Science and the Legal System: Truth, Justice and Fairness (Keynote Speech)

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I appreciate Dr Blom's generous introduction and am deeply flattered by your invitation. The organizers have planned an impressive program, one that I am delighted to travel cross-continent to share.

I have reason to believe that your invitation was a recognition of my role as co-chair of a new venture established by the three units of our National Academy of Sciences—the NAS itself, the National Academy of Engineering, and the Institute of Medicine. My co-chair is Dr Donald Kennedy, a renowned biologist and former President of Stanford University, who recently assumed the post of editor-in-chief of *Science* magazine.

Our venture is titled the Panel on Science, Technology, and Law, and we have been in business just over a year. Last month, the Panel, two-dozen scientists and lawyers, sponsored our first public event, a day long "workshop" on scientific evidence in judicial proceedings—a topic that is a focus of several sessions here.

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No one can view the establishment of our Panel—or this conference for that matter—as marking the discovery of new arenas for research, discussion, and debate. Science and law have been co-participants for many decades. At our recent workshop, Professor Michael Hoeflich of the University of Kansas recounted the parallel emergence of common law

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reasoning and the scientific method in the early 18th century in England.[1] Legal scholars and practising scientists of that era, he argued, shared common social origins and embraced similar principles of neutrality and objectivity.

One need not fully embrace Dr Hoeflich's account to agree that at the end of the 20th century, science and law collaborate in the performance of important social functions. In some legal settings, the contributions of science are not merely central; they are decisive. In others, science is a secondary but still important contributor. In short, the legal system is a user—a major consumer—of scientific theories and scientific research. But of course the legal system also invades the scientific domain, setting standards for the conduct of law-relevant research, guiding the investigation of charges of scientific fraud, and influencing, sometimes dictating, the terms on which the results of scientific research may be seen or used by third parties.

These areas of intersection—and sometimes of conflict—are by no means new. For example, courts in both our countries have wrestled with issues of the admissibility and interpretation of purportedly scientific evidence—such as fingerprints, ballistics and handwriting identification—for much of the past century. Our regulatory bodies responsible for evaluating the safety and effectiveness of new medical treatments have historically relied largely on the results of scientific research, interpreted by scientific experts, to reach decisions. In the domain of environmental regulation, the role of scientists is at least as influential as that of lawyers.

Thus, you might well ask why our National Academy of Science now claims to have created a "new" program to explore the connections between science and the legal system. Surely this must be viewed as "old news", if "news" at all.

The reality, however, is that while the two domains have long interacted, they rarely have self-consciously cooperated and the systematic study of how they relate is relatively new. One can see this in the recent emergence, in North American universities, of research centers and institutes, and even degree programs, in "science policy" and the arrival of courses with "science" in the title in many U.S. law schools.

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[1] M.H. Hoeflich & K.J. Nordheden, "Lawyers & Scientists" [preliminary draft].

I cannot say for certain what has kindled this surge of interest among scholars and within institutions—among practitioners of both professions. The explanations surely are multiple and complex. But it may be instructive to describe the origins of the NAS program I have the privilege of assisting, because it says something about both the importance of mutual understanding and the impact of efforts to improve the quality and relevance of the science provided to legal decision makers.

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As many of you know, over the past two decades American courts have been the scene of many large—often class-action—suits seeking damages for injuries assertedly caused by consumer products or industrial chemicals. One need only name some of the materials involved—DES, the Dalkon Shield, Agent Orange, Bendectin—to confirm the point. (Many of these have triggered lawsuits in Canada as well.)

In these "toxic tort" suits, lawyers for both plaintiffs and defendants have typically relied on scientific experts and, often, on the reports of scientific research that the expert witnesses, or others, had conducted. A common issue in almost all of these cases was whether the chemical that the plaintiffs ingested or the product to which they were exposed caused the injuries from which, in most instances, they undoubtedly suffered.

The common pattern was for the plaintiff to offer expert testimony, sometimes based on epidemiologic studies, that her injury was of a kind that the defendant's product could cause and was, in fact, likely to have been caused by exposure to the product. The defendant would offer its own experts who, pointing to other studies, testified that the product had not been shown to cause harm of the type the plaintiff experienced and in any case could not be found to have caused the plaintiff's harm.

In many individual cases, of course, each side offered additional evidence about the type of injury and the extent of exposure to the product, but the core of each side's case was usually studies conducted on groups of persons who used or were exposed to the defendant's product. (In most such cases the plaintiff's illness is one also experienced by persons who have never been exposed to the defendant's product, and examination of the plaintiff cannot differentiate her case from this "background.") Generally, these studies had not been conducted by either party or for the litigation; they were undertaken for other purposes and reported in the scientific literature.

The key point is that in the cases fitting my mold, the parties were asking the court (alone or through a jury) to reach a conclusion about a critical issue based on evidence produced, and often presented, by scientific experts. Just as important, the issue requiring resolution by the legal system—whether a product or chemical could cause human disease—was at the same time an issue of interest for the public health community.

This seeming congruence between judicial inquiry and scientific curiosity was dramatized when a succession of plaintiffs sought to recover damages for the same type of harm, thus inviting the legal system to resolve the same "scientific" issue repeatedly and exposing the diversity of legal answers to what scientists (or at least any who noticed) would have considered the same question. When many alleged victims were drawn into a single judicial proceeding, as in our famous *Agent Orange* litigation before U.S. District Judge Jack Weinstein, the congruence seemed inescapable. It is obvious that Judge Weinstein appreciated the potential for conflict between the emerging consensus among scientists who had studied the evidence and a jury verdict that dioxin had in fact caused the plaintiffs' injuries. He wrote an opinion that as much as said that the legal system should not permit an answer that the informed scientific community would not accept as "true."[2]

This brief survey provides the background for a trio of cases in which our Supreme Court has wrestled with the treatment of scientific evidence.

In the early 1990s, the maker of the drug Bendectin found itself faced by several hundred lawsuits by women who had taken the drug during pregnancy and later given birth to children suffering from birth defects. A recurrent issue, obviously, was whether Bendectin could cause such defects, and expert witnesses—often the same witnesses—offered their conflicting opinions on this issue in series of cases. Eventually, one of these cases reached our Supreme Court from the Ninth Circuit Court of Appeals, which had ruled that the expert testimony offered by the plaintiff, a Mrs Daubert, did not meet the standard for admission under the Federal Rules of Evidence. The Supreme Court had not previously addressed the Rules' standard for the admission of scientific evidence.

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2 *In Re Agent Orange* Product Liability Litigation, 597 F. Supp. 740 (E.D.N.Y. 1984).

Some of you may be familiar with the Court's now famous *Daubert* decision.[3] In an opinion by the late Justice Harry Blackmun, a student of mathematics who harbored a continuing interest in scientific issues, the Court held that the new evidence rules had replaced the old *Frye* standard for admission of expert testimony. Under the new rules, before admitting such testimony, a trial judge should be satisfied that it rests on sound and relevant science.

In the key passage of the Court's majority opinion, Justice Blackmun wrote:

> "Faced with a proffer of expert scientific testimony […] the trial judge must determine at the outset […] whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue […]."

Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge… will be whether it can be (and has been) tested…

Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication…

Additionally, in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error…

I will turn presently to the results of the Supreme Court's *Daubert* ruling. Immediately, I want to address how the case was presented to the Court. In addition to briefs by the immediate parties, the case attracted briefs by several "friends of the court." Among these was a brief submitted jointly on behalf of the American Association for the Advancement of Science, our country's largest organization of scientific professionals, and by the National Academy of Science.

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[3] *Daubert* v. *Merrell Dow Pharmaceuticals Inc*., 509 U.S. 579 (1993).

I was not privy to the deliberations that went on before the officers of the AAAS and the NAS decided to take the unusual step of communicating their views to the Supreme Court in a case whose immediate outcome could not have affected them in any way. However, I have to think that they saw the *Daubert* case as a rare opportunity to try to convince the Justices that civil lawsuits sometimes require resolution of factual issues of as great concern to the scientific community as to the immediate parties, and to try to convince them that the evidentiary standards should not differ.

The *Daubert* decision has sparked a barrage of scholarly commentary and a veritable avalanche of judicial discussion.[4] Of most immediate interest, though, the decision created two opportunities for the Court to revisit the general issue of expert scientific evidence in civil litigation.

As I have described, Justice Blackmun's majority opinion imposed on federal trial judges the responsibility to scrutinize proffered testimony for its scientific reliability as well as its factual relevance. This mandate had implicit, albeit uncertain, implications for the federal appellate courts that would be asked to review the performance of trial judges. In *General Electric Co*. v. *Joiner*,[5] the Court addressed this question. It endorsed the primacy of trial judges, holding that their rulings on admissibility—whether to admit or exclude—were to be upheld unless an obvious abuse of discretion.

A few terms later, the Court was asked to address the standard for admission of a different kind of expert testimony. In *Daubert*, the evidence in question had been the testimony of a plaintiff's expert who put forward an unorthodox (and unpublished) approach to the interpretation of the at best equivocal epidemiologic evidence on Bendectin's capacity to cause birth defects. In *Kumho Tire Co*. v. *Carmichael*,[6] a suit for injuries resulting from a motor vehicle accident caused by an exploding tire, the disputed testimony was that of a purported expert who was to explain to the jury how the tire failed. Writing for the Court, Justice Breyer—who has taken personal interest in the work of our Panel—ruled that the same criteria of scientific

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4 Much of the commentary, academic and judicial, is described in M. Berger, "Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts" (1997) Colum. L. Rev. 2117. See also L. Finley, "Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules" (1999) 49 De Paul L. Rev. 335.

5 522 U.S. 136 (1997).

6 119 S.Ct. 1167 (1999).

reliability should be considered in determining whether to admit "engineering" testimony.

This cursory survey of what has become known as the Supreme Court's "trilogy" has two roles in my remarks this morning.

First, it helps explain why our Panel was established in the first place. Participation in the *Daubert* litigation stemmed from a recognition among the Academy's officers that science and law had overlapping, potentially conflicting, responsibilities. Our Panel's charge is, in part, to identify, study, and recommend strategies for dealing with these areas of intersection.

But the *Daubert* story is more significant as lens through which our Panel—and perhaps this conference—might view the contexts in which law and science meet and assess the impact of efforts to improve the legal system's handling of scientific evidence. With the latter focus, I want to explore with you, briefly, one implication of *Daubert* in its immediate context—the adjudication of "toxic tort" suits.

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As a formal matter, *Daubert* is binding only on our federal courts, and federal trial judges are clearly taking pains to follow the Supreme Court's lead. Among the state courts, where most tort cases are still tried, the picture is more complicated. In many states that have copied the Federal Rules of Evidence, courts have accepted the Supreme Court's interpretation. Several other state courts, however, have explicitly declined to abandon the old "general acceptance" standard of *Frye*.[7] Since that standard also permits judicial scrutiny of proffered expert testimony, however, it is unclear whether this formal division of authority signifies a real difference in judicial behavior.

We lack good evidence about *Daubert*'s impact on case outcomes. Several studies are under way but none has been reported. There is, however, concern among some scholars—echoed by the plaintiffs' trial bar—that *Daubert*'s insistence on "good science" will systematically favor defendants by making it harder to link a plaintiff's disease with exposure to a particular product or chemical.[8] These scholars point out that some federal courts have

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[7] See H. Hamilton, "The Movement from Frye to Daubert: Where Do the States Stand?" (1998) 38 Jurimetrics J. 201.

[8] See, *e.g.*, M. Berger, *supra* note 4; L. Finley, *supra* note 4.

refused to admit testimony that would previously have permitted a jury finding that a plaintiff's illness was probably caused by the defendant's product. The reasoning reflected in these cases may seem occult, but it is worth exploring briefly because it reveals a possible tension between expectations that courts rely on "good science", on the one hand, and do justice, on the other.

The current controversy centers around the proper handling of epidemiologic evidence—testimony based on studies designed to reveal whether a material, such as, for example, the silicone in breast implants, is a cause of human disease and, if so, with what frequency. In the community of epidemiology, the convention is to report the results of such studies in terms of "relative risk"—a numerical expression of the frequency with which persons exposed to a material experience disease compared with the frequency exhibited by a control population of persons who were never exposed. A Relative Risk of 1.0 stands for no difference in frequency. A Relative Risk greater than 1.0 is evidence of a positive association between exposure and disease.

(For a few well-studied exposures, *e.g.*, smoking, Relative Risks as high as 10 have been reported, but these are rare; most environmental exposures, even those acknowledged to be hazardous, are not responsible for risks as great as 2.0, though they are recognized as legitimate targets of regulation.)

Among reported post-*Daubert* decisions, one can find several that suggest that judgment for the defendant is appropriate in the absence of epidemiological studies showing a Relative Risk greater than 1.0—on the premise that without such evidence a jury could not reasonably conclude that the defendant's product was a possible cause of the plaintiff's disease. Though noteworthy, these decisions do not excite controversy. But another set of decisions does.

These are cases that hold that a plaintiff must offer evidence that the defendant's product has been shown responsible for a Relative Risk of 2.0 or greater in order even to get to the jury. The reasoning in these cases is a merger of epidemiological analysis with the law's preponderance of the evidence standard, and it goes like this: unless a product carries a Relative Risk of greater than 1.0, it cannot be considered a possible cause of the plaintiff's disease. But even if the Relative Risk is, say, 1.5, such evidence cannot support a finding for the plaintiff because it means that the product could, at most, have caused a third of the cases of disease observed—two-thirds being the result of some other cause(s). Only if the Relative Risk

exceeds 2.0, *i.e.*, only if the product doubles the risk, can it be said that the product was more likely than not to have been the cause in a specific case.

Of course, the scientific evidence surrounding the issue of causation is not always this simple, but lawyers can often make it appear sufficiently clear-cut to support a motion to exclude or for judgment in favor of the defendant. The result of accepting the reasoning reflected in these cases is to take from the jury cases that, prior to *Daubert*, would likely have been decided there and might well have resulted in a verdict for the plaintiff.

These cases distress critics who see the tort system as serving functions in addition to the accurate attribution of responsibility for disease or injury. Taken on their own terms, they also expose a troubling flaw in a legal regime that is designed to assign responsibility—or establish causation—on an individual, retail basis. The denial of recovery to every plaintiff who cannot show a doubling of risk means that all who are actually injured by the product will be denied recovery. But consider the case in which the epidemiological evidence suggests that the defendant's product is responsible for three fifths of the cases of disease—a Relative Risk of 2.5. On such facts, every person suffering from the disease would, in theory, be entitled to recover even though 40 % of such cases could not have been caused by the defendant's product.

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I have explored one of the implications of our Supreme Court's recent rulings on scientific evidence in some detail because they illustrate a potential tension between the goal of scientific accuracy and the goal of societal fairness. Our NAS Panel has identified several other issues with similar potential. I will mention only a few of them to share some of the flavor of our discussions.

1. It is relatively uncommon for parties in civil suits to undertake relevant scientific research for purposes of litigation. However, one of our Panel members, a Stanford engineering professor, agreed to serve as an expert witness in litigation involving the Dalkon Shield on the condition that he be given support to conduct his own study of the possibility that the filament attached to this contraceptive device to assist removal could become a wick for bacterial transmission. The client agreed; the study was conducted; but only with difficulty was it admitted in the case. Our colleague was disappointed by the resistance of opposing counsel. But he was even more disappointed by the parties' failure to commission and the court's failure to order other research that might have illuminated the issues in the case.

His experience has prompted us to ask ourselves whether there should not be means by which judges could encourage, perhaps even mandate, generation of relevant technical evidence that the parties to litigation seem disinclined to provide.

2. We have put on our agenda the role and responsibilities of expert scientific witnesses. More than a few observers have pointed out the propensity of litigants to polarize factual issues by enlisting experts whose views mark the extremes of respectable scientific belief, obscuring—or ignoring—what often are broad areas of consensus within the scientific community as a whole.

A number of devices have been suggested to assist judges (and juries) to cope with this reality. In a widely publicized class action involving silicone breast implants, U.S. District Judge Sam Pointer (since retired) invoked his authority, under the rules, to appoint his own experts to assess the evidence surrounding the critical issue—whether women with implants experience an increased incidence of auto-immune disease. From nominees provided by the parties, Judge Pointer assembled a group of four independent academic scientists whose review of all of the public epidemiological studies he then directed the parties to fund. The group's assessment was then made available to the parties to rebut or support, and each of the panel members submitted to one videotaped deposition for introduction at trial.[9]

I don't cite Judge Pointer's novel experiment in order to endorse his solution, but to highlight the growing interest in finding ways to help judges and juries to receive evidence about critical scientific issues in ways that facilitate understanding and contribute to objectivity. In cooperation with the Federal Judicial Center, our Panel will be studying the utility and practicality of this, and various other strategies.

3. The recent spate of litigation in our courts over the health effects of environmental chemicals and consumer products has stimulated interest in judicial education. The aim is to help judges understand the growing volume of technical evidence that they confront. There have been several innovations in this area, though assessment of their use and utility still lags.

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[9] See W. Schwarzer & J. Cecil, "Management of Expert Evidence" in FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (2d ed. 2000), at 59-66.

One of the most useful measures, in my view, was the Federal Judicial Center's publication a few years ago of a "Reference Manual" for judges.[10] The official audience is federal judges, but the manual is available to state judges as well. It contains chapters—written for lay understanding—on epidemiology, toxicology, statistics, regression analysis, and various social science research methodologies.

In 1980, my own law school, with the support of the ABA Appellate Judges Conference, launched a new degree program for appellate judges. The curriculum is designed to expose judges to disciplines that most escaped in law school but now encounter increasingly in litigation. The University of Virginia program features courses in social science methods (including statistical analysis), economic analysis, and regulation of, and liability for, toxic chemicals (my own course, which includes large doses of epidemiology and toxicology). Since the program's inception, nearly 300 judges—over a third of the state appellate bench—have completed our curriculum.

Our program is unique in its breadth and duration, but not in its objectives. Several other respected organizations offer advanced training for judges with emphasis on the research disciplines they confront in court.

4. My remarks suggest a preoccupation with court litigation, but in fact our Panel's interest extends well beyond the judicial arena. One could legitimately argue that the important intersections between science and law lie elsewhere—in the work of administrative agencies and the legislative branch. Agencies like our Environmental Protection Agency and Food and Drug Administration—like their counterparts here in Canada—are omnivorous consumers of scientific evidence. Indeed, they are dependent on the work product of scientists, and of course they are largely staffed with scientists. Competence to understand the evidence available may therefore be presumed.

But dependence on scientific research raises other issues: how do regulators obtain relevant information about the nature of environmental hazards to health, the clinical performance of medicines and medical devices, the nutritional value of new foods, or the ecological implications of biotechnology? How is scientific quality to be assured? By what means can decision makers confirm that research is honestly reported? And through what processes can agencies allow for public examination of research results—whether publicly funded or privately commissioned?

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[10] See *supra* note 9.

Recently, a major controversy over our EPA's efforts to force further reductions in certain common air pollutants, specifically particulate matter, brought several of these issues before our Congress. Under our complex air pollution law, EPA is to establish health-based National Ambient Air Quality Standards for the major health-affecting pollutants, including particulates. The States then are responsible for imposing control measures sufficient to achieve the standards.

In 1996, EPA announced a new, lower standard for particulates based in part on the results of a study conducted at the Harvard School of Public Health. Achievement of the standard would impose significant costs on many industrial dischargers and on the localities where they are located, so there were immediate protests and threats of litigation. Opponents of the EPA initiative demanded to see the data compiled by the Harvard researchers—not just the report of their study which had been published in one of the nation's premier scientific journals, but the actual records of pollution levels, exposure patterns, and patient health records. They contended that they could not effectively contest the EPA findings without an opportunity to see, study, and challenge the researchers' recorded accounts of what they found.[11]

EPA resisted this demand on two grounds. First, it pointed out that it was not in possession of the raw data; the researchers still had it. Second, it argued that disclosure of all of the material sought would invade the privacy of the individuals whose health records had been studied. The agency's critics caught the attention of members of Congress, which in the closing days of the 1998 session enacted legislation providing that all research data compiled by researchers whose work has been supported by the government shall be available for public disclosure under our Freedom of Information Act.[12] The law does not apply to research conducted without federal funding. However, neither is it limited to research whose results are relied upon for regulatory purposes.

The implications of this new "open government" law for American scientists are profound. If research records are subject to public disclosure, they must be more carefully compiled. They must be kept accessible. Money must be spent both in maintenance and, when requested, in production. The burdens of responding, indeed of just preparing to respond, to an agency

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[11] See J. Kaiser, "Showdown over Clean Air Science" (1977) 275 Science 466.

[12] Pub. L. N° 105-277. See E. King & R. Merrill, "The Shelby Amendment and Informal Rulemaking" [preliminary manuscript, September 18, 2000].

request generated by a demand from rulemaking participants will be significant.

This is a disconcerting picture of what lies in store for researchers who accept federal money, but the truth is that the interest that inspired the so-called Shelby Amendment is both understandable and, at bottom, legitimate. When a government agency purports to rely on important research findings to support a major new program—whose benefits should justify the cost—affected enterprises, not to mention members of Congress and of the public, have an understandable interest in assuring that the reported findings actually match the recorded data. This interest cannot be easily satisfied without providing—someone—an opportunity to validate the underlying data.

This argument, of course, is not limited to data supporting government funded research; it applies with equal force to research to which government has not contributed a penny. This would include the studies that manufacturers of medicines and devices and other licensed products conduct to secure governmental approval—studies that are now kept secret. In this respect, the new amendment is one-sided.

The debate over public access to research data is growing in both intensity and scope. Our Panel has just begun its effort to identify, characterize, and assess the competing interests. The first exhibition of this interest will be a public workshop next March in Washington. But even at this preliminary stage, it should be obvious that finding a balanced solution that recognizes the burdens on researchers, the interests of parties affected by research-based governmental regulation, and the interest of citizens in the way their tax dollars are spent will not be easy.

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I have trespassed on your time long enough. The design of this program makes clear that this audience does not need convincing that science plays an important role—an increasingly important role—in the legal system. My survey of issues that prompted the creation of the NAS Panel illustrates the extent of our dependence on the scientific community. I hope that my introduction also confirms the importance of the subject to which you have committed the next three days.