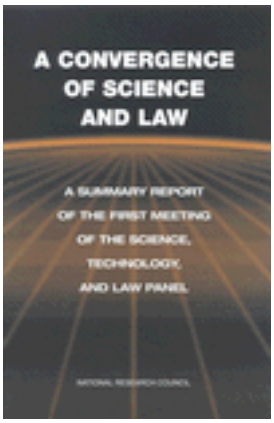

A Convergence of Science and Law: A Summary Report of the First Meeting of the Science, Technology, and Law Panel

Science, Technology, and Law Panel, National Research Council

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A CONVERGENCE OF SCIENCE AND LAW

A SUMMARY REPORT OF THE FIRST MEETING OF THE SCIENCE, TECHNOLOGY, AND LAW PANEL

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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 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 objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

We wish to thank the following individuals for their review of this report: Honorable Danny J. Boggs, U.S. Court of Appeals for the Sixth Circuit; Carl Cranor, University of California-Riverside; Bernard D. Goldstein, The University of Medicine and Dentistry of New Jersey-Robert

Wood Johnson Medical School; Honorable Pauline Newman, U.S. Court of Appeals, Federal Circuit; Anthony Z. Roisman, Hershenson, Carter, Scott & McGee; and Nathan A. Schactman, McCarter & English.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the report nor did they see the final draft of the report before its release. The review of this report was overseen by Harold Forsen appointed by the NRC's Report Review Committee, who 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 authoring committee and the institution.

In addition, the Panel wishes to acknowledge the work of the Science, Technology, and Law Program staff: Anne-Marie Mazza; Susie Bachtel; Maarika Liivak; and consultant writer Duncan Brown.

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1

Introduction

This report is a summary of the first meeting of the Science, Technology, and Law Panel of The National Academies, convened on March 16-17, 2000, at the Beckman Center in Irvine, California. The Science, Technology, and Law (STL) Program was established to monitor and explore the growing number of areas in which the processes of legal decision making utilize or impinge on the work of scientists and engineers. One of the major activities of the STL Program is convening a distinguished panel of individuals drawn from both the science and engineering and legal communities. The purpose of the Panel's first meeting was to share information about a number of areas in which science and law interact so that all the members of the Panel, with their different backgrounds, would be in a better position to determine the Panel's future agenda.

The principles of science and law developed over the centuries in response to their differing objects of interest. Science, engineering, and technology seek knowledge through an open-ended search for expanded understanding, whose "truths" are subject to revision. Law, too, conducts an open-ended search for expanded understanding; however, it demands definite findings of fact at given points in time. When these two disciplines meet in the courtroom the differences between the two cultures are magnified. For example, the legal tradition of adversarial proceedings contrasts with the cooperative ethic of science. Even the search for truth does not serve the same aims and may not be subject to the same constraints and requirements. Simply stated, science, engineering, and

technology[1] aim to understand, predict, modify, and control aspects of the natural and manufactured world, while the law seeks current truth about scientific and other facts of cases in order to serve the much different goal of justice between parties (as well as other societal goals).

In today's high-technology society the two professions are increasingly often forced to interact in legal disputes involving patents, product liability, environmental torts, regulatory proceedings, and criminal cases. Further, law and science encounter each other in the laboratory through a number of federal actions governing intellectual property, research misconduct, access to research data, and conflicts of interest. The fact-finding agendas of the two disciplines now frequently have begun to overlap, if not merge. Because there is a general lack of understanding of each culture, these interactions often lead to a cognitive friction that is both disturbing and costly to society.

As was noted throughout the meeting, scientists tend to be leery of lawyers and the legal process, preferring not to venture into the courtroom. Lawyers are often frustrated by a scientific community that believes that its methods and procedures are above legal scrutiny and questioning. Lawyers and scientists may seldom speak the same language, but it should be possible for each to develop a better understanding of the principles and methods of the other's profession. Bridging this divide will be a challenge for the STL program as it attempts to build a better understanding between the two communities.

RECENT DEVELOPMENTS

Several events in the past decade have significantly increased the tension at the interface of science and law. First, scientific and technical evidence is more frequently presented in litigation and has become more complex. Judges indicate that the number of cases involving scientific and technical information has increased significantly. Such proceedings often attempt to resolve issues that scientists and engineers view as within their domain (for example, whether or not breast implants cause autoimmune disease). The recent *Daubert*, *Joiner*, and *Kumho* decisions of the Supreme Court[2] demand an active "gatekeeping" role for judges in assessing expert testimony, requiring them to take account of professional practices outside the courtroom.

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[1]Throughout this report, science will be used to include science, engineering, and technology.

[2]*Daubert* v. *Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993); *General Electric Co.* v. *Joiner*, 522 U.S. 136 (1997); *Kumho Tire Co.* v. *Carmichael*, 199 S. Ct. 1167 (1999).

Second, health, safety, and environmental regulations are more frequently based on epidemiology, ecological modeling, and other statistical methodologies, and are intended to address risks that incorporate assumptions that may be difficult to verify. Parties affected by such regulations often challenge the scientific foundations of these rules, opening up for public review the internal process of the underlying science.

Third, the legal doctrines defining intellectual property have become increasingly prominent in the past two decades. New industries have arisen to exploit fundamental science, most notably in molecular biology. These advances have presented new challenges to the patent system. In response to the Bayh-Dole and Stevenson-Wydler Acts and related measures to encourage nonprofit institutions to transfer technology to industry, academic institutions and other nonprofit research organizations also have grown more interested in patenting new knowledge. The number of patents is rising rapidly; approximately 160,000 were granted in 1999, up from 100,000 a decade earlier (Barton, 2000). Federal courts are called upon to rule on a number of highly sophisticated scientific and technical issues in patent infringement cases.

Finally, in a number of ways legal decisions are a part of every scientist's and engineer's daily existence. Laws and regulations governing intellectual property, access to research data, research misconduct, and grants and contracts are a few examples. Just as science and engineering are increasingly present in the courtroom, legal decisions are having a more prevalent affect on how scientists and engineers conduct their research and design activities.

FORMATION OF THE SCIENCE, TECHNOLOGY, AND LAW PROGRAM

For several years The National Academies explored the notion of a new program to study the interactions of science, technology, and law. Serious discussion dates from spring 1996, when Supreme Court Associate Justice Stephen G. Breyer discussed the idea in an informal dinner with leaders of The National Academies. That discussion led to a day-long symposium in November 1997, at which a group of knowledgeable scientists, engineers, judges, lawyers, business executives, and government officials discussed possible roles for The National Academies in this area.

During the 1990s The National Academies submitted amicus curiae briefs to the Supreme Court in two of the three earlier mentioned cases involving significant issues at the boundaries of science and law. In January 1993, the National Academy of Sciences (NAS) and the American Association for the Advancement of Science (AAAS) joined in an amicus

curiae brief in support of the respondent, Merrell Dow Pharmaceuticals, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* The National Academy of Engineering (NAE) in August 1998 submitted a brief in support of the petitioners in *Kumho Tire Company v. Carmichael.* The need for scientists participation in the legal arena was evident when Associate Justice Breyer addressed the 150th Annual Meeting of the AAAS in February 1998, saying "In this age of science we must build legal foundations that are sound in science as well as in law."

To continue exploration of these opportunities The National Academies established the Science, Technology, and Law (STL) Program. A major activity for the program is to convene a distinguished panel. The Panel was duly formed and held its first meeting on March 16–17, 2000. The Panel's desire is to establish a regular dialogue between the science and engineering community and the legal community to study pressing issues, improve communication, and help resolve disagreements.

ORGANIZATION OF THIS REPORT

Following this introductory chapter, this report summarizes the Panel's initial meeting and its future agenda. Chapter Two reviews issues arising as a result of three Supreme Court decisions regarding admissibility of expert testimony. During its deliberations the Panel considered a number of measures that might help judges, juries, and expert witnesses in the courtroom.

Chapter Three discusses the effect of law on the conduct of scientific and engineering activities. In particular, it reviews the impact of recent legal, legislative, and regulatory developments on ownership rights to research data. Some observers contend that permitting greatly expanded access to research data that is still under way by those who seek to influence decisions of courts and regulatory agencies will hinder the research enterprise and will impose excessive burdens on researchers. Others argue that the public has a right to the data generated by federal funds. In addition, this chapter discusses intellectual property and the new federal policy for research misconduct. Chapter Four summarizes the STL program's agenda for future activities.

2

Scientific and Technical Evidence in the Courtroom

During its first day and into the morning session of the second day, the Panel reviewed three Supreme Court cases dealing with the admissibility of expert evidence and the implications of these cases for judges, juries, and expert witnesses. Complicated questions of fact increasingly demand scientific and technical judgments by jurists, juries, and lawyers, who are usually not well prepared by education or experience to make such decisions. These deliberations are summarized below.

THE SUPREME COURT TRILOGY

The law of expert evidence has changed substantially in the past decade as the result of three Supreme Court decisions. In 1993, the *Frye* rule[3] for determining admissibility of expert testimony gave way after nearly 70 years to the *Daubert* criterion of scientific reasoning and methodology. Frye looked to the scientific community for guidance, allowing judges to admit testimony if the theory underlying the expert's opinion had "gained general acceptance in the particular field in which it belongs."

The first case in the trilogy, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, is a 1993 case involving birth defects alleged to have resulted from a mother's use of Bendectin, a morning sickness remedy. In this case, the Supreme Court established a test for the admissibility of scientific evi-

[3]*Frye* v. *United States*, 293 F. 1013 (D.C. Circuit, 1923).

dence that required that the testimony not only to be relevant to the facts of the case, but also to be reliable. The new admissibility test requires judicial assessment of "whether the reasoning or methodology underlying the testimony is scientifically valid and of whether the reasoning or methodology properly can be applied to the facts in issue." To meet the reliability test, the testimony must be the result of scientific reasoning and methodology evidenced by four factors:

1. whether the theory can be tested;
2. whether the theory has been published in a peer-review publication;
3. whether there exists known or potential error rates; and
4. whether there are standards for controlling the technique's execution.

In specifying these factors, the Supreme Court gave the trial judge responsibility for assessing the soundness of the scientific information and reasoning that an expert witness presents in court. In so doing, the Supreme Court assigned the role of "gatekeeper" to the trial judge, requiring that the judge screen expert testimony to determine both its relevance and reliability while respecting the role of the jury to resolve disputed factual issues.

The second case in the trilogy, *General Electric v. Joiner*, a toxic tort case in which the plaintiff alleged that his lung cancer was a result of his exposure to polychlorinated biphenyls (PCBs), is a case in which the trial judge applied the *Daubert* criteria, excluded the testimony, and granted summary judgment. The appellate court reversed and set the stage for the Supreme Court's consideration. In *Joiner*, the Supreme Court held that the appellate courts, when reviewing a lower court's decision admitting or excluding expert testimony, must use an abuse of discretion standard that requires deference to the trial judge's ruling. The Supreme Court then went further, reviewing the evidence and finding that the trial judge had not abused her discretion in excluding testimony, since the expert failed to adequately relate his testimony in the case to the scientific studies on which he had relied.

The third case in the trilogy, *Kumho Tire Co. v. Carmichael*, is a product liability case in which the plaintiff claimed that a tire on his vehicle blew out as a result of a defect. In this 1999 case, the Supreme Court extended the trial judge's gatekeeper obligation to all expert testimony, not just purely scientific testimony. The Court "concluded that *Daubert's* general holding—setting forth the trial judge's general 'gatekeeping' obligation—applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." The Court declared that the expert in the courtroom must employ "the same

level of intellectual rigor that characterizes the practice of an expert in the relevant field."[4]

In response to the Supreme Court's trilogy on expert proof, Rule 702 of the Federal Rules of Evidence ("Testimony by Experts") was amended in 2000. The rule now states that [additions underscored], "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

Implications of the Trilogy for Judges, Juries, and Experts

As a result of these decisions and the amended rules, the STL Panel was interested in knowing how the legal system is responding, what the implications of these decisions are for the key players in litigation (judge, juror, and expert) and what mechanisms would help these players fulfill their responsibilities in court. The STL Panel discussed a number of mechanisms to help courts deal more effectively with scientific and technical evidence. Many of these approaches, such as court-appointed experts, are controversial and most are fraught with complexities. Existing and proposed remedies are discussed below.

For Judges

It was noted that judges have little spare time for in-depth study of science or engineering. Nonetheless, in today's courtroom, they need intensive, focused information and educational tools to help them understand the scientific and technical basis of expert testimony.

Special Masters. Judges currently may appoint special masters in certain exceptional cases. These officials are generally experts on the law, but sometimes they have specialized scientific or technical expertise. The powers and duties of the special master vary widely. They may include supervising the discovery of evidence, preparing reports for consideration by the judge or jury, or overseeing expert depositions.

[4]While the focus in this discussion is on civil litigation, these three Supreme Court decisions similarly affect criminal litigation as judges rule on the admissibility of forensic science.

Court-Appointed Witnesses. Under Rule 706 of the Federal Rules of Evidence, a judge may appoint an expert witness, or even a panel of witnesses, of his own choosing. Such a witness may be asked to report on a particular scientific or technical issue for the case, and is then deposed by both parties as part of the discovery process. The federal judge overseeing most of the federal cases involving silicone gel breast implants, for example, appointed a four-member scientific panel to prepare a report on the scientific basis of competing claims made by the parties. The Panel was appointed with the approval of both the plaintiffs' and the defendants' counsel. Its costs were defrayed by the Administrative Office. Over the course of 2 years, the Panel reviewed relevant scientific literature, produced a report, and was deposed. Special counsel were retained to represent the Panel. (See Hulka et al., 2000.)

One experiment in making independent experts more conveniently available to judges is the recently launched Court Appointed Scientific Experts (CASE) demonstration project of the Scientific Freedom, Responsibility and Law Program of the AAAS. As part of the project, judges wishing to appoint experts may call on CASE staff for help in identifying highly qualified scientists and engineers to serve as experts to the courts, rather than to the parties in litigation. CASE staff use several methods to identify suitable experts, including requesting help from professional and scientific societies and institutions. A CASE Recruitment and Screening Panel composed of respected scientists and engineers screen and recruit experts. Subcommittees will prepare educational and resource materials for courts and for the scientists and engineers identified as prospective experts, and will advise on such matters as conflicts of interest. An advisory committee (chaired by a federal appeals court judge) oversees the project. The Federal Judicial Center (the research and education arm of the federal judiciary) will evaluate CASE.

The Private Adjudication Center, Inc., of Duke University School of Law also maintains a registry of independent scientific and technical experts who are willing to provide advice to courts or serve as court-appointed experts. In addition, the Federal Judicial Center offers a series of programs to acquaint judges with scientific principles and evidentiary standards used to evaluate the admissibility of technical proof.

Technical Advisors. Some suggested that judges should have established sources of technical and scientific information, who could be called upon not to serve as witnesses, but as tutors. A roster of such individuals who could explain difficult technical aspects of cases, for example, those that might involve advanced statistics or the chemistry of gene expression, could provide assistance to judges.

Video, Print, or Online Summaries. The Internet provides new opportunities for "learning on demand" or "just-in-time learning" that could provide judges with access to scientific and engineering materials over the course of a case. In theory, a judge might also be able to visit an Internet site covering a scientific or engineering topic, and then navigate by hyperlink through a great mass of authoritative information.

In practice, however, developing such materials is not a trivial task. Such materials must be prepared and reviewed by both scientific and legal communities to ensure that they are not only accurate and represent the consensus of the field, but are without bias. Sources able to provide funding for such materials are not readily identifiable.

Short Courses. A number of academic institutions host brief summer sessions to help judges understand the role of science and technology in the courtroom. These include the Program in Judging Science of Duke University's Private Adjudication Center; the University of Virginia's Graduate Program for Judges; and various courses at the National Judicial College. However, attendance at these sessions tends to be sparse, due to competing demands on judges' time and the scarcity of funds in court budgets.

Specialized Courts. Specialized courts have been proposed as a way to help courts deal more effectively with scientific and technical evidence (see, for example, Kantrowitz, 1967). However, today federal judges are normally assigned cases by lot, not on their expertise. Some particularly complex or broadly significant cases may be aggregated regionally or nationally for limited purposes as authorized by statute, as occurred with the federal cases involving silicone gel breast implants.

Long-Term Independent Research Programs and Periodic Reviews. One promising approach could be to conduct a series of long-term studies of scientific topics of potential regulatory interest both to establish a basis for consensus and at the same time give judges forewarning of emerging scientific and technical issues. These types of studies have been used to reduce disputes about the facts in contentious regulatory arenas including the health effects of air pollution. For areas of science in which a long-term view is possible, this approach might reduce some of the inevitable conflicts over regulation. However, this approach is less applicable to the fast-moving fields of science and technology, such as those issues arising in the increasing number of intellectual property cases heard by federal courts.

For Juries

The right to a trial by a jury is guaranteed by the Constitution. The challenges of presenting scientific and technical information to jurors are at least as great, if not greater, as those of helping judges understand such material. The STL Panel considered a number of approaches, discussed below, that could improve the jury's understanding and assessment of scientific and technical testimony.

Providing Scientific and Technical Information. Background materials explaining the scientific process and addressing specific scientific or technical questions could be prepared to help juries understand and assess the pertinent facts at issue in a particular case. These materials would have to be developed in a "just-in-time" manner.

Developing Model Jury Instructions. Jury instructions are critical sources of information on the law and the rules of evidence. Many jurors, some judges say, are swayed unduly by the aura of certainty that scientists and engineers may present in court. Judges' instructions to juries could be formulated to help jurors better evaluate expert testimony and to focus on the reasoning underlying the expert testimony rather than traditional credibility assessments. A model set of instructions might, for example, be developed to aid jurors' understanding of probability, risk, or a particular scientific or technical question at issue.

For Experts

Several STL Panelists noted that the *Daubert* and *Kumho* decisions shine a spotlight on the methodology and reasoning of the expert witness. This scrutiny itself may force an improvement in the quality of testimony that experts offer. The STL Panel discussed several other ways to improve expert testimony.

Preparing Tutorials for Expert Witnesses. Many scientists and engineers who are required to testify in court are unprepared for the experience. Several different kinds of guides for experts might be useful including:

1. Ways to present information that will be useful to juries and judges.
2. Tutorials on the legal processes of discovery and testimony.
3. Tutorials on the legal demands for confidentiality and how these demands may constrain one's analysis.

Developing Ethical Standards for Expert Witnesses. While experts who appear in court represent the interests of particular parties, it is not clear from a legal perspective to whom experts owe ethical obligations and whether they are governed by the ethical standards that apply to lawyers, to their professions, or to something more. Scientific and technical associations could find it useful to develop or support strong codes of ethics for members who testify as experts. Some professional associations, such as the American Psychological Association and the American College of Occupational and Environmental Medicine have developed standards for conduct in the courtroom.

3

Law and the Conduct of Scientific and Engineering Activities

On the second day of the meeting, the STL Panel explored several areas where law places constraints and requirements on the conduct of academic research. Specifically, the Panel reviewed issues regarding 1) access to research data, 2) intellectual property, and 3) research misconduct.

ACCESS TO RESEARCH DATA

The social and economic stakes of research are rising. Federal regulatory and policy decisions of great importance hinge more and more on questions of cutting-edge science and technology. Traditional mechanisms for conveying policy-relevant research findings permit researchers to retain a proprietary interest in their underlying research data. However, in today's climate a variety of legal proceedings require scientists and engineers to justify their findings and disclose their research data and methods in unaccustomed degrees of detail. These include the following:

- recent federal legislation gives the public the authority under the Freedom of Information Act (FOIA) to access federally sponsored research data
- scientists' data are on occasion subpoenaed even in cases in which the scientists have no involvement in the litigation.

These proceedings represent another area where the cultures of science and law clash. Openness and a willingness to share research data are paramount to the scientific enterprise. For the scientific community, the common means of ensuring accuracy and quality of research is replication. Publication of one's findings is the means by which scientists communicate with each other and provide the information necessary for replication and reanalysis. Most scientific journals rely on peer review to ensure that scientific papers meet a threshold of credibility. Peer review is handled in a decentralized way, much of it by volunteers, and coordinated by editors of individual professional journals. While peer review is not a substitute for replicability, it does provide the scientific community with a level of confidence about the integrity of the research findings. In litigation, however, a lawyer, in carrying out his or her duty to represent his client, may seek independent verification of research results. Consequently, he or she may accord little weight to the fact that the results may have been peer reviewed and published when questioning and challenging the expert. A vigorous attack of the expert witness and his or her research results may be just what is needed in order to provide his or her client with a good defense, but it may leave the expert most uneasy.

PUBLIC ACCESS TO FEDERALLY FUNDED RESEARCH DATA THAT UNDERLIES REGULATION

The regulatory requirement of publication and notice seeks public consensus as to the accuracy of facts and reasonableness of proposed new rules and regulations. However, the facts may be disputed, and regulators then labor under a handicap in establishing public credibility. For example, the U.S. Environmental Protection Agency (EPA) in 1997 proposed to tighten federal air quality regulations for particulate matter. The proposed new standard was based partly on the results of the Harvard "Six Cities" epidemiological study, which identified a correlation between death rates and airborne particulates in several middle-sized cities. Implementing these standards would cost industry billions of dollars, much of it passed on to industry. While EPA's action followed a typical regulatory path, concerns about the underlying data resulted in a legislative action that sought to change the manner in which the public gains access to federally sponsored research data.

Industry groups (and several members of Congress) asked EPA for the underlying research data from these studies in order to conduct their own analysis. The Harvard researchers, funded by the National Institutes of Health (NIH), refused to release the research data, citing privacy concerns of the human subjects and the researcher's traditional right to control data. EPA agreed with this view. As an alternative, EPA and the

researchers offered to have the data reanalyzed by the Health Effects Institute (HEI), an independent research institute jointly funded by industry and the EPA, whose policy is set by an independent board. The results of that study were not expected to be available, however, until 2 years after the regulation had become final.

EPA argued that the peer review undergone by the Harvard study was sufficient to support regulations. Critics (for example, Cohen and Hahn, 1999) pointed out that academic peer reviews are often flawed (the expectation is that mistakes will wash out in the long run, as other scientists try to replicate the results), and that regulations costing billions of dollars to enforce should not be built solely on such a foundation.

Meanwhile, Congress, through the Shelby amendment, directed the Office of Management and Budget (OMB) to revise regulations covering research grants to nonprofit organizations (*OMB Circular A-110,* subpart C.36) to give the public access under FOIA to data relating to all federally funded research. After much public discussion, OMB issued the final rule. The final rule provides public access to "research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law."

The rule—which applies only to nonprofit research grantees—raises a number of questions that may lead to litigation:

1. Does the new rule apply retroactively or only prospectively?
2. What are the potential costs and administrative burdens of complying with requests, and how will researchers be reimbursed?
3. How, in practice, will privacy concerns regarding research data that involve human subjects or patient records be handled?
4. How will agencies and courts set the threshold of cost or significance below which federal "agency actions" are not subject to this requirement?
5. Will requests be made to harass researchers or hinder their ability to conduct research?

As was pointed out during the STL Panel discussion, achieving the right balance for the public good in such cases is difficult. The results of complex statistical studies used for regulatory purposes can be subject to various interpretations, and on these grounds deserve the widest possible scrutiny. Traditional peer review alone may not be sufficient in such cases to ensure credibility. On the other hand, many in the academic community see the new OMB rule as an invasion of privacy, a potentially onerous burden that will divert researchers from work that is of broader benefit, and in the extreme case, view the rule as a license to harass and discour-

age federally funded researchers from pursuing areas of research that are meaningful to broad advances in public health and safety.

COURT-ORDERED DISCLOSURE OF ACADEMIC RESEARCH

The STL Panel turned its attention to the situation that arises when parties bring academic researchers into a legal proceeding by obtaining subpoenas for their research data. A federally funded researcher studying the effects on communities of the Exxon Valdez oil spill, for example, was served with a subpoena from Exxon demanding all materials from an ongoing study, including notebooks, letters, working papers, handwritten survey responses from residents, and other raw material (Picou, 1996).[5] In another case, several researchers studying impacts of cigarette advertising on children were served with similarly broad subpoenas by a cigarette manufacturer defending a suit in a California court (Fischer, 1996). It has been suggested that in these cases, the legal process was bent to serve extralegal purposes—in fishing expeditions that had little to do with resolving the case.

Some Panel members suggested that the duty to provide evidence, which is strongly rooted in law, must be balanced against the potential for harassment in such cases. Even more important, courts, when they review subpoenas, might require a demonstration of a substantial need for the research information that cannot otherwise be satisfied.

CONFLICTS BETWEEN INTELLECTUAL PROPERTY RIGHTS AND OPENNESS OF RESEARCH

Another topic discussed by the STL Panel is the concern of some researchers that an emphasis on intellectual property in academic institutions has led to internal tension between those who advocate the traditional goal of open scientific communication and those who promote the newer goal of royalty income to the institution. As discussed below, some fear that recent developments may have a chilling affect on research.

The Patenting of Research Tools

Intellectual property claims on research tools are proliferating. Researchers who wish to use some basic research tools or databases are now

[5]In 1991, the NRC sponsored a workshop on science and litigation that explored the effect of confidential settlements and sealed court records on scientific research. See Anderson, Frederick R., "The legal system obstructs science," in *The Atlanta Journal and Constitution,* November 29, 1991.

being required to sign license agreements, material transfer agreements, or nondisclosure agreements. Some experts believe that the delays and costs involved in these transactions are so large that they discourage research in certain fields (Heller and Eisenberg, 1998). Others (Rosenthal, 1996) view nondisclosure agreements as immoral, since theoretically they can require a clinical researcher to withhold an effective treatment simply because it is based on proprietary knowledge.

Tighter Restrictions on Publication

Industrial sponsors of research at universities impose controls (generally delays) on publication to allow their companies to assess the potential for intellectual property in their findings. Do these controls shift researchers' incentives? NIH and other research agencies regard a 60-day publication delay as acceptable (although they have not issued blanket policies). Surveys suggest that many agreements sanctioned by universities permit longer withholding periods. More worrisome, one study found, is that universities tend to understate the degree of commercial secrecy they tolerate (Blumenthal et al., 1997).

QUASI-JUDICIAL PROCEEDINGS IN RESEARCH MISCONDUCT CASES

The STL Panel received a briefing on the new federal policy governing research misconduct for researchers who have accepted federal awards. Such a policy is necessary due to the fact that researchers are sometimes accused of misconduct, such as misrepresenting research results or plagiarism. In investigating these cases, research institutions have developed a variety of quasi-judicial procedures in the past decade.

The White House National Science and Technology Council recently revised the federal policy on research misconduct. The new policy defines research misconduct more narrowly, limiting it to "fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results." Other types of misconduct (e.g., theft, harassment, and discrimination) that have been subjects of such inquiries in the past are left to be addressed through other laws and regulations.

In implementing the new policy, the HHS Office of the Inspector General will assume the main responsibility for investigating research misconduct. The ORI will then be responsible for the tasks of oversight and education. Under the new policy, institutions that administer HHS grants are responsible for initial inquiries and investigations when research misconduct is suspected or alleged. When further fact-finding is

required by the federal government, it will be carried out by the HHS Office of Inspector General rather than the ORI.

In the worst cases of research misconduct, the courts become involved. A researcher who is penalized or debarred by administrative action of the agency may appeal to federal court. Federal courts do not have jurisdiction to review scientific or research misconduct investigations under the Administrative Procedure Act until there is a final agency action and the imposition of a sanction [*Abbs v. Sullivan*, 963 F.2d 918 (7th Cir. 1992)].

4

Science, Technology, and Law Panel's Agenda

In establishing the STL Program's future activities, the STL Panel was faced with a wealth of opportunities. The interface of science, technology, and law is complex, with four obvious dimensions:

- The law itself, including varied legislative, executive, and judicial functions;
- The substantive areas of science and technology themselves, including physical and mathematical sciences, biological sciences, engineering, medical sciences, behavioral and social sciences, and applied biological and agricultural sciences;
- The vector of a particular interaction between science and law (whether one is interested in the effect of law on science and technology, or the effect of science and technology on law); and
- Crosscutting issues (such as intellectual property, access to research data, identification of expert witnesses, ethical responsibilities of professionals, and the economic effects of regulation).

Nearly any aspect of today's science- and technology-dependent society could be examined by the STL Panel. However, to have its greatest impact, the STL Panel will focus its initial activities on two specific areas. At the meeting, the STL Panel formed two working groups that correspond to the topics featured most prominently during its first meeting:

(1) Judicial Use and Understanding of Scientific and Technical Evidence, and
(2) Access to Research Data.

In advance of the STL Panel's next meeting, scheduled for September 8, 2000, each working group was asked to map and recommend a process by which the full STL Panel could more fully understand the issues underlying these topics.[6]

[6]Following the Panel's first meeting, the Working Group on Judicial Use and Understanding of Scientific and Technical Evidence organized a workshop on scientific evidence on September 7, 2000. The workshop transcript is available at <www.nas.edu/stl>. A report of the workshop will be available in 2001. In addition, the Access to Research Data Working Group held a workshop on March 12, 2001. The transcript and webcast from this meeting are available at <www.nas.edu/stl>. A report of the workshop also will be available in 2001.

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