Discussion of the Committee on Daubert Standards: Summary of Meetings

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SUMMARY OF MEETINGS

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Committee on Daubert Standards
Committee on Science, Technology, and Law
Policy and Global Affairs

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Academies' 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 and objectivity. The review comments and draft manuscript remain confidential to protect the integrity of the process.

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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 Richard A. Meserve, Carnegie Institution of Washington, appointed by the National Academies. He was 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 authors and the institution.

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INTRODUCTION

In 1993, the U.S. Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, laid out a new test for federal trial judges to use when determining the admissibility of expert testimony. In the *Daubert* case, the Court recognized that issues requiring expert testimony are, by definition, outside the realm of an ordinary juror's scope of knowledge. The Court ruled that judges should act as gatekeepers in the courtroom, assessing the reliability of the scientific methodology and reasoning that supports expert testimony as a condition of allowing such testimony to be presented to the jury. The resulting judicial screening of expert testimony has been particularly consequential in toxic tort litigation. The crucial contested issue in these cases is whether the defendant's product or emission caused the plaintiff's injury—a proposition that often cannot be proved without expert testimony. Consequently, how courts evaluate the admissibility of evidence of causation determines whether such cases end with a grant of summary judgment for the defendant—if the court excludes plaintiffs' expert testimony so that plaintiffs cannot meet their burden of proof—or continue and are heard and determined by a jury. In short, decisions on the admissibility of expert testimony can often determine the outcome of litigation. While the Supreme Court sought to bring better science into the courtroom, questions remain about whether the lower courts' application of *Daubert* accords with scientific practices.

Supported with a grant from the Common Benefit Trust, the Committee on Science, Technology, and Law of the National

Academies convened an *ad hoc* committee to consider the impact of *Daubert* and subsequent Supreme Court opinions and to identify questions for future study. During its meetings, the Committee did not seek to reach consensus and thus no recommendations are made in this summary report. The committee included individuals with expertise in scientific evidence, litigation, epidemiology, toxicology, and other areas of science and law. This document summarizes the committee discussions held in January and March of 2005.

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OVERVIEW OF KEY SUPREME COURT DECISIONS

The *Daubert* case was by no means the first proceeding in which the courts had to struggle with the challenge of deciding when and which scientific expertise is needed to decide a case. In the past 30 years there has been an increase in toxic tort litigation, that is, cases in which the plaintiffs bringing the action allege that their injuries or diseases have been caused by exposure to the defendant's product or discharge. These cases have received a great deal of attention, in part because they often involve claims of significant injury, demands for large amounts of money, and allegations that some of the expert testimony did not meet appropriate scientific standards. *Daubert* was the first of three Supreme Court cases that significantly shaped the way in which federal courts would evaluate scientific testimony. All three cases centered on the admissibility of expert testimony concerning the data required to establish causation, an exercise that involves synthesis of available evidence, and all three cases recognized that expert testimony must be subject to a strong and careful judicial gatekeeper function. The most recent of the three, *Kumho Tire Co. v. Carmichael*, while involving causation, was not a toxic tort case.

For 70 years, many federal courts relied on the general acceptance standard laid out in *Frye v. the United States* (1923) to determine the admissibility of expert testimony. Under the *Frye* standard expert testimony is admissible only if its methodology is "generally accepted" (i.e., a consensus has been reached) in the relevant scientific community. The *Daubert* decision essentially

held that *Frye* did not survive the enactment of the Federal Rules of Evidence, and interpreted Rule 702 of the Federal Rules of Evidence as requiring that scientific expert testimony be grounded in the methodology and reasoning of science (i.e., the expert must show the underlying validity of his opinion). In finding that the epidemiological and toxicological evidence offered by the plaintiff experts was inadmissible, the lower court in *Daubert* had applied the *Frye* general acceptance test. However, the Supreme Court spelled out a new test for the admissibility of scientific evidence, aimed to ensure that it "is not only relevant, but reliable."

The *Daubert* case was one of many in which plaintiffs claimed that birth defects exhibited by their children were caused by Bendectin, an anti-morning sickness pill that had been taken by their mothers (and approximately 20 million other pregnant women). In response to these suits, the defendant manufacturers took the drug off the market even though it never lost its Food and Drug Administration approval.

A central message of the *Daubert* decision was the Court's designation of the trial judge as the gatekeeper, responsible for screening expert testimony to determine whether the relevancy and reliability requirements are met. In the second part of his majority opinion, over the dissent of Chief Justice Rehnquist and Justice Stevens, Justice Blackmun wrote that federal judges have a duty to ensure that "an expert's testimony rests on a reliable foundation and is relevant to the task at hand." He suggested that the reliability of scientific testimony be judged using the following criteria: 1) whether or not it could be tested and falsified; 2) whether it had been subject to peer review and publication; 3) whehter there existed known or potential rate of error and standards controlling the technique's operation; and 4) whether or not it was generally accepted within the scientific community. However, Blackmun emphasized the flexible nature of this reliability requirement, a point that would be reiterated in a later decision (*Kumho*). To satisfy the reliability standard, the experts' opinion must be the product of

scientific reasoning and methodology. This requirement reinforces the concept of science as an empirical endeavor. The Court also stated that the testimony must be relevant, that is, it must fit the facts of the case. The expert may not testify about a hypothesis that cannot be applied to the facts under consideration.

A second case provided courts with additional guidance. In *General Electric v. Joiner* (1997) a plaintiff who was a longtime smoker with a family history of lung cancer claimed the exposure to polychlorinated biphenyls (PCBs) had promoted the development of his small-cell lung cancer. Relying on the *Daubert* criteria (described previously), the trial court excluded the plaintiff's expert testimony and granted summary judgment. The intermediate appellate court reversed the lower court decision. The Supreme Court then held that in reviewing a trial judge's evidentiary ruling an appellate court must use an abuse of discretion standard, which requires the reviewing court to defer to the rulings of the trial court unless they are clearly in error. The Court concluded that the trial judge had not abused her discretion when she refused to admit the plaintiff's expert testimony, because the claims of a causal connection between the exposure and the injury made by the expert witness were too speculative.

A third opinion issued in 1999, *Kumho*, dealt with inadmissibility of engineering testimony offered to prove defect and causation in a product-liability action. In this case, the plaintiffs claimed that the blowout of a defective tire on a minivan caused death and serious injuries. The plaintiffs relied on testimony by an expert in tire-failure analysis, who concluded that the tire must have been defective due to the absence of a number of indicia of abuse by the driver. The trial court concluded that the testimony satisfied none of the four *Daubert* criteria and excluded it, granting the defendants' motion for summary judgment. The appellate court reversed, ruling that the *Daubert* standards did not extend to such engineering evidence. The Supreme Court rejected this narrow application of *Daubert* and directed the courts to use flexible

standards appropriate to different fields of expertise. The *Kumho* opinion contemplated that in some cases some expert witnesses may be permitted to testify based on expertise arising from their experience. The objective of *Daubert's* gatekeeping requirement said the Court "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."

In toxic tort cases, the plaintiff normally must show (1) plaintiff's exposure to a toxic substance for which the defendant is responsible; (2) exposure to the toxic substance is known to cause the type of injury suffered by the plaintiff (general causation); (3) the toxic substance did in fact cause the plaintiff's injury (specific causation); and (4) the extent of the injury to the plaintiff. Much of the proof for each of the above elements (and especially 2 and 3), must come in the form of expert testimony. Insistence on applying *Daubert* to each element of expert testimony means the plaintiff must make a detailed showing that the expert applies sound science every step of the way.

When a trial judge excludes expert testimony, he or she preempts the opportunity for a jury to consider the issue at hand. If the judge excludes expert evidence that is essential to meeting a party's burden in a case, the judge will also grant a motion for summary judgment and terminate the litigation in favor of the opponent of the excluded expert testimony. This means that the case will not be heard by a jury. Under current law this is the correct outcome if a party is unable to present admissible evidence on an essential element of the case.

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THE LEGAL LANDSCAPE POST-DAUBERT

These three Supreme Court decisions have led to increasing attention on the part of judges to scientific and technical issues (Berger, 2000). For instance, the Federal Judicial Center has published two editions of the *Reference Manual on Scientific Evidence* that contain a number of chapters on topics such as epidemiology, toxicology, and statistics that are highly relevant to determining causation in toxic tort cases. In addition, numerous training programs have been held for judges and lawyers on issues relating to scientific proof. Despite this educational effort, difficult issues remain. The *Daubert* criteria are too general to resolve many of the difficult problems facing the courts when complex scientific evidence is presented to prove causation. The factors discussed by the Supreme Court do not necessarily help the courts evaluate the consistency of expert judgment, determine when it is reasonable to extrapolate from other studies, determine whether the methodology used in one study is comparable to that used in another, or assess how conflicting standards and methodologies across varying areas of science should be considered. Nor does the Court provide guidance when scientific evidence is suggestive about where to draw the line between reasonable inference (which is permitted) and speculation (which is not permitted). Moreover, there are some areas of science that are so new and so complex that deciding what evidence is admissible and what testimony should be heard remains a formidable challenge.

There is some evidence that application of the *Daubert* standards has in fact restricted the presentation of expert evidence,

as indicated by increased exclusions of expert testimony in federal courts (Dixon and Gill, 2001). A 2001 study by the Rand Institute for Civil Justice found that judges are acting as gatekeepers for reliability and relevance; they are examining the methods and reasoning underlying the evidence; and they appear to be using general acceptance as only one of many factors that can enter into a reliability assessment. A 1998 survey of judges found that a third claimed to admit expert evidence less often than they did before *Daubert* and well over half of the attorneys surveyed reported the same trend in judges' rulings (Krafka et al., 2002).

Many view this as demonstrating improvement in the quality of scientific evidence presented in the courtroom. They see the data as showing that the courts are complying with the obligation established by *Daubert* and its progeny to act as gatekeepers to ensure the integrity of scientific evidence. Some claim that judges have continued to admit scientific evidence that properly should have been excluded. But others have argued that the application of these standards has been inconsistent with accepted scientific practice in certain cases, and that judges have been too aggressive in excluding evidence. For example, some judges tend to assess scientific testimony by examining each item of supporting evidence in isolation rather than examining the cumulative weight of the evidence in the manner in which the scientific community reaches a consensus of opinion. Moreover, many judges have expressed a preference for some forms of scientific evidence over other types (e.g., epidemiology may be preferred over toxicology in toxic tort cases) without an assessment of the relative strength or statistical power of the study designs. Judges also may be hesitant to generalize from specific research findings to conclusions, following the warning of Chief Justice Rehnquist to beware of testimony that is based on "too great an analytical gap between the data and the opinion proffered" (*General Electric v. Joiner*, 1997).

The diversity of views within science on the nature of

causation[1] and the methodology needed to make claims about causation has complicated the efforts of the courts to identify credible views that should be presented to a jury. Judges have sometimes excluded testimony that some within the scientific community might consider relevant, reliable, yet still somewhat uncertain, and at times have allowed testimony that scientists might view as unreliable or irrelevant. The role of uncertainty in the culture of science is a particularly complex question, not always easily grasped in the legal arena.

Judges often must review testimony from several different scientific disciplines. In toxic tort cases, for example, the evidence pertaining to causation could involve laboratory studies from toxicology and molecular biology, clinical studies (including randomized trials), observation, epidemiological studies of various designs, and case studies. Depending on the state of the science, some or no information might be available from each of these disciplinary areas. Compounding this complexity is another issue: for any given case, there may be published reviews of these same scientific studies, providing the court with analysis and synthesis of the evidence, and often an assessment of the likelihood of causation. There are, then, two major categories of scientific evidence available to the courts: individual analytic studies and summary syntheses of bodies of evidence; both categories may be peer-reviewed but they involve quite different methodologies.

Several concerns have been raised about the courts handling of scientific evidence and expertise, in particular:

- Whether decisions are being made consistently.
- Whether there is sufficient recognition of minority views in science.

[1]For a discussion of these different viewpoints, see M. Parascandola and D.L. Weed. Causation in epidemiology. *Journal of Epidemiology and Community Health* 55:905-912, 2001.

- Whether courts appreciate differences among the sciences in collecting, validating, and synthesizing evidence.
- Whether courts appreciate that much of the available research relates to populations rather than to individuals and that complex questions may arise in extrapolating data to a particular person.
- Whether the Supreme Court's comprehension of the concept of validity corresponds with the scientific community's understanding of the term.
- Whether forensic evidence in criminal cases is receiving an appropriate level of scrutiny;
- Whether judges, by excluding too much evidence, are intruding on the constitutional role of the jury to resolve disputed facts.

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EVIDENCE SYNTHESIS: THE QUESTION OF CAUSATION

As noted earlier, one of the most difficult issues in toxic tort cases is causation. All three of the Supreme Court cases described above are centered on the evidence required to establish causation, an exercise that often involves synthesis of many types of data.

The power of science arises from the objectivity of its methods. Scientists, nevertheless, generally recognize the limits of their methods and have developed best practices for addressing them: data sharing in open meetings, peer review, publication of results, disclosing conflicts of interests, and maintaining active research programs examining the validity of their methods as methods. Establishing general causation in science combines the analytic methods used in single studies with the synthetic methods used to summarize many studies (the bodies of evidence). No precise set of methodologic standards exists to establish causation in science, but that is what the courts seek: carefully drawn lines between evidence that establishes causation and that which does not. When parties to a case demand a decision, courts cannot wait for the experiments to be conducted, conferences to be held, or consensus to be built, and must therefore rely on available evidence at a given moment in time. In such a case, a plaintiff who cannot present relevant and reliable evidence on causation has not met his or her burden of proof, and under established law, should have his or her case dismissed. Some believe that the necessity faced by courts to decide cases before the science is fully developed raises questions about judicial management, that is, how and on what basis should

judges make decisions about which experts to hear when relevant research is insufficient to point clearly toward causation.

Scientific methods for determining cause differ from judicial methods (Hulka et al., 2000) and might even differ among scientific disciplines. Epidemiologic research offers an important example. Epidemiology studies obtain observational data on different groups of individuals to determine if exposure results in different outcomes. Methods used by epidemiologists to examine scientific evidence for general causation typically involve a systematic narrative review of the literature that may exclude some studies on grounds of poor quality or lack of relevance. Within such a review, the so-called "criteria" of causation are applied to the summary body of evidence. The use of these criteria, which include an assessment of the current state of biological knowledge (sometimes called "biological plausibility") has considerable flexibility built in so that scientists can select, prioritize, and assign evidentiary rules to these criteria with some impunity. What counts as a "weak association" for one user may be seen as a "consistent association" by another. In addition to biological plausibility, strength of association, and consistency of association, there are several other criteria in use, including "coherence," which is often considered to be an overarching summary consideration of the extent to which the evidence fits together as a whole. This method of determining general causation, which epidemiologists have been discussing at their open meetings and in peer reviewed literature, is as subjective as it is objective, and is more qualitative than quantitative (Weed, 2003). Each profession has its own standards for evidence.

In the field of law it is sometimes difficult to square the legal standards of proof with the scientific standards of proof. Thus, courts must assess the range of acceptable disagreements within the scientific community and measure these various opinions against legal standards of admissibility and sufficiency of evidence. This sometimes can result in admission of questionable science or the

exclusion of what most would consider reliable science, or at the very least, inferential judgments such as clinical medical assessments in the absence of other evidence.

Even though trial judges are expected to examine the underlying basis of testimony to ensure that only testimony supported by valid methods of inquiry is admitted, judges are not always issuing consistent legal decisions in otherwise similar medical cases (Kassirer and Cecil, 2002). In some cases judges have excluded medical testimony on cause-and-effect relationships because it was not based on published, peer-reviewed, sound studies, even though in certain kinds of cases practitioners may rely on other evidence of causality in making clinical decisions when such data are not available. In effect, some courts have required standards for expert testimony that exceed those that relevant experts would use to assess causation.

Finally, it has been the practice of some courts to assess evidence offered to prove causality piece by piece, that is, looking at the results of one scientific investigation as an isolated event rather than considering these findings in the context of other research. This is not the approach scientists would follow. Science accumulates knowledge incrementally. Before trying to answer a scientific question, a good scientist will look at what others have done to see if the answer might already exist, build on partial knowledge already discovered, and learn from the mistakes and insufficiencies of prior work. Thus, scientists consider it illogical to ignore a study simply because it did not offer a definitive answer to the question being asked. The tendency in science is to include rather than exclude such data for consideration.

The committee discussed several areas where it might be useful to explore further the different approaches used by scientists, lawyers, and judges in the selection, summarization, and interpretation of scientific evidence when trying to determine causation. In particular:

- Are there distinctions between the way *Daubert* is functioning in the courts and the way scientists think it should function with respect to synthesis of evidence?
- Do courts and scientists agree on a hierarchy in types of evidence they select to consider, for example, in favoring evidence that comes from a particular discipline like epidemiology over another like toxicology?
- Do courts and scientists agree on how to assess individual studies? If a particular study is insufficient by itself to conclusively demonstrate causation is it therefore unreliable evidence on which experts should not rely in drawing causal inferences?
- What are the scientific approaches to synthesizing a body of knowledge that includes different disciplines (e.g., toxicology, epidemiology, clinical research) or different methodologies within disciplines?
- To what extent is evidence synthesis in science a well-established (vs. a dynamic even controversial) practice?
- What guidelines exist to conduct evidentiary assessments in science?
- What kind of research/education needs to be done in this area?
- What advice can be offered to judges to use when considering a body of scientific information that includes different study designs, methodologies, and disciplines?

Another topic discussed was the availability of data from studies needed to establish causation. Some argue that there are cases where data should have been developed or made available, but were not. Concern about the availability of research results has been expressed by the biomedical community and recently the International Committee of Medical Journal Editors (ICMJE) published a joint editorial aimed at promoting registration of all

clinical trials (De Angelis et al., 2004). ICMJE stated that it will consider a trial for publication only if it has been registered before the enrollment of the first patient and took as its goal "to foster a comprehensive, publicly available database of clinical trials." Further, ICMJE called for such information to be publicly available "to guide decisions about patient care," as patients "deserve to know that decisions about their care rest on all of the evidence, not just the trials that authors decided to report and that journal editors decided to publish."

Concerns about the availability of relevant studies, led several members of the NRC committee to ask if there should be consequences when an information gap exists because a party to a lawsuit failed to undertake studies that need to be done or failed to divulge negative results?

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AREAS NEEDING FURTHER STUDY

The National Academies committee also discussed two other areas needing further study: (1) differences between scientists and lawyers and (2) education and training of scientists and lawyers.

Cultural Differences

Science is not simply a body of knowledge; rather it is an ongoing process of proposing and refining explanations about the world that are subject to further testing. By training and temperament, scientists value precision and accuracy, which are gained over extended periods of time often involving the work of many. In contrast, the legal system operates with a different set of values and rules. It seeks resolution on its version of the truth, that is, pragmatic justice at a particular point in time so that "people can get on with their lives" (Frankel, 2001).

The standards of evidence that apply in medical practice or scientific research are developed in a collaborative and cooperative manner. In contrast expert testimony comes into the courtroom in an adversarial setting in which each party seeks to present its strongest case. This invariably leads to conflicts among experts representing the parties.

In the adversarial process scientific data generally are interpreted by expert witnesses employed by the plaintiffs or the defendants with no assurance of their scientific neutrality or the merit of their testimony (Hulka et al., 2000). Even the testimony of well-known and highly respected scientists can be distorted by other experts, by counsel or by the court. And, the expert might be

made to feel as if he or she is on trial rather than the defendant. In fact, the adversarial system places great emphasis on discrediting the expert, thereby diverting attention away from the expert scientific opinion. As a result academic scientists have been hesitant to testify as expert witnesses because they are concerned about the potential for bias and loss of their own credibility. Many scientists believe that being used by one side or the other in litigation could impugn their scientific integrity.

The committee concluded that further consideration is needed regarding the involvement, role, and responsibilities of scientists in the courtroom. Specifically:

- Has *Daubert* altered the role of scientific experts in litigation? What is the appropriate role of scientists in litigation?
- Has *Daubert* changed the boundary of expertise that a scientific expert can speak to? How has *Daubert* changed the relevance of qualifications? Which scientists qualify or are disqualified in *Daubert* hearings?
- Is it appropriate to require experts to testify in terms of legal standards, such as reasonable degree of certainty, that are not understood in their own disciplines?
- How can we provide esteem and prestige to scientists who work with and participate in the legal system? Are there models that could be used to encourage scientists to participate as experts?
- If experts were selected using a court-appointed process, rather than by adversaries retaining experts, would more scientists be willing to participate?
- If we moved to a consensus model approach, that is, convening a panel of experts to arrive at a consensus about the reliability of the evidence provided, what protocols should govern the interactions of scientists and lawyers in the courtroom?

Education of Scientists and Lawyers

The scientific and legal communities often display a mutual wariness that has interfered with the development of consistent standards and practices for identifying, reviewing, and receiving expert testimony. The courts need help from the scientific community in cases requiring analysis of highly technical data. The scientific community is obligated to assist the courts by ensuring that the best science is being used in the interest of social policy. As discussed previously, the culture and standards, as well as the terminology and knowledge base of the two professions are vastly different. Although some organizations have been working hard to provide venues in which the scientific and legal communities can meet and learn from each other, more can be done. The committee identified several questions that should be asked in going forward to ensure that scientific and technical information entered into judicial proceedings meets the highest standards and the public interest.

- What should students in law schools, graduate schools, and professional schools know about the law and the use of science in litigation?
- What types of curricula could be developed to encourage understanding of multidisciplinary issues in law, graduate, and professional schools?
- What types of programs should be developed to educate scientists and lawyers about the intersection of these two disciplines in a post-*Daubert* environment?
- How can we encourage opportunities for the two communities to talk together?
- How can we encourage more empirical research conducted by both lawyers and scientists about the role of science in the courts?

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APPENDIX A

COMMITTEE BIOGRAPHIES

Margaret A. Berger, *Co-Chair*, A.B., Radcliffe College, J.D., Columbia University School of Law, is the Suzanne J. & Norman Miles Professor of Law at Brooklyn Law School in Brooklyn, New York. Professor Berger is widely recognized as one the nation's leading authorities on evidentiary issues, in particular scientific evidence, and is a frequent lecturer across the country on these topics. She is the recipient of the Francis Rawle Award for outstanding contribution to the field of post-admission legal education by the American Law Institute/American Bar Association for her role in developing new approaches to judicial treatment of scientific evidence and in educating legal and science communities about ways to implement these approaches. Professor Berger recently completed her service as the Reporter for the National Commission on the Future of DNA Evidence's Working Group on Post-Conviction Issues. She has been called on as a consultant to the Carnegie Commission on Science, Technology and Government, and served as the Reporter to the Advisory Committee on the Federal Rules of Evidence. She is the author of numerous amicus briefs, including the brief for the Carnegie Commission on the admissibility of scientific evidence in the landmark case of Daubert v. Merrell Pharmaceutical, Inc. She has also contributed chapters to both editions of the Federal Judicial Center's Reference Manual on Scientific Evidence (1994, 2000). Her textbook, Evidence: Cases and Materials (9th ed. 1991)(with Weinstein, Mansfield and Abrams), is a leading evidence casebook. Professor Berger has been a member of the Brooklyn Law School faculty since 1973. Her past service on

National Academies committees includes (1) Committee on Tagging Smokeless and Black Powder, and (2) Committee on DNA Technology in Forensic Science: An Update. She currently serves as a member of the National Academies Science, Technology, and Law Panel.

Doug Weed, *Co-Chair*, is Chief, Office of Preventive Oncology and Dean of Education and Training in the Division of Cancer Prevention at the National Cancer Institute (NIH). He directs the Cancer Prevention Fellowship Program and the Summer Curriculum in Cancer Prevention and Control at the NCI. Dr. Weed is trained in engineering (B.Sc. 1974) and internal medicine (M.D. 1977) from the Ohio State University and public health (M.P.H. 1980) and epidemiology (Ph.D. 1982) from the University of North Carolina. He is a Fellow of the American College of Epidemiology and chairs its Ethics and Standards of Practice Committee. He holds academic appointments at Johns Hopkins University, Uniformed Services University of the Health Sciences, and Georgetown University, where he is Senior Research Fellow at the Kennedy Institute of Ethics. His research interests include the ethics and philosophy of epidemiology and public health, theory and practice of causal and preventive inference, theories of disease causation, quantitative and qualitative methodologies of epidemiology, and cancer prevention and control. Recently, Dr. Weed gave the Advances in Oncology lecture at McGill University, the Samuel Harvey lecture at the American Association for Cancer Education meeting, the keynote lecture for the Korean Society of Preventive Medicine, Grand Rounds at the Ohio State University Cancer Center, and seminars at the schools of public health at the University of California, Berkeley, Tulane University, and Harvard University.

Shirley S. Abrahamson, B.A., New York University (1953); J.D., Indiana University Law School (1956); LL.B. (American Legal History), University of Wisconsin Law School, is Chief Justice,

Wisconsin Supreme Court. She was appointed in 1976 (then the only woman to serve on the Court); was elected in 1979, 1989, and 1999. Since August 1996 she has served as Chief Justice and, in that capacity, serves as the administrative leader of the Wisconsin court system. Abrahamson was previously in private practice for 14 years and taught at the University of Wisconsin Law School and Marquette University Law School. She is a member of the Institute of Judicial Administration (New York University School of Law), chair of the board of directors of the National Center for State Courts, and president of the Conference of Chief Justices. She was chair of the National Institute of Justice, National Commission on the Future of DNA Evidence, and is a member of the Council of the American Law Institute. She has served on the State Bar of Wisconsin's Commission on the Delivery of Legal Services. She is the recipient of 14 honorary doctor of laws degrees and the Distinguished Alumni Award of the University of Wisconsin Law School. She is a fellow of the Wisconsin Academy of Arts and Science and the American Academy of Arts and Sciences and an elected member of the American Philosophical Society. In 2004, she received the Dwight D. Opperman Award for Judicial Excellence from the American Judicature Society. Her current term expires in 2009.

Joe S. Cecil, Ph.D. (Psychology), Northwestern University; J.D., Northwestern University, is a Project Director in the Division of Research at the Federal Judicial Center. Currently he is directing the Center's Program on Scientific and Technical Evidence. As part of this program he is responsible for judicial education and training in the area of scientific and technical evidence and serves as principal editor of the Center's Reference Manual on Scientific Evidence which is the primary source book on evidence for federal judges. He has also published several articles on the use of court-appointed experts. He is currently directing a research project that examines the difficulties that arise with expert testimony in federal courts, with an emphasis on clinical medical testimony and forensic

science evidence. Other areas of research interest include federal civil and appellate procedure, jury competence in complex civil litigation, and assessment of rule of law in emerging democracies. Dr. Cecil serves on the editorial boards of social science and legal journals and on the National Academies He previously served on the National Academies Panel on Confidentiality and Data Access. He currently is a member of the National Academies Science, Technology, and Law Panel and was a member of its Subcommittee on Access to Research Data: Balancing Risks and Opportunities.

Joel E. Cohen (NAS), Dr. P.H. (Population Sciences and Tropical Public Health), Harvard University; Ph.D. (Applied Mathematics), Harvard University, is Professor of Populations at the Rockefeller University and Columbia University and heads the Laboratory of Populations at Rockefeller and Columbia. Cohen is a member of the American Academy of Arts and Sciences, the American Philosophical Society, and the National Academy of Sciences. Dr. Cohen serves as a member of the worldwide Board of Governors of The Nature Conservancy. 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 served as a Special Master in silicone gel breast implant products liability. Cohen's most recent book (October 2004), with Eric Stallard and Kenneth G. Manton, is *Forecasting Product Liability Claims: Epidemiology and Modeling in the Manville Asbestos Case.* The Foreword by Judge Jack B. Weinstein sets the historical context of this Court-commissioned analysis of asbestos injury projections. Cohen has published 11 other books, including *How Many People Can the Earth Support?* (1995) and 321 papers. He served on the Council of the National Academy of Sciences. He currently serves on the Governing Board of the National Research Council and as a member of the National Academies Science, Technology, and Law Panel. He received the Tyler Prize for Environmental Achievement in 1999.

Steven Goodman is an Associate Professor of Oncology, Pediatrics, Epidemiology and Biostatistics at the Johns Hopkins Schools of Medicine and Public Health. He received his BA from Harvard, MD from New York University, trained in pediatrics at Washington University, and received masters and doctoral degrees in Biostatistics and Epidemiology from Johns Hopkins. He is the Editor of the journal *Clinical Trials: The Journal of the Society for Clinical Trials*, and has been statistical and associate editor of the *Annals of Internal Medicine* since 1987. He is the scientific advisor to the National Blue Cross/Blue Shield Technology Assessment program, is a member of the US Medicare Coverage Advisory Commission and has served on numerous IOM panels, including Veterans and Agent Orange and Immunization Safety. He serves as co-director of the Johns Hopkins Evidence-Based Practice Center, and directs the Johns Hopkins epidemiology doctoral program. He was a court-appointed expert in the Phen-Fen class action, and consulted in the recent case on cell phones and brain cancer. He authored the chapters on causal criteria and evidence synthesis in the last two Surgeon General reports. In 2000, he was a recipient of the Myrto Lefkopolou award from the Harvard Department of Biostatistics. He has collaborated on a wide range of studies in cancer research and medicine, and teaches and writes on inferential, methodologic and ethical issues in clinical research and epidemiology.

Sander Greenland, Dr.Ph.D. (Epidemiology), Harvard University, M.S. (Public Health), University of California—Berkeley, and M.A. (Mathematics), University of California—Berkeley, is Professor of Epidemiology, UCLA School of Public Health, Professor of Statistics, UCLA College of Letters and Science, and Research Professor of Preventive Medicine, University of Southern California School of Medicine. Dr. Greenland is considered a leading authority on quantitative methods and statistical theory in epidemiology. His current research interests include epidemiologic methodology; statistical methods for epidemiologic data; epidemiologic assess-

ment of medicines and medical technology; foundations of nonexperimental inference. He is a member of the American Statistical Association, Biometric Society, Royal Statistical Society, and the Society for Epidemiologic Research.

Patrick A. Malone, J.D., Yale Law School, is a partner in the law firm of Stein, Mitchell & Mezines in Washington, D.C. After graduating from Yale in 1984, Mr. Malone clerked for United States District Judge Gerhard Gesell before joining the firm. At Stein, Mitchell & Mezines he represents seriously injured people in lawsuits against hospitals, doctors, drug companies, and other defendants. He is president of the Trial Lawyers Association of Metropolitan Washington, D.C., in 2005-06. He was elected in 2002 to the Inner Circle of Advocates, a prestigious invitation-only society that limits its membership to 100 of the best plaintiffs' personal injury attorneys in the United States. His notable cases include *Benedi v. McNeil-PPC Inc.*, 66 F.3d 1378 (4th Cir. 1995) (affirming an $8 million verdict against the manufacturer of Tylenol for a client who suffered liver failure). Mr. Malone has been a "Lawyer of the Year" of the Trial Lawyers Association of Metropolitan Washington, D.C. He is a member of the American Law Institute and is a certified civil trial advocate of the National Board of Trial Advocacy. Mr. Malone is a frequent speaker at continuing legal education courses both locally and nationally. He has lectured at grand rounds at Yale-New Haven Hospital and has spoken to other doctors' groups. He has written articles on legal subjects for, among others, *Trial Magazine*, *Litigation*, the Health Section of the *Washington Post*, and *The American Scholar*. At Yale, he was editor of the *Yale Law Journal* and won the Harlan Fiske Stone Prize and Potter Stewart Prize for best moot court efforts, along with the C. LaRue Munson Prize for legal clinic work. Before attending law school, Mr. Malone was a journalist, writing for United Press International and the Miami Herald. He was a finalist for the Pulitzer Prize in 1980 for a series of articles co-authored on "Dan-

gerous Doctors." Other journalism awards were received from The Newspaper Guild, American Bar Association, Sigma Delta Chi, National Headliners Club, American Academy of Family Physicians and Florida Medical Association. He is a member of Phi Beta Kappa. Mr. Malone currently serves as a member of the National Academies Science, Technology, and Law Panel.

Jennifer Mnookin, who earned a Ph.D. in History and Social Study of Science and Technology at MIT, joined the faculty in 1998 as an associate professor. She was previously a doctoral fellow at the American Bar Foundation, completing a two-year, residential research fellowship at an interdisciplinary, legal studies think tank. An expert on evidence law, Mnookin's scholarship particularly focuses on scientific, forensic, and visual evidence. She has written or co-authored articles on fingerprinting and its origins, the history of handwriting identification evidence, the effects of photography on the 19th-century criminal justice system, and the early use of film as legal evidence. Much of her work examines the interplay between popular and legal ideas about proof and persuasion. Since 2001, Mnookin has served as an editorial board member of Law and Social Inquiry. Mnookin received her J.D. from Yale Law School, where she was senior editor of the Yale Law Journal. She teaches evidence, scientific evidence, torts, law and literature, and law and film.

Judith Resnik is the Arthur Liman Professor of Law at Yale Law School, where she teaches courses on procedure, large-scale litigation, federal courts, federalism, feminist theory, and gender, locally, globally. Prior to joining Yale, she was the Orrin B. Evans Professor of Law at the University of Southern California Law Center. She has also been a visiting professor at NYU, Harvard, and the University of Chicago Law Schools. Professor Resnik is a graduate of Bryn Mawr College and New York University School of Law, where she held an Arthur Garfield Hays Fellowship. She is the co-author (with

Owen Fiss) of the book Adjudication and Its Alternatives: An Introduction to Procedure and is the author of Process of the Law: Understanding Courts and Their Alternatives. Recent contributions to books include the chapter Civil Processes in The Oxford Handbook of Legal Studies and The Rights of Remedies: Collective Accountings for and Insuring Against the Harms of Sexual Harassment, in Directions in Sexual Harassment Law. Professor Resnik has chaired the Section on Procedure, the Section on Federal Courts, and the Section on Women in Legal Education of the American Association of Law Schools. She has served on committees and task forces of the American Bar Association, is a member of the American Law Institute, and was a consultant to the Institute for Civil Justice of RAND. At Yale, Professor Resnik is a co-chair of the Women's Faculty Forum, a university-wide group aimed at fostering scholarship about gender and community for women at Yale. She is also the founding director of the Arthur Liman Public Interest Program and Fund, which provides fellowships to Yale Law School graduates and summer stipends to undergraduates at Yale, Brown, and Harvard, and which supports seminars and programs on public interest law for law students. Professor Resnik was a member of the Ninth Circuit Gender Bias Task Force, the first to report on the effects of gender in the federal court system; she is a co-author of its monograph, The Effects of Gender. Professor Resnik has testified many times before congressional and judicial committees, most recently before the subcommittee of the Senate Judiciary Committee regarding the Senate's role in the nomination process and before a committee of the United States Judiciary on revisions to the class action rules. She is also an occasional litigator and court-appointed expert. Professor Resnik has received several awards, including in 1993, the Florence K. Murray Service Award from the National Association of Women Judges; in 1994, the USC Associates Award for Creativity in Research; in 1995, the Teaching Award from the Alumni Association of the NYU Law School, and in 1998, the Margaret Brent Award from the Commission on Women of the

American Bar Association. In 2001, she was elected a member of American Academy of Arts and Sciences, and in 2002, a member of the American Philosophical Society.

Staff

Anne-Marie Mazza, B.A., Economics; M.A., History and Public Policy; Ph.D., Public Policy, The George Washington University. 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. In 1999 she was named the first director of the Committee on Science, Technology, and Law (CSTL). Between October 1999 and October 2000, she divided her time between CSTL and the White House Office of Science and Technology Policy, where she served as a Senior Policy Analyst. Before joining the National Academies, Dr. Mazza was a senior consultant with Resource Planning Corp.

Stacey Speer, B.S., Biomedical Engineering, University of Tennessee, is a Program Associate. She joined the National Academies CSTL in September 2002, as a Christine Mirzayan Science and Technology Policy Graduate Fellow. She is attending the George Washington University and received her masters of forensic science in May 2005.

Kathi Hanna, M.S., Ph.D. is a science and health policy consultant, writer, and editor specializing in biomedical research policy and bioethics. She served as Research Director and Senior Consultant to President Clinton's National Bioethics Advisory Commission and as Senior Advisor to President Clinton's Advisory Committee on Gulf War Veterans Illnesses. More recently, she served as the lead author and editor of President Bush's Task Force to Improve Health Care Delivery for Our Nation's Veterans. In the 1980s and 1990s, Hanna was a Senior Analyst at the congressional Office of Technology

Assessment, contributing to numerous science policy studies requested by congressional committees on science education, research funding, biotechnology, women's health, human genetics, bioethics, and reproductive technologies. In the past decade, she has served as an analyst and editorial consultant to the Howard Hughes Medical Institute, the National Institutes of Health, the Institute of Medicine, the National Academy of Sciences, several charitable foundations, voluntary health organizations, and biotechnology companies. Before coming to Washington, D.C., she was the Genetics Coordinator at Children's Memorial Hospital in Chicago, where she directed clinical counseling and coordinated an international research program in prenatal diagnosis. Hanna received an A.B. in Biology from Lafayette College, an M.S. in Human Genetics from Sarah Lawrence College, and a Ph.D. from the School of Business and Public Management, George Washington University.

APPENDIX B

MEETING AGENDA

First Meeting of the Committee on *Daubert* Standards
January 27, 2005
Agenda

9:30 **Handling Science in the PPA Litigation**

A Judge's Perspective

Barbara J. Rothstein, Director, Federal Judicial Center

11:15 **Wrestling with Causation in Tort Litigation**

Steven Goodman, Associate Professor of Oncology, Pediatrics, Epidemiology and Biostatistics, Johns Hopkins School of Medicine
Michael D. Green, Bess and Walter Williams Distinguished Chair in Law, Wake Forest University Law School

12:00 **Lunch**

1:00 **Breast Implants Panel of Expert Scientists**

Margaret Berger, Suzanne J. and Norman Miles Professor of Law, Brooklyn Law School
Joe S. Cecil, Project Director, Program on Scientific and Technical Evidence, Federal Judicial Center

2:45 **Media Perspective: Academic Science and Drug Development**

David Korn, Senior Vice President, Association of American Medical Colleges
Barry Meier, The New York Times

4:00 **Improving the Gatekeeper's Decision-Making**

Shirley S. Abrahamson, Chief Justice, Wisconsin Supreme Court
Marina Corodemus, Superior Court of New Jersey
Barbara J. Rothstein, Director, Federal Judicial Center

5:15 **Adjourn**

Second Meeting of the Committee on *Daubert* Standards
March 27, 2005
Agenda

1:30 ***Daubert Revisited – Areas Needing Further Study***

Committee Co-Chairs:

Margaret Berger, Suzanne J. and Norman Miles Professor of Law, Brooklyn Law School
Douglas Weed, Chief, Office of Preventive Oncology, National Cancer Institute, NIH

1. Evidence Synthesis in Science and Law – A consideration of the different approaches used by scientists, lawyers, and judges in the selection, summarization, and interpretation of scientific evidence.
2. Involvement of Scientists in the Legal Process – A consideration of how the *Daubert* decision has changed the involvement, role, and responsibilities of scientists in the courtroom, and opportunities and challenges for

more multi-disciplinary education and research in science and law.

3. Availability of Information – A consideration of how courts and the public respond when scientific information is not forthcoming, whether because pertinent studies were never undertaken, or were conducted but never disclosed, or were sealed in settlement/secrecy agreements.

5:30 Adjourn