) not release the records to other agencies, publish data so individuals could be identified, or contact family members of decedents. Furthermore, the investigators had had to sign non-disclosure agreements to obtain information from the National Death Index. Hence, although the investigators were willing to share data sets, which is a common scientific practice, they believed that to open their thousands of boxes of original records would be unethical.⁹ Nonetheless, the study was criticized on the general grounds that the public had paid for the study (through NIH funding to Harvard) and, therefore, the public had a right to all the data.

The Health Effects Institute Analysis. In an effort to accommodate public demand for access to the data so the study findings could be contested or confirmed, the investigators ultimately agreed to make an arrangement with an independent entity, the Health Effects Institute (HEI), to re-analyze the data. Funded jointly by the EPA and the automobile manufac-

⁹The study director said that he was able to find on the Internet the deaths in Watertown, Mass., for the month preceding the workshop and easily identify a 54-year-old male who was a member of the study.

turers, the HEI describes itself as an “unbiased source of information on the health effects of motor vehicle emissions.”¹⁰ The HEI was given the task of reanalyzing and validating the original data.

The HEI organized an open, international competition to assemble a “reanalysis team” and established a separate review committee to examine the results of the reanalysis. The review involved a sensitivity analysis using methods not available during the original analysis and an examination of new data. The HEI found the original data to be of high quality, and essentially confirmed the validity of the original findings and conclusions.

¹⁰The following description of the HEI, located in Boston, Mass., is offered on its web site: “The Health Effects Institute (HEI) is an independent, nonprofit corporation chartered in 1980 to provide high-quality, impartial, and relevant science on the health effects of pollutants from motor vehicles and from other sources in the environment. Supported jointly by the U.S. Environmental Protection Agency (EPA) and industry, HEI has funded over 170 studies and published over 100 Research Reports and several Special Reports producing important research findings on the health effects of a variety of pollutants, including carbon monoxide, methanol and aldehydes, nitrogen oxides, diesel exhaust, ozone, and most recently, particulate air pollution.” See <http://www.healtheffects.org/pubs-special.htm>.

3

Public Access to Research Data Used in Rule Making

During the workshop, a panel moderated by Alan Morrison and composed of individuals representing various interests (Bruce Alberts, National Academy of Sciences; Wendy Baldwin, National Institutes of Health; William H. Farland, U.S. Environmental Protection Agency; David G. Hawkins, Natural Resources Defense Fund; Jim J. Tozzi, Center for Regulatory Effectiveness; and William L. Kovacs, U.S. Chamber of Commerce) was asked to consider the following questions and to offer their opinions:

- Is the primary purpose of the Shelby Amendment to strengthen the public's "right to know" how tax dollars are spent, or is it to create a "right to see and contest data" that are used to support federal decision making?
 - Should access to data be limited to data used for formal rule making, or should there be access to data used for general policy making?
 - The Shelby Amendment does not set a timetable for making data available. Should the data be available when a rule is proposed, or when a final rule is issued?
 - Who should bear the cost of responding to a Shelby Amendment request? The agency? The grantee? The requester?
 - In what form should the data be delivered to the public? Who should bear responsibility for putting it into this form?
 - FOIA treats all requesters equally. Should there be any limits on who may request research data?

- The careers of researchers often depend on the continuing use of already collected data. Must they give up such data if it means jeopardizing their careers?
- Should the public have access to data funded and produced by for-profit entities who oppose a regulation, such as an industry coalition?

Responses to these questions are presented under the identified respondents.

The perspective of a bench scientist (Bruce Alberts-National Academy of Sciences). Science is a community effort; it succeeds only if other scientists can analyze, interpret, and extend each other's work. Science requires full disclosure and availability to other scientists of the research methods, results, and, when necessary, special materials used in research. For example, Dr. Alberts noted the Human Genome Project requires extensive sharing not only of data, but also of materials, such as DNA clones and human cell lines. Virtually all scientific conclusions are based on a body of evidence, a complex web of studies related to one another in subject matter and reasoning.

While the academic community believes that the OMB did a thoughtful job in narrowing the Shelby Amendment, he said that concerns still exist. For example, the Shelby Amendment includes no "need to know" provision; anyone can request data for any reason. Without some front-end filtering mechanism, there is a danger that the amendment could be used to harass scientists whose work is found objectionable by anyone, for any reason. The potential for harassment is already real in some fields, and additional disincentives could further discourage the best young people from choosing careers in science and thus jeopardize the United States' leadership position. Therefore, while sharing data with those outside the laboratory environment is a good and necessary idea, bench scientists believe that FOIA is not the best mechanism to achieve this.

The perspective of a funding agency (Wendy Baldwin-NIH). Over the past 10 to 20 years, the norms of data sharing have shifted dramatically, said Dr. Baldwin. Previously, investigators kept very large data sets virtually until they became historical records. Today, they have started to put data into the public domain even before they have published their findings based on the data.

There are several purposes to this custom of data sharing. As the NIH representative said, it "supports and forces scientific inquiry." Data sharing allows researchers to make maximum use of the very large investments needed to create complex data sets. Additionally, data sets are effective vehicles for teaching the next generation of scientists. They help scientists develop new methodologies and a diversity of analytical views.

Data sharing also allows conclusions to be tested by people with different outlooks, disciplines, or statistical techniques.

FOIA, however, was not designed to force the sharing of data sets. She said that it was designed to make available certain government records, normally in written form, to members of the general public who can read and understand them. Scientific data are shared for the purpose of re-analysis—a scientific activity, not a public activity. Although it is easy to understand the appeal of gaining access to “original data,” this access can serve little purpose for those without the skills to reanalyze it.

Another problem raised by using FOIA is that the Act imposes no limits on how accessed information might be used. In a typical data-sharing environment, the researcher is allowed to put some restrictions on data use. One restriction might be against using data for non-research purposes, such as identifying a market segment or contacting people who took part in a study.

Under FOIA, someone besides the investigator strips away the “identifiable” personal information. However, it is the investigator who is in the best position to understand how the combinations of variables might be used to identify individuals. Deleting only a name, Social Security number and address may not be sufficient to protect the identities of research subjects who might object to having their personal information released. When awards are made to institutions, those institutions have the obligation to protect the confidentiality of the data gathered under the award.

To facilitate compliance with the Shelby Amendment, the NIH has begun to encourage investigators to put data into public archives, data enclaves, and other mechanisms that allow access for research purposes. Furthermore, it has begun a review and revision of informed consent forms and research on human subject clearances and procedures. The revised forms would alert individuals participating in human subjects research to the possible implications of the Shelby Amendment.

Failure to comply with the amendment may be deemed a violation of the terms and conditions of an NIH award. However, no mechanism is in place to handle disputes over access to the data. Such resolutions are potentially complex, because there are four potential parties: the principal investigator, the home institution, the funding agency, and the requestor. It is likely that differences in opinion will arise not only between a scientist and a requestor, but also between scientists and their home institutions.

The perspective of a regulatory agency (William H. Farland-EPA). Dr. Farland said that scientific data and studies used by the EPA move through a process designed to help decision makers. In doing risk analysis, the EPA’s job is to seek the best available data to reduce uncertainty

with regard to a particular risk. Most important, the agency tries to describe at the outset of a regulatory process how scientific information supports the decision, and to communicate the impact of that information. This is especially important when the debates among epidemiologists or statisticians confuse the public, who do not know which side to believe and who may lose faith in both the scientific process and the regulatory process.

The Shelby Amendment, Farland said, raises several questions for the EPA about rule making as a legal and deliberative process. At what point should the agency disclose what type of regulation is going to be considered or issued? The timing of the release can influence its reception. Should the agency use contracts to support the research needed for regulations? Contracting, as opposed to grants that support more flexible work, might narrow the type of information the agency receives and could possibly limit the scope of the science underlying the regulation.

In 1999, the EPA established a new Office for Environmental Information, which tries to provide environmental decision makers, both inside and outside government, with information needed to protect public health and the environment. The volume of information involved is large. The agency receives information from several sources: (1) in-house research programs, (2) contracts and grants, (3) routine or compliance monitoring data, (4) the regulatory process and the regulated industries, (5) rules from other agencies, (6) voluntarily submitted data, and (7) the open literature. For data generated under grants agreements, the EPA is already required to follow FOIA procedures. This also is true for data generated by agency researchers or contractors as part of in-house programs, if the contractor delivers the data to the agency.

The perspective of a public interest advocacy group (David G. Hawkins-Natural Resources Defense Council). Openness and transparency improve government actions and are necessary for democracy, said Mr. Hawkins. However, the Shelby Amendment may not yield these results.

First, application of the Shelby Amendment is "one-sided" because it applies only to federally funded research. "If access to the basic information upon which agencies make their decisions is the issue," he said, "there is no principled basis for saying that access should be available only when the research has been federally funded." For example, public advocacy groups do not have the right to use FOIA to demand the underlying data that may be present in industry-supported studies that have been submitted on a confidential basis to an agency to assert a claim of economic harm.

Second, he said, the Shelby Amendment increases the burden on an agency to justify its judgment that a hazard exists that warrants precautions. If affected interests can easily use the Shelby-modified OMB rules

to invalidate studies, federal agencies will have no basis for moving forward toward improved regulation. In other words, how does the government responsibly use scientific information that by its nature always contains uncertainties and ambiguities to describe potentially legitimate issues of hazards to public health and the environment?

One alternative to the Shelby Amendment, suggested by the NRDC representative, is to challenge the data used in rule making under the Administrative Procedure Act (APA). The APA, which is 50 years old, addresses legitimate issues about the reliability of data. For example, an agency that bases an action either on its own data or on a published study is responsible for responding to comments about the validity of the data. If the study design, or performance, or conclusion are said to raise any doubts, the agency has a duty under the APA to respond to such comments.

In addition, Hawkins said, the federal courts are experienced in evaluating the reasonableness of agency responses to public comment. For example, an agency might receive a request from a study participant or a study from another interested party during rule making. If the agency fails to respond to the request or refuses to accept the findings of the study because it could not get access to the original data, a court can determine whether there is cause for action. Such a determination can be made without having access to the underlying data or without creating an environment that encourages harassment, as is feared the Shelby Amendment does.

The perspective of the U.S. Chamber of Commerce (William L. Kovacs). For the scientific community to simply “fight Shelby,” said Mr. Kovacs, would be to “abdicate its responsibility. We need to take a step back, . . . and look at ways in which we can work together on those regulations that have an impact on public policy.”

The Chamber representative deplored the current number of federal regulations applicable to business. He said that there currently exist some 150,000 pages of federal regulations; that 4,000 new regulations are issued each year; and that regulation costs the economy \$725 billion a year. This, he estimated, is the equivalent of three times the total value of the taxes paid by all U.S. companies.¹¹ He urged greater sharing of any data that is instrumental in setting public policy, and emphasized that industry is not

¹¹The figure of \$725 billion was drawn from the work of Thomas D. Hopkins of the Rochester Institute of Technology and has been repeated in several contexts, including Senator Shelby’s own article on the topic (see Senator Richard Shelby, “Public Access to Federally Funded Research Data,” *Harvard Journal on Legislation*, Vol. 37, Harvard University, 2000, p. 370). The use of such figures to characterize the cost of federal regulations is controversial. Even with the best of intentions, it is extremely difficult to estimate the actual

interested in obtaining trade secrets, commercial information, or the identity of individuals.

Further, he commented that “maybe Shelby is too broad” but asserted that “no disclosure is not very good for democracy.” Rather than calling for “all data,” Mr. Kovacs suggested limiting the OMB requirement to data used in the development of public policy and he agreed with the notion of expanding the Shelby Amendment to apply to federal contracts as well.

The Chamber’s representative was asked about the HEI’s reassessment of the Six Cities Study. He listed several objections. The first was that the Chamber had filed a FOIA request with the EPA for “original data,” which it did not get. Second, the Chamber questioned the initial statement by the EPA that the new regulation would save 40,000 lives at \$45 billion to \$47 billion annually. “Whether it’s \$45 billion a year or \$150 billion a year,” said the representative, “we felt that when you have something which is going to put major areas of the country in non-attainment, that permits aren’t going to be permitted, businesses aren’t going to be expanded, it’s going to affect everything . . . , we thought that we should have a right to the data.” He noted that the denial of the Chamber’s FOIA requests was “the predicate for the lawsuit” that may be filed by the Chamber.

The perspective of a lobbying organization (Jim J. Tozzi-Center for Regulatory Effectiveness). According to Mr. Tozzi, the House of Representatives and Senate “leadership” set up the Center for Regulatory Effectiveness (CRE) in 1996 as part of the Congressional Review Act. The Center’s top priority is to ensure that high-quality data are used in setting regula-

total costs and benefits of all existing federal regulations to any degree of precision. There are at least two types of intractable problems: the “baseline problem,” i.e., the difficulty of estimating how things would have been without the regulation, and the “apples and oranges problem,” the common practice of determining total costs by adding together diverse individual studies.

For more detail, see the following:

- Hahn, Robert W. and John A. Hird. “The Costs and Benefits of Regulation: Review and Synthesis,” *Yale Journal on Regulation*, Vol. 8, No. 1, Winter 1991.
- Thomas D. Hopkins, “Regulatory Costs in Profile,” *Journal of Policy Sciences*, Vol. 31 (1998), pp. 301-320. Hopkins published a series of studies on this topic from 1991 to 1996.
- Jaffe, Adam B., Steven R. Peterson, Paul R. Portney and Robert Stavins. “Environmental Regulation and the Competitiveness of U.S. Manufacturing,” *Journal of Economic Literature*, Vol. 33, No. 1 (March 1995).
- Office of Management and Budget, “Report to Congress on the Costs and Benefits of Federal Regulations,” OMB Office of Information and Regulatory Affairs (Sept. 30, 1997).

tory standards, noted Mr. Tozzi. Access to data is considered a prerequisite to assessing the quality of data used in regulatory decision making.

In recent years, the federal government has concluded that the efforts of various groups to oppose federal regulations in their traditional form had virtually halted the federal regulatory process. As a result, agencies began “off-register regulation”; that is, actions taken outside the Federal Register through appropriations bills, litigation, the release of information, and other means. For example, the Internet was used to publicize studies by federal agencies, which were then interpreted as official agency policy. Such practices were among the stimuli for the newly proposed “data quality legislation.”

Data quality legislation was passed in 2000 as an amendment to the Omnibus Appropriations Act. It specifies that the OMB must issue regulations to define minimum thresholds of data quality that can be disseminated by the federal government. It also declares that the agencies, after the OMB’s action, must issue their own data quality regulations.

4

Privacy vs. Openness: A View from the Bench

A distinguished federal trial judge, Honorable Jack B. Weinstein addressed the workshop on the “difference between the basic and often irresolvable conflicts of openness and secrecy.” He said that our society’s democratic ideology seeks to balance sometimes conflicting commitments to both openness (nothing should be hidden) and privacy (everything should be hidden).

With regard to privacy, he noted that some of the public’s concern might have been provoked by the arguments of advocacy groups. Unintentionally, he said, some scientists might be helping to frighten people into worrying more about privacy than they have reason to.

One danger of opening all data to public view is the potential for the harassment of scientists by those who would alter or block scientific research for various reasons, for example, a ban on the use of animals in experiments. The original language of the Shelby Amendment (“all data produced . . .”), he said, opened the door for virtually anyone to request virtually everything in the laboratory of a scientist receiving public funds. It might be anticipated that requests would be made for many reasons that have little to do with responsible regulatory actions.

The judge said that the tensions of the Shelby Amendment might be resolvable only on a pragmatic, case-by-case basis. How this new law is applied has important implications in the development of science, the efficiency and fairness of governmental regulations, and the fact finding of courts.

Traditionally, Judge Weinstein said, judges in court cases tend to come

down rather heavily in favor of openness. They invariably ignore scientists' privileged relationship to their data in favor of finding facts. To date, the judge commented, the courts have not given sufficient weight to scientists' need to do their own work. In the cases involving Agent Orange, for example, the courts ruled that the public interest overrides secrecy issues. The public interest may be similarly strong in some cases: toxic torts, environmental issues, and breast implants.

Increasingly, cases are sent to arbitration or reach settlement without any litigation. In such cases, the underlying issues may not be debated and the administrative agencies, the courts, and the public may know little about the resolution. The route of private settlement is taken in part in order to avoid revealing certain information, which is kept secret as a condition of the settlement.

In such cases, lawyers may argue that their only obligation is to their clients. The courts, however, may have a larger obligation to consider not only the protection of privacy, which is good, but also scientists' obligation to society to reveal important information. Should tobacco scientists have revealed some of the information they had several years ago? What is the obligation of scientists as whistleblowers?

The traditional role of the American judge is based on the English model. The judge presides, takes only the information presented by the two parties, and makes a decision. But the challenge of resolving science-based questions may call for a more active judicial role. For one thing, the judge must become scientifically literate to evaluate certain cases and to make full use of the scientific community in understanding the issues.¹² The speaker suggested that judges may have the potential to seek fairer solutions than the federal agencies, which are subject to many constraints and rigidities.

¹²See NRC, *The Age of Expert Testimony: Science in the Courtroom*, 2002.

Alternative Approaches to Data Access

In the interest of investigating ways to provide greater access to research data, the workshop invited representatives of various organizations to describe several alternative approaches. In order of presentation, these approaches were described by Robert O'Keefe, Health Effects Institute; E. William Colglazier, National Research Council; Barry S. Kramer, Office of Medical Applications of Research, NIH; and Kenneth W. Harris, National Center for Health Statistics.

Health Effects Institute. As discussed in Chapter 2, the HEI agreed to accept the data from the Six Cities Study and undertake a reevaluation. The Harvard researchers agreed to open their voluminous files to them. The mission of the HEI, said Dr. O'Keefe, is to perform and evaluate the health effects of mobile source emissions and to inform regulatory decision making. The Institute's procedures are specifically designed to maintain objectivity in controversial regulatory situations. HEI has a separate board of directors, standing research committee, and peer-review committee, with no direct sponsor participation.

The HEI reanalysis model is not a complete substitute for public access to data. If not carefully considered, a reanalysis may be used as a tool to delay action. It also requires the participation of the original investigators. However, it may have a role in testing major studies that bear on important policy or health questions.

HEI also has another alternative approach to data sharing that flows from its National Morbidity and Mortality Air Pollution Study (NMMAPS). The goal of the new program, called "The Internet Health and Air Pollu-

tion Surveillance System," is to provide public access to data and statistical software and methods that are used in the NMMAPS. The system is regularly updated as new data are made available and investigators publish new work.

Phase I will create an Internet site to disseminate the NMMAPS data and provide statistical software. Phase II, funds permitting, will create an interactive system so that users can download analytical tools and manipulate data on their own. This approach is designed to provide easy access to data and to facilitate interaction with complex public data sets, including an EPA air database, mortality data from the NCHS, weather data, and Census data. Among the benefits of this approach is to open access to those with small budgets.

National Research Council. The National Research Council of the National Academies provides a different mechanism for data sharing and data assessment through independent studies by panels of experts. The NRC was chartered during the administration of Abraham Lincoln to provide advice to the government about scientific and technical matters. About 80 percent of its work is paid for by government agencies, but it remains administratively independent from the government as a private non-profit organization.

The studies conducted by the NRC, said Dr. Colglazier, are advisory in nature, not regulatory, although many of them influence regulatory policy. Typically, the NRC is asked to look at not only the underlying data, but also the experimental design, the methods of analysis and the execution of a study (studies). In addition to the work of the expert committee and National Academies staff, an independent group of experts reviews the finished report before release.

The National Academies work under an amendment to the Federal Advisory Committee Act to provide certain kinds of public access to their studies. When the National Academies receive information from outside parties, they do so in an open meeting. That information is put in a public access file that is subject to FOIA exemptions. The law also allows the National Academies to close their meetings when committees are deliberating on their final conclusions and recommendations. Draft reports and reviewers' comments do not go into the public access file. The findings are made public when the report is publicly released.

NIH Office of Medical Applications of Research. The Office of Medical Applications of Research, said Dr. Kramer, is the focal point for medically based assessments of medical practices and state of the science. It is not directly advisory to the NIH; instead, it appoints a panel of experts to lead a "consensus development conference." The panel is asked to form an independent judgment based on available evidence. This report is not vetted by the NIH and stands as an independent report.

The issue for a conference must meet several criteria: it must have public health importance; affect or broadly apply to a significant number of people; reflect a gap between current knowledge and practice; and draw primarily on available scientific information. Additional elements of importance are the impact on health care costs and the degree of public or congressional interest.

The consensus development conference is a relatively new tool. It begins with a solicitation of topics followed by the formation of a planning committee that nominates a panel of independent experts and speakers and drafts questions. Panel members cannot have made a public statement about the conference topic and cannot be speakers. A memorandum of understanding is made with the Agency for Health Care Research and Quality (AHCRO), which arranges for a systematic review of the literature. The panel then meets to study the issue, using rigid criteria for filtering and rating the quality of evidence.

The conference itself features a presentation of the literature review, speakers, and public input. The Evidence-Based Practice Center, commissioned by the AHCRO, helps formulate questions so that they are searchable through electronic databases. After the conference, the panel drafts its final assessment.

National Center for Health Statistics (NCHS). The National Center for Health Statistics, said Dr. Harris, is the federal agency primarily responsible for the collection and dissemination of data related to the health of the United States population. The data are collected through national surveys and vital registration systems, including the National Health Interview Survey, the National Health and Nutrition Examination Survey, and the National Survey of Family Growth.

Despite the value of its data collection, the NCHS has been hampered by researchers' inability to make maximum use of it. For example, the NCHS cannot release data files to the public that contain detailed information about the subjects that could facilitate identification; nor can geographic places of fewer than 100,000 people be identified. Such restrictions severely limit the ability of researchers to address urgent health-care questions. Accordingly, about 2 years ago the Research Data Center was created within the NCHS to help researchers gain access to important data. They do this by ensuring confidentiality and monitoring use of the data.

Costs of Alternative Approaches. Each of the previously mentioned approaches has benefits and shortcomings. Of note is the cost associated with these mechanisms. The HEI reanalysis of the Six Cities Study was moderately expensive and time consuming; costing approximately \$1 million over 2.5 years. A full committee report of the NRC at the National Academies costs several hundred thousand dollars to produce. An NIH

consensus development conference costs about \$500,000 and takes approximately 1 year. The NCHS charges for access to its research data in several ways, with remote access costs at \$500 per month for fields of under 130,000 records, and on-site access costs at \$200 per day, plus a \$500 set-up fee to retrieve the data files.

6

Closing Remarks

The STL Panel Cochair, Richard A. Merrill, offered a summary and several closing comments. He acknowledged that society is moving toward greater openness and availability of federally funded research data. However, he also expressed skepticism that either the Shelby Amendment or its interpretation by the OMB defines an adequate process for making data publicly accessible.

The larger legal context from which Shelby emerges. The Shelby Amendment is best viewed from a legal perspective beginning in the late 1950s and early 1960s, he said, when only the Food and Drug Administration and a few other agencies issued administrative rules having the force of law; the practice was then uncommon. At the time, regulatory agencies generally approached issues case by case, challenging individual company practices one at a time. They did so through procedures that afforded the defenders of private-sector activity full adjudicatory rights to challenge the admission of evidence and to contest those who proffered the evidence.

Prior to the 1970s, most proposed rules were accompanied by only brief discussions of the underlying factual justification. But soon agencies began to publish bibliographies of the sources they had used as evidence. Federal agencies no longer worked on a case-by-case basis. Regulation in the United States began to change dramatically.

Nova Scotia Food Products v. United States. An important case decided by the Second Circuit Court of Appeals in 1976, *Nova Scotia Food Products v. United States* established two important and enduring propositions

about agency rule-making procedures.¹³ First, agencies were obliged to reveal to the public the information they used to propose a rule; i.e., they had to disclose the affirmative case. Second, they were required to respond to the opponent's affirmative case by explaining why their arguments or the information should not prompt a change in agency position. In *Nova Scotia*, it was decided that the U.S. FDA had not followed these steps, and so its rules (for smoking fish) were set aside.

In a broad sense, then, the Shelby Amendment is a turn-of-the-century echo of a proposition laid down by the Second Circuit almost 35 years ago. But the Shelby Amendment has the potential to go significantly further. It opens the way for the kind of trial-type process that agencies abandoned some 40 years ago. Unless the scientific community appreciates the significance of this change, said Mr. Merrill, they will fail to understand the long-term implications of this legislative solution to a data access problem.

Shortcomings of Shelby. Although there are alternative instruments for approaching the disclosure problem, they are unlikely to be wholly satisfactory as long as the Shelby Amendment remains in force, noted Mr. Merrill. There are at least three ways in which the Shelby Amendment, though well intentioned, represents a problematic design.

1. The obligation to collect and release data is potentially serendipitous. Many federally supported researchers will have no idea that the work they are doing may someday be the basis, or part of the basis, of a regulatory action by some agency before which they have never appeared and about which they know little.

2. There is no "need-to-know" requirement. The mere desire of the requester is sufficient to trigger the obligations of the Shelby Amendment. As a consequence, it does not allow for the kind of nuanced, case-by-case judgment that many speakers at the workshop described as desirable. Under the Shelby Amendment there is no opportunity for balancing the interests of privacy and researcher independence and the interest of public participation in agency rule making.

3. The Shelby Amendment is not bilateral in its application. The amendment and its interpretation by the OMB seem to apply only to data that are generated with public dollars and that become the basis for regulatory decision making. They do not apply to data that are generated by private dollars that are submitted to support agency decisions.

The lack of direct answers to such fundamental concerns indicates that an issue of great complexity has not yet been resolved.

¹³The issue addressed in the case was the temperature and salinity at which smoked fish was prepared. Though the topic itself was not widely significant, the case established a precedent of general importance.

Appendixes

Appendix A

Science, Technology, and Law Panel

Cochair: **Donald Kennedy (NAS/IOM)**, Ph.D. (Biology), Harvard, is Bing Professor of Environmental Sciences Emeritus and codirector, Center for Environmental Science and Policy, Institute for International Studies, Stanford University. He is President Emeritus of Stanford University. He also serves as Editor in Chief, *Science*. He served as Commissioner of the U.S. Food and Drug Administration. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law.

Cochair: **Richard A. Merrill (IOM)**, L.L.B., Columbia University School of Law, is the Daniel Caplin Professor of Law and the Sullivan and Cromwell Research Professor of Law at the University of Virginia Law School. From 1975-1977 he served as Chief Counsel to the U.S. Food and Drug Administration. He was Dean of the University of Virginia Law School from 1980 to 1988. Since 1991, he has been special counsel to Covington & Burling. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law.

Frederick R. Anderson, J.D., Harvard Law School, is a partner at Cadwalader, Wickersham & Taft in Washington, D.C. He is a former Dean of the Washington College of Law at American University. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law.

Margaret A. Berger, J.D., Columbia University, is the Suzanne J. and Norman Miles Professor of Law at Brooklyn Law School in Brooklyn, New York. She has written extensively on science and law, and in particular on three key Supreme Court cases (*Daubert*, *Joiner*, *Kumho*) dealing with evidence. She is the coauthor of *Weinstein's Evidence*.

Paul Carrington, L.L.B., Harvard, is the Harry R. Chadwick Senior Professor at Duke University Law School. He is the former Dean of Duke's Law School and has taught and published extensively on civil procedures. He was Reporter to the Advisory Committee on Civil Rules of the Judicial Conference of the United States. He also established the Private Adjudication Center that developed a Registry of Independent Scientists to provide disinterested advice to lawyers and judges on scientific issues that are the subject of legal disputes.

Joe S. Cecil, Ph.D., (Psychology) and J.D., Northwestern University, is Project Director, Program on Scientific and Technical Evidence, Division of Research, Federal Judicial Center, in Washington, D.C. He is responsible for judicial education and training in the area of scientific and technical evidence and the lead staff of the Federal Judicial Center's Scientific Evidence Manual, which is the primary source book on evidence for federal judges.

Joel E. Cohen, (NAS), Dr. P.H., (Population Sciences and Tropical Public Health) and Ph.D., (Applied Mathematics), Harvard, is the Abby Rockefeller Mauze Professor and Head, Laboratory of Populations, The Rockefeller University and Professor of Populations, Columbia University, in New York City. From 1991 to 1995, Dr. Cohen served as a U.S. Federal Court-appointed neutral expert on projections of asbestos-related claims associated with the Manville Personal Injury Settlement Trust. In addition, he has served as a Special Master in silicone gel breast implant products liability.

Rebecca S. Eisenberg, J.D., is a Professor of Law at the University of Michigan in Ann Arbor, Mich. Ms. Eisenberg teaches courses in intellectual property and torts and has taught on legal regulation of science and on legal issues associated with the Human Genome Project.

David Goodstein, Ph.D., (Physics), University of Washington, is Vice Provost and Professor of Physics and Applied Physics at the California Institute of Technology. His book, *States of Matter*, helped launch a new discipline, condensed matter physics. In recent years, he has been particularly interested in societal issues that affect science as a profession.

Barbara S. Hulka, (IOM), M.D., Columbia College of Physicians and Surgeons, is Kenan Professor, Department of Epidemiology, School of Public Health, University of North Carolina at Chapel Hill. Dr. Hulka's current research activities are in the field of cancer epidemiology—breast, uterine and prostate—and the application of biological markers to cancer epidemiology. Dr. Hulka is working on the development of a process for incorporating scientific data into the judicial system.

Sheila Jasanoff, Ph.D., Harvard, J.D., Harvard, is Professor of Science and Public Policy at Harvard University's John F. Kennedy School of Government and the School of Public Health. Jasanoff's long standing research interests center on the interactions of law, science, and politics in democratic societies. She is the author of numerous papers and books including *The Fifth Branch: Science Advisors as Policymakers* and *Science at the Bar: Law, Science, and Technology in America*.

Robert E. Kahn, (NAE), Ph.D., Electrical Engineering, Princeton University, is Chairman, CEO, and President of the Corporation for National Research Initiatives (CNRI), a not-for-profit organization that provides funding and leadership to the research and development of the National Information Infrastructure. Dr. Kahn is a coinventor of the TCP/IP protocols and a recipient of the 1997 National Medal of Technology awarded by President Clinton.

Daniel J. Kevles, Ph.D., (History), Princeton, is the Stanley Woodward Professor of History at Yale University. Prior to this he was the Koepfli Professor of Humanities and directed the Program in Science, Ethics, and Public Policy at the California Institute of Technology in Pasadena, California. He has written extensively on issues regarding science and society including genetics, patenting, and scientific misconduct.

David Korn, (IOM), M.D., Harvard, Senior Vice President for Biomedical and Health Sciences Research, Association of American Medical Colleges, in Washington, D.C. Previously, he served as Dean of Stanford University School of Medicine.

Eric S. Lander, (NAS/IOM), D.Phil., (Mathematics) Oxford University, is Member, Whitehead Institute for Biomedical Research, Professor of Biology, MIT, Director, Whitehead Institute/MIT Center for Genome Research, and Geneticist, Massachusetts General Hospital, Massachusetts Institute of Technology in Cambridge, Mass. He is a geneticist, molecular biologist, and a mathematician, with research interests in human genetics, mouse genetics, population genetics, and computational and mathemati-

cal methods in biology. He also has taught in the area of management and economics. Dr. Lander is a member of the American Academy of Forensic Sciences and has written about DNA fingerprinting and other issues of science and law.

Patrick A. Malone, J.D., Yale Law School, is a partner with Stein, Mitchell & Mezines in Washington, D.C. Mr. Malone, a former medical journalist, represents plaintiffs in medical malpractice and product liability lawsuits. He is a member of the Association of Trial Lawyers of America and Trial Lawyers for Public Justice.

Richard A. Meserve, Ph.D., (Applied Physics) Stanford, J.D., Harvard, is Chairman of the Nuclear Regulatory Commission. Prior to his appointment he was a partner with the Washington, D.C., firm Covington and Burling, where he represented a number of corporate and non-corporate clients. He was a member of the NAS planning committee that initiated the 1997 Academy Symposium on Science, Technology, and Law. He wrote the *amicus* briefs on behalf of the National Academy of Engineering in the *Kumho* case and on behalf of the National Academy of Sciences in the *Daubert* case. These landmark cases established the basis for admitting expert testimony into court.

Alan B. Morrison, L.L.B., Harvard Law School, is Director, Public Citizen Litigation Group, Washington, D.C. Public Citizen, Inc., is a non-profit citizen research, lobbying, and litigation organization founded in 1971 by Ralph Nader.

Harry J. Pearce, J.D., Northwestern University School of Law, is Chairman of Hughes Electronics Corporation, a subsidiary of General Motors Corporation in El Segundo, California. He previously served General Motors as Vice Chairman, and prior to that as General Counsel. Mr. Pearce has been admitted to the U.S. Supreme Court, U.S. Court of Military Appeals, Eight Circuit Court of Appeals, various U.S. District Courts and State District Courts and the Michigan Supreme Court.

Henry Petroski, (NAE), Ph.D., University of Illinois, is the A.S. Vesic Professor of Civil Engineering, Duke University in Durham, North Carolina. He has been very involved in engineering and law issues. Most recently, he authored a chapter on engineering expert testimony for the Federal Judicial Center's evidence project.

Channing R. Robertson, Ph.D. (Chemical Engineering), is the Ruth G. and William K. Bowes Professor, School of Engineering, and Professor,

Department of Chemical Engineering, Stanford University. Dr. Robertson has conducted research on several products in which there was extensive litigation and in which he served as an expert.

Pamela Ann Rymer, L.L.B., Stanford, is a Circuit Judge on the U.S. Court of Appeals for the Ninth Circuit in Pasadena, California. She was appointed in 1989 by President George Bush. Judge Rymer currently serves as the Chair of the AAAS Court-Appointed Scientific Experts Demonstration Project.

STAFF OF THE SCIENCE, TECHNOLOGY, AND LAW PROGRAM

Anne-Marie Mazza, Ph.D., Director. Dr. Mazza joined the National Academies in 1995. She has served as Senior Program Officer with both the Committee on Science, Engineering, and Public Policy and the Government-University-Industry Research Roundtable. Between October 1999 and October 2000, she divided her time between the STL Program and the White House Office of Science and Technology Policy, where she chaired an interagency working group on the government-university research partnership. She received a Ph.D. in Public Policy from George Washington University.

Susie Bachtel, Staff Associate. Ms. Bachtel joined the National Academies in 1998. Previously she was Special Assistant to the Director, White House Office of Science and Technology Policy, from 1993 to 1998, and before that was Executive Assistant to the Director of the U.S. Office of Technology Assessment from 1979 to 1993. She received a BA in Social Sciences from Ohio State University.

Kirsten A. Moffatt, Ph.D., Consultant. Dr. Moffatt received her Ph.D. in Experimental Pathology from the University of Colorado Health Science Center. Her thesis work focused on the molecular mechanism(s) through which vitamin D acts to decrease the growth of prostate cancer cells.

Alan Anderson is a consultant writer who has written Academy reports on a variety of topics, including science policy, graduate and postdoctoral education, capitalizing on the results of research, the cyclicity of the semiconductor industry, the "new economy," women in science and engineering, and the Government Performance and Results Act. He also writes for the Institute for Advanced Study, in Princeton, N.J., and other clients. He has been a science writer for *Time* magazine and other publications, and holds a master's degree from the Columbia University School of Journalism and a B.A. in English from Yale University.

Appendix B

Agenda

**Seeking Access to Research Data in the 21st Century:
An Ongoing Dialogue Among Interested Parties
Science, Technology, and Law Program
The National Academies
Washington, D.C.**

March 12, 2001
Auditorium

- 7:30 *Continental Breakfast – Great Hall*
- 8:00 *Welcome*
Don Kennedy, President Emeritus, Stanford
University, and Editor-in Chief, *Science*
Cochair, Science, Technology, and Law Program
- 8:20 *Historical Perspective: Overview of Forsham v. Harris, the Shelby
Amendment, Public Comment, OMB revisions to Circular A-110
OMB.*
- Frederick R. Anderson, Jr.**, Partner, Cadwalader,
Wickersham & Taft

8:45 *Question and Answer*

- 9:00 *Panel 1: Understanding the scientific process: What is the universe of data, what is publication, how are scientific data validated?*
- a. The scientific process from experimental design to data collection and analysis to publication/peer review. What is meta-analysis? What are its strengths and limitations?
 - b. The Harvard Six Cities Study. What was the experimental design? What data were collected? What protections of confidentiality were promised to study participants?

Moderator

David Korn, Senior Vice President for Biomedical and Health Sciences Research, Association of American Medical Colleges

Panelists:

Steven Goodman, Associate Professor, Department of Biostatistics, Johns Hopkins University

Douglas W. Dockery, Professor of Environmental Epidemiology and Professor of Medicine, Department of Environmental Health, Harvard Medical School

10:10 *Question and Answer*

10:30 *Break – Great Hall*

- 10:45 *Panel 2: Public accessibility to research data used in rule making. What is the problem? (Who should have access, and by what process, to data the agency relies on or proposes to rely on, and to data submitted by public and private entities seeking agency consideration? What are the countervailing concerns about permitting access to such data, and what protections must be in place to protect trade secrets, individual privacy, etc.?)*

Moderator

Alan Morrison, Director, Public Citizen Litigation Group

Panelists

William L. Kovacs, Vice President, Environment, Technology, and Regulatory Affairs, U.S. Chamber of Commerce

Bruce Alberts, President, National Academy of Sciences

William H. Farland, Acting Deputy Assistant Administrator for Science, Office of Research and Development, U.S. Environmental Protection Agency

Wendy Baldwin, Deputy Director for Extramural Research,
National Institutes of Health
David G. Hawkins, Director, Air and Energy Program,
Natural Resources Defense Council
Jim J. Tozzi, Member, Board of Advisors, Center for
Regulatory Effectiveness

12:30 *Question and Answer*

1:00 *Lunch – The Great Hall*
Protective Orders -The Impact of Secrecy on Public Health and
Safety Decisions

The Honorable Jack B. Weinstein, Senior Judge, United States
District Court for the Eastern District of New York

2:30 *Panel 3: Alternative approaches to permitting public access to data
used in regulatory/policy decisions*

Moderator

Joel E. Cohen, Abby Rockefeller Mauze Professor and Head,
Laboratory of Populations, The Rockefeller University and
Professor of Populations, Columbia University

Panelists

Robert O’Keefe, Vice President, Health Effects Institute
E. William Colglazier, Executive Officer, National
Research Council

Barry S. Kramer, Director, Office of Medical Applications of
Research, National Institutes of Health

Kenneth W. Harris, Acting Director, Research Data Center,
National Center for Health Statistics

3:40 *Question and Answer*

4:00 *Closing*
Richard A. Merrill, Daniel Caplin Professor of Law and
Sullivan and Cromwell Research Professor of Law
University of Virginia Law School
Cochair, Science, Technology, and Law Program

4:30 *Reception – The Great Hall*

Appendix C

List of Registrants

Dr. Bruce Alberts
President
National Academy of Sciences
The National Academies
Washington, D.C.

Mr. Frederick R. Anderson, Jr.
Partner
Cadwalader, Wickersham & Taft
Washington, D.C.

Ms. Jessica Aungst
Research Assistant
Committee on Assessing the
System for Protecting Human
Research Subjects
Institute of Medicine
The National Academies
Washington, D.C.

Ms. Susie Bachtel
Staff Associate
Science, Technology, and Law
Program
The National Academies
Washington, D.C.

Dr. Wendy Baldwin
Deputy Director for Intramural
Research
National Institutes of Health
Bethesda, Md.

Dr. Avital Bar-Shalom
Intern
National Cancer Policy Board
Institute of Medicine
The National Academies
Washington, D.C.

Professor Margaret A. Berger
Suzanne J. and Norman Miles
Professor of Law
Brooklyn Law School
Brooklyn, N.Y.

Dr. Richard E. Bissell
Executive Director
Policy and Global Affairs Division
The National Academies
Washington, D.C.

Ms. Donna Boswell
Partner
Hogan & Hartson, LLP
Washington, D.C.

Ms. Michelle L. Bragg
Intern
Board on Children, Youth, and
Families
Commission on Behavioral and
Social Sciences and Education
The National Academies
Washington, D.C.

Mr. David E. Broome
Senior Associate General Counsel
North Carolina State University
Raleigh, N.C.

Ms. Wanda V. Brownlee
William J. Brownlee, MDPC
Washington, D.C.

Dr. William J. Brownlee, III
William J. Brownlee, MDPC
Washington, D.C.

Ms. Nancy S. Bryson
Partner
Crowell & Moring, LLP
Washington, D.C.

Dr. Jane L. Buck
President
American Association of
University Professors
Chesapeake City, Md.

Mr. Matthew E. Caia
Research Assistant
Committee on National Statistics
The National Academies
Washington, D.C.

Professor Paul D. Carrington
Harry R. Chadwick Senior
Professor
Duke University Law School
Durham, N.C.

Dr. Joe S. Cecil, Ph.D., J.D.
Project Director
Program on Scientific and
Technical Evidence
The Federal Judicial Center
Washington, D.C.

Dr. David R. Challoner
Professor and Vice President for
Health Affairs Emeritus
Institute for Health Policy and
Epidemiology
University of Florida
Gainesville, Fla.

Mr. Christopher W. Chapman
Program Analyst
Bureau of Labor Statistics
U.S. Department of Labor
Washington, D.C.

Mr. Frederick J. Charney
Policy Analyst
Office of Management of Budget
Executive Office of the President
Washington, D.C.

Dr. E. William Colglazier
Executive Officer
National Research Council
The National Academies
Washington, D.C.

Mr. David P. Clarke
Senior Director
Regulatory Reinvention & Legal
Reform
American Chemistry Council
Arlington, Va.

Ms. Camille M. Collett
Program Associate
Board on Science, Technology, and
Economic Policy
The National Academies
Washington, D.C.

Mr. Joseph E. Clawson, Jr.
Patent Examiner, Retired
Great Falls, Va.

Mr. Geoff Cooper
Attorney/Advisor
U.S. Environmental Protection
Agency
Washington, D.C.

Ms. Abby Cohen
Intern
Ocean Studies Board
Commission on Geosciences,
Environment, and Resources
The National Academies
Washington, D.C.

Dr. Katie Cottingham
Writer, GrantsNet and Science's
Next Wave
Science Magazine
American Association for the
Advancement of Science
Washington, D.C.

Professor Joel E. Cohen
Abby Rockefeller Mauze Professor
and Head, Laboratory of
Populations
Columbia University and The
Rockefeller University
New York, N.Y.

Ms. Nancy A. Crowell
Staff Officer
Division on Behavioral and Social
Science Education
The National Academies
Washington, D.C.

Mr. Stephen H. Cohen
Director
Mathematical Statistics Research
Center
Office of Survey Methods
Research
Bureau of Labor Statistics
U.S. Department of Labor
Washington, D.C.

Mr. John C. Crowley
Vice President for Federal
Relations
Massachusetts Institute of
Technology
Washington, D.C.

Dr. Susan A. Daniels
Intern
Board on Biology
The National Academies
Washington, D.C.

Mr. Martin H. David
Consultant
Joint Program in Survey
Methodology
University of Maryland
College Park, Md.

Ms. Virginia A. de Wolf
Senior Project Officer
CNSTAT
The National Academies
Washington, D.C.

J. Michael Dean, M.D.
Professor and Vice Chairman
Department of Pediatrics
Division of Critical Care
Primary Children's Medical
Center
University of Utah
Salt Lake City, Utah

Dr. Douglas W. Dockery
Professor of Environmental
Epidemiology Medicine
Department of Environmental
Health
Harvard School of Public Health
Boston, Mass.

Dr. Gregory Downing
Health Science Policy Analyst
Office of the Director
National Institutes of Health
Bethesda, Md.

Dr. Sidney Draggan
Senior Science and Science Policy
Advisor
U.S. Environmental Protection
Agency
Washington, D.C.

Mr. Alan M. Ehrlich
Patent Counsel
U.S. Environmental Protection
Agency
Washington, D.C.

Mr. George C. Elliott
Fellow
Science, Technology, and
Economic Policy Program
The National Academies
Washington, D.C.

Ms. Julie M. Esanu
Program Officer
International Organizations Board
The National Academies
Washington, D.C.

Dr. William H. Farland
Acting Deputy Assistant
Administrator
Office of Research and
Development
U.S. Environmental Protection
Agency
Washington, D.C.

Ms. Jean Feldman
Head, Policy Office
National Science Foundation
Arlington, Va.

Mr. Kevin Finneran
Editor-in-Chief
Issues in Science and Technology
The National Academies
Washington, D.C.

Dr. Eric A. Fischer
Senior Specialist
Science and Technology
Congressional Research Service
The Library of Congress
Washington, D.C.

Mr. Peter F. Folger
Public Affairs Manager
American Geophysical Union
Washington, D.C.

Mr. Forrest R. Frank
Research Staff Member
Science and Technology Division
Institute for Defense Analyses
Alexandria, Va.

Dr. Mark S. Frankel
Director
Program on Scientific Freedom,
Responsibility, and Law
American Association for the
Advancement of Science
Washington, D.C.

Dr. Carole Ganz-Brown
Senior Associate for Digital
Information
International Division
National Science Foundation
Arlington, Va.

Professor Joseph L. Gastwirth
Department of Statistics
The George Washington
University
Washington, D.C.

Dr. J. Paul Gilman
Vice President and Director of
Public Planning
Celera Genomics, Inc.
Rockville, Md.

Mr. Morton David Goldberg
Partner
Cowan, Liebowitz & Latman, P.C.
New York, N.Y.

Dr. Karen A. Goldman
Extramural Technology Transfer
Policy Specialist
Office of Science Policy, Director's
Office
National Institutes of Health
Rockville, Md.

Dr. Steven Goodman
Associate Professor
Department of Biostatistics
The Johns Hopkins School of
Public Health
Baltimore, Md.

Ms. Susan Goodman
Director of Stewardship
Development Office
The National Academies
Washington, D.C.

Professor David L. Goodstein
Vice Provost and Professor of
Physics and Applied Physics
Frank J. Gilloon Distinguished
Teaching and Service
Professor

Department of Physics
California Institute of Technology
Pasadena, Calif.

Ms. Jane Bortnick Griffith
Assistant Director for Policy and
Legislative Development
National Library of Medicine
Bethesda, Md.

Ms. Elizabeth R. Groff
Social Science Analyst
National Institute of Justice
Washington, D.C.

Mr. Kenneth W. Harris
Acting Director
Research Data Center
National Center for Health
Statistics
Hyattsville, Md.

Ms. Patricia Harsche
Vice President
Business Development Planning
and Regulatory Affairs
Fox Chase Cancer Center
Philadelphia, Pa.

Mr. David G. Hawkins
Director, Air and Energy Program
Natural Resources Defense
Council
Washington, D.C.

Mr. Stephen J. Heinig
Senior Staff Associate
Association of American Medical
Colleges
Washington, D.C.

Dr. Rouget F. Henschel
Associate
Lyon & Lyon, LLP
Washington, D.C.

Ms. Lauren R. Hersh
Legislative Correspondent
Office of the Honorable Steven
Rothman
U.S. House of Representatives
Washington, D.C.

Mr. Henry R. Hertzfeld
Senior Research Scientist
Center for International Science
and Technology Policy
The George Washington
University
Washington, D.C.

Ms. Patricia K. Hirsch
Assistant General Counsel for
Information
Office of the General Counsel
U.S. Environmental Protection
Agency
Washington, D.C.

Professor Barbara S. Hulka
Kenan Professor
Department of Epidemiology
School of Public Health
University of North Carolina
Chapel Hill, N.C.

Ms. Ann C. Hurley
Trial Attorney
Environment and Natural
Resources Divisions
U.S. Department of Justice
Washington, D.C.

Mr. William E. Hurt
International Trade Specialist
U.S. Department of Commerce
Washington, D.C.

Ms. Kathleen S. Irwin
Senior University Legal Counsel
University of Wisconsin-
Madison
Madison, Wisc.

Dr. Robert E. Kahn
Chairman, CEO, and President
Corporation for National Research
Initiatives
Reston, Va.

Mr. Brian A. Jackson
Associate Physical Scientist
Science and Technology Policy
Institute
RAND
Arlington, Va.

Mr. Lars B. Karle
Vice President
Fraunhofer Center for Research in
Computer Graphics
Providence, R.I.

Professor Sheila Jasanoff
Professor of Science and Public
Policy
JFK School of Government
Harvard University
Cambridge, Mass.

Professor Donald Kennedy
Bing Professor of Environmental
Studies
President Emeritus,
Stanford University, and
Editor-in-Chief, Science Magazine
Stanford, Calif.

Mr. James E. Jensen
Director
Office of Congressional and
Government Affairs
The National Academies
Washington, D.C.

Ms. Kay K.A. Kim
Director
Office of Patent Quality Review
U.S. Patent and Trademark Office
Arlington, Va.

Ms. Sabrina R. Johnson
Policy Analyst
Office of Policy Analysis and
Review
Office of Air and Radiation
U.S. Environmental Protection
Agency
Washington, D.C.

Mr. David Kleffman
Human Subjects Protection Officer
National Institutes of Justice
Washington, D.C.

Mr. William L. Jordan
Science Advisor
Office of Pesticides Programs
U.S. Environmental Protection
Agency
Washington, D.C.

Ms. Bonnie G. Klein
Program Manager for
Copyrighted Information
Defense Technical Information
Fort Belvoir, Va.

Ms. Genevieve Knezo
Specialist, Science and Technology
Resources, Science, and Industry
Division
Congressional Research Service
The Library of Congress
Washington, D.C.

Dr. Andrea F. Kollath
Manager
Merck Research Laboratories
Public Affairs
Merck & Company, Inc.
Whitehouse Station, N.J.

Dr. David Korn
Senior Vice President for
Biomedical and Health
Sciences Research
Association of American Medical
Colleges
Washington, D.C.

Mr. William L. Kovacs
Vice President
Environment, Technology, and
Regulatory Affairs
U.S. Chamber of Commerce
Washington, D.C.

Dr. Sylvia K. Kraemer
Visiting Professor
School of Public Policy
George Mason University
Arlington, Va.

Dr. Barnett S. Kramer
Director
Office of Medical Applications of
Research
National Institutes of Health
Bethesda, Md.

Dr. John W. Krueger
Scientist-Investigator
Office of Research Integrity
U.S. Department of Health and
Human Services
Bethesda, Md.

Dr. Howard S. Kurtzman
Chief, Cognitive Science Program
National Institute of Mental
Health
Bethesda, Md.

Mr. Richard A. Lambert
Counsel for Intellectual Property
National Institutes of Health
Bethesda, Md.

Professor Eric S. Lander
Professor of Biology and Director
Whitehead Institute/MIT Center
for Genome Research
Cambridge, Mass.

Mr. Rolf Lehming
Acting Director
Science & Engineering Indicators
National Science Foundation
Arlington, Va.

The Honorable Richard A. Levie
(Ret.)
Principal
ADR Associates, L.L.C.
Washington, D.C.

Ms. Rachel E. Levinson
Assistant Director for Life Sciences
Office of Science and Technology
Policy
Executive Office of the President
Washington, D.C.

Ms. Catherine Liebowitz
Project Associate II
Survey Research Center
University of Michigan
Ann Arbor, Mich.

Dr. Stephen Lingle
Director
Environmental Engineering
Research Division
U.S. Environmental Protection
Agency
Washington, D.C.

Mr. Terry J. Lynch
Senior Licensing Officer
National Institute of Science and
Technology
U.S. Department of Commerce
Gaithersburg, Md.

Mr. Christopher D. Mackie
Program Officer/Study Director
Committee on National Statistics
Commission on Behavioral and
Social Sciences and Education
The National Academies
Washington, D.C.

Ms. Ekaterini K. Malliou
Public Health Advisor
U.S. Department of Health and
Human Services
Washington, D.C.

Mr. Patrick A. Malone
Partner
Stein, Mitchell & Mezines
Washington, D.C.

Ms. Diane Maloney
Associate Director for Policy
Center for Biologics Evaluation
and Research
U.S. Food and Drug
Administration
Rockville, Md.

Ms. Kelli Marciel
Presidential Management Intern
Medical Applications of Research
National Institutes of Health
Bethesda, Md.

Mr. Alan D. Margolis
Attorney-Advisor
U.S. Environmental Protection
Agency
Washington, D.C.

Mr. Jeffrey P. Marks
Director, Air Quality
National Association of
Manufacturers
Washington, D.C.

Ms. Jennifer E. Marsh
Research Associate
The Federal Judicial Center
Washington, D.C.

Ms. Lisa S. Matthews
Special Assistant for Science
Office of the Administrator
U.S. Environmental Protection
Agency
Washington, D.C.

Dr. Thomas S. Mayer
Research Psychologist
Center for Survey Methods
Research
Statistical Research Division
U.S. Bureau of the Census
Washington, D.C.

Dr. Anne-Marie Mazza
Director
Science, Technology, and Law
Program
The National Academies
Washington, D.C.

Ms. Barbara M. McGarey
General Counsel
NIH Foundation
Bethesda, Md.

Dr. Marilyn M. McMillen
Chief Statistician
National Center for Education
Statistics
Washington, D.C.

Ms. Susan G. Merewitz
Senior Attorney
Office of the General Counsel/
Public Health
U.S. Department of Health and
Human Resources
Washington, D.C.

Professor Richard A. Merrill
Daniel Caplin Professor of Law
University of Virginia Law School
Charlottesville, Va.

Dr. Steve Merrill
Director
Science, Technology, and
Economic Policy Program
The National Academies
Washington, D.C.

The Honorable Richard A.
Meserve
Chairman and Commissioner
U.S. Nuclear Regulatory
Commission
Rockville, Md.

Ms. Alexandria L. Mincey
Grants Policy Specialist
Office of Grants and Debarment
U.S. Environmental Protection
Agency
Washington, D.C.

Dr. Kirsten A. Moffatt
Intern
Science, Technology, and Law
Program
The National Academies
Washington, D.C.

Mr. Alan B. Morrison
Director
Public Citizen Legislation Group
Washington, D.C.

Dr. Tamara J. Nameroff
Department Head
Policy Affairs
Office of Legislative and
Government Affairs
American Chemical Society
Washington, D.C.

The Honorable Pauline Newman
Circuit Judge
U.S. Court of Appeals for the
Federal Circuit
Washington, D.C.

Ms. Patricia M. O'Connell
Counsel, Research Team
American Chemistry Council
Arlington, Va.

Dr. Linda E. O'Donnell
Research Professor
Center for Research on Learning
Dole Human Development Center
University of Kansas
Lawrence, Kan.

Dr. Robert M. O'Keefe
Vice President
The Health Effects Institute
Cambridge, Mass.

Dr. Aristides Patrinos
Associate Director of Science for
Biologic Environmental
Research
Office of Biological Research
U.S. Department of Energy
Germantown, Md.

Ms. Ellen Paul
Public Policy Representative
American Institute for Biological
Sciences
Washington, D.C.

Dr. Carol V. Petrie
Director
Committee on Law and Justice
Commission on Behavioral and
Social Sciences and Education
The National Academies
Washington, D.C.

Dr. Henry Petroski
Professor
Department of Civil &
Environmental Engineering
Duke University
Durham, N.C.

Mr. Frank J. Pita
Director of Corporate Legal
Affairs
Semiconductor Research
Corporation
Research Triangle Park, N.C.

Mr. Dean Matthew Powell
Assistant General Counsel
National Science Foundation
Arlington, Va.

Dr. Donald Prosnitz
Chief Science and Technology
Advisor
U.S. Department of Justice
Washington, D.C.

Dr. Thomas P. Ratchford
Distinguished Visiting Professor
National Center for Technology
and Law
George Mason University School
of Law
Arlington, Va.

Mr. Richard M. Rau
Senior Forensic Program Manager
National Institute of Justice
Washington, D.C.

Mr. John H. Raubitschek
Patent Counsel
U.S. Department of Commerce
Washington, D.C.

Ms. Holly E. Reed
Research Associate
Committee on Population
The National Academies
Washington, D.C.

Mr. Jerome H. Reichman
Bunyan S. Womble Professor of
Law
Duke University School of Law
Durham, N.C.

Mr. Lawrence J. Rhodes
Director, Division of Education
and Integrity, Office of
Research Integrity
U.S. Department of Health and
Human Services
Rockville, Md.

Professor Edward P. Richards III
Professor of Law
Kansas City School of Law
University of Missouri
Kansas City, Mo.

Professor Channing R. Robertson
Ruth G. and William K. Bowes
Professor
Department of Engineering
Stanford University
Stanford, Calif.

Mr. Theodore Rockwell
Founding Officer and Director
Radiation, Science & Health, Inc.
Chevy Chase, Md.

Ms. Sally A. Rood
Washington Representative
Federal Laboratory Consortium
Arlington, Va.

Dr. Susan Rossi
Deputy Director
Medical Applications of Research
National Institutes of Health
Bethesda, Md.

Mr. Craig M. Schultz
Research Associate
Science, Technology, and
Economic Policy Program
The National Academies
Washington, D.C.

Mr. William B. Schultz
Deputy Assistant Attorney
General
Civil Division
U.S. Department of Justice
Washington, D.C.

Dr. Frances E. Sharples
Director
Board on Life Sciences
The National Academies
Washington, D.C.

Mr. Brendan R. Sheehan
Corporate Counsel
Pfizer, Inc.
New York, N.Y.

Mr. John F. Shenk
Program Analyst
U.S. Bureau of the Census
Washington, D.C.

Ms. Stephanie Shipp
Director
Economic Assessment Office
Advanced Technology Program
National Institute of Standards
and Technology
Gaithersburg, Md.

Mr. Ronald Simon
Attorney
Simon & Associates
Washington, D.C.

Dr. Daljit Singh
Counsellor, Science and
Technology
Embassy of India
Washington, D.C.

Mr. Mark F. Smith
Associate Director of Government
Relations
American Association of
University Professors
Washington, D.C.

Mr. James M. Solyst
Team Leader
American Chemistry Council
Arlington, Va.

Mr. Philip M. Steel
Mathematical Statistician
Staff Disclosure Limitation
U.S. Bureau of the Census
Washington, D.C.

Dr. Kathryn E. Stein
Director
Division of Monoclonal
Antibodies
Center for Biologics Evaluation
and Research
U.S. Food and Drug
Administration
Bethesda, Md.

Mr. Lester K. Su
Science Fellow
Office of The Honorable Vernon
Ehlers
U.S. House of Representatives
Washington, D.C.

Ms. Margaret A. Thomson
Attorney
Office of the General Counsel
U.S. Department of Energy
Washington, D.C.

Professor Jerry G. Thursby
Professor of Economics
Purdue University
West Lafayette, Ind.

Professor Marie C. Thursby
Executive Director
Technology Transfer Initiative,
and
Professor of Economics
Purdue University
West Lafayette, Ind.

Ms. Syntrina Toon
Program Analyst
Bureau of Labor Statistics
U.S. Department of Labor
Washington, D.C.

Dr. Jim J. Tozzi
Member of the Advisory Board
The Center for Regulatory
Effectiveness
Washington, D.C.

Dr. Sheldon L. Trubatch
Attorney
Foley & Lardner
Washington, D.C.

Ms. Lois A. Tully
Program Manager
National Institute of Justice
Washington, D.C.

Dr. Myron F. Uman
Associate Executive Officer
National Research Council
The National Academies
Washington, D.C.

Mr. Steven I. Wallach
Partner
Pennie & Edmonds, LLP
New York, N.Y.

The Honorable Jack B. Weinstein
Senior Judge
U.S. District Judge for the Eastern
District of New York
Brooklyn, N.Y.

Ms. Mary J. Weiss
Program Analyst
Defense Technical Information
Center
U.S. Department of Defense
Fort Belvoir, Va.

Dr. Elora J. Weringer
Technical Advisor, Bioethics
Pfizer Global Research and
Development
Groton, Conn.

Mr. John A. Wertman
Assistant Director for Government
Relations
Consortium of Social Science
Associations
Washington, D.C.

Mr. Andrew A. White
Director
Committee on National Statistics
Commission on Behavioral and
Social Sciences and Education
The National Academies
Washington, D.C.

Dr. Valerie L. Williams
Policy Analyst
Science and Technology Policy
Institute
RAND
Arlington, Va.

Mr. J. Warren Wood III
Vice President, General Counsel,
and Secretary
The Robert Wood Johnson
Foundation
Princeton, N.J.

Dr. Karen Woodrow-Lafield
Associate Professor
Department of Sociology,
Anthropology, and Work
Mississippi State University
Mississippi State, Miss.

Dr. Gillian R. Woollett
Associate Vice President
Biologics and Biotechnology
PhRMA
Washington, D.C.

Dr. Catherine Woytowicz
Science Policy Fellow
American Chemical Society
Washington, D.C.