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Burden of Proof: Judging Science and Protecting Public Health in (and out of) the Courtroom

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A bankruptcy court in Bay City, Mich, is currently deciding whether to accept Dow Corning's bankruptcy reorganization plan, which includes $3.2 billion to settle claims by approximately 170 000 women that its silicone breast implants injured them in a wide variety of ways. When the plan was filed in November 1998, the president of Dow Corning said, "This is a landmark settlement that moves the process forward to fairly resolve the breast implant controversy. . . . Both sides have compromised so that women can finally resolve their claims."[1] Others were not so sanguine: "What doesn't seem likely to result from this otherwise sensible conclusion is any real progress toward final or official answers on the questions that have propelled this foggy saga from the beginning."[2] Those questions regard the cause of some of the harms suffered by implant recipients. Most recent epidemiological evidence, for example, seems to support Dow Corning's position that silicone breast implants do not cause systemic diseases such as sclerosis, rheumatoid arthritis, and lupus erythematosus.[3,4]

That Dow Corning opted to settle these cases thus seems strange and has occasioned many responses, including the decision to publish this series of papers on the implications of the settlement in this issue of the Journal. Does the Dow Corning settlement, made in the absence of epidemiological evidence regarding systemic disease, indicate that something is fundamentally wrong with the rules under which liability may be imposed on manufacturers whose products cause harm to users? The short answer is no; the longer answer follows.

The Rules of Courts

Courts provide a neutral forum in which private citizens can sue those they believe have caused them harm. Beyond their legal function to provide compensation for injury and to give the makers of dangerous products a financial incentive to try to make them safe, courts also provide a public, democratic forum in which injured consumers can voice their complaints against manufacturers. As any reader of *A Civil Action* knows, it is extraordinarily difficult for an individual citizen or group of citizens, who have the burden of proof, to challenge a major American corporation in the courtroom.[5] This is true even when epidemiological evidence supports causation, as has been true of each of the hundreds of individual tobacco cases that the industry has nonetheless won because juries found that the risk was known to the smoker, who voluntarily accepted it.[6] The breast implant cases alleging systemic disease would all likely have been lost as well had recipients been properly warned of potential dangers by the manufacturer or their surgeons, or had Dow Corning done adequate safety testing before marketing its product. As class action suit critic Marcia Angell has noted, in 1992 "there was... little evidence that [breast implants] were safe, because the manufacturers had not fulfilled their responsibility to look for [dangers]."[4]

Those who think that Dow Corning was nonetheless unfairly forced to settle these cases before the scientific evidence was in have made a number of "tort reform" proposals. One proposal would require judges to permit only published, peer-reviewed scientific evidence into the courtroom.[7] The concern is that juries are overly influenced by "junk science." What would be the effect of making women who believe they have been injured by silicone breast implants delay trying to get compensation for their injury until scientists perform clinical trials that demonstrate causation at the 95% confidence level and publish them in the peer-reviewed literature? Would this make it more or less likely that corporations would adequately test their products for safety prior to marketing them?

In the absence of a federal requirement (there was no such requirement for medical devices when breast implants were first marketed), safety studies are almost never conducted except in response to litigation.[8] This was true of the silicone breast implant studies, which were not begun until after some plaintiffs had prevailed in court. Studies are still being done, and there is no evidence that juries ignore their results. Since 1995, for example, defendants have won 14 of 17 jury verdicts in breast implant cases.[9] What does an injured plaintiff have to prove to demonstrate causation in court?

Causation in the Courtroom

Causation in law is not the same as causation in epidemiology, and the law had to deal with the causation issue long before the field of epidemiology existed. Most scientific journals require epidemiologists to prove their causation hypotheses at the 95% confidence level for publication. This could be translated into the criminal law standard of proof, beyond a reasonable doubt. But the civil standard of proof in product liability cases is preponderance of the evidence (i.e., more likely than not). The goal in the courtroom is not to determine ultimate "truth" but rather to resolve a dispute between 2 adversaries.

Three questions must be addressed in all litigation: Who has the burden of proof? What must be proven? and By what standard must it be proven? One way to decide the answers to these questions is to determine what kind of errors we prefer to make in the process.[10] Specifically, are we more interested in preventing type I or type II errors? Type I error refers to detecting something when it does not exist (false positive), and type II error refers to failing to detect something when it in fact does exist (false negative). Public health professionals are generally much more concerned with avoiding type II errors, since such errors can have wide implications for the public's health.

In the criminal law context, type II errors that allow the guilty to go free are preferred to type I errors that put innocent people in jail. This is why proof beyond a reasonable doubt is required to convict. In the tort context, the type of error one wants to avoid will depend almost exclusively on one's perspective: corporations will favor avoidance of type I errors, whereas consumers will generally favor avoidance of type II errors. Because corporations, through proper design, marketing, and warnings about their products, have the ability to avoid injuries, tort law permits injured individuals to bring suits against manufacturers when-

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Editor's Note. See related articles by Stein (p 484), Macklin (p 487), and Fox (p 493) in this issue.

ever they believe they have been injured and without regard to whether epidemiological evidence has been collected or analyzed. This increases the chance of a type I error, as may be the case in the breast implant litigation, while decreasing the chance of a type II error. Nonetheless, plaintiffs always have the burden of proof.

Legal causation is determined in a context in which the question is whether the defendant is sufficiently responsible for the plaintiff's injuries that the defendant should have to compensate the plaintiff for those injuries.[11] As William Prosser has put it, "As a practical matter, *legal* responsibility must be limited to those causes which are so closely connected with the result and of such significance that the law is justified in imposing liability. Some boundary must be set to liability for the consequences of any act, upon the basis of some social idea of justice or policy."[12] Robert Proctor may, for example, be correct in concluding that by abrogating federal regulatory responsibilities in "the areas of environmental health, consumer product safety, and occupational health and safety . . . Ronald Reagan may have been the most potent new carcinogen of the 1980s."[13] Nonetheless, because of the lack of legal causation, the law would rule as untenable any lawsuit against President Reagan for causing cancer in a particular individual or group of individuals.

Legal causation is thus fundamentally a policy question, but it does have a factual core. Before the jury is permitted to decide whether a defendant caused the plaintiff's injury, the plaintiff must demonstrate "causation in fact."[11] Specifically, the plaintiff must demonstrate, by a preponderance of evidence, that the defendant's acts or omissions were a "substantial factor" in causing injury to the plaintiff.[12] Only if the judge determines that the plaintiff's evidence (usually including expert witnesses) could lead a reasonable person to conclude, as a matter of fact, that the defendant more likely than not caused the injury will the jury be permitted to consider the next question: Should the defendant be held responsible for the injury? This is another way of asking, Is the defendant not only the "legal cause" of the injury but also one of the primary factual causes? How do courts deal with scientific evidence introduced to demonstrate causation in fact?

Science in the Courtroom

Until 1993, the 1923 *Frye* rule, sometimes referred to simply as the "general-acceptance" rule, governed the admissibility of scientific evidence. The *Frye* rule was enunciated by a federal court of appeals in a criminal case in which the defendant sought to present evidence that a crude "deception test" measuring systolic blood pressure (the precursor to the modern polygraph test) showed that he was telling the truth. In affirming its decision to exclude the evidence, the court declared:

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidentiary force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.[14]

In 1993, in the *Daubert* case,[15] the Supreme Court decided that the *Frye* rule had been superseded by the *Federal Rules of Evidence*, which apply to all federal courts and have been adopted by most states as well. These rules basically provide that unless there is a specific exception, all relevant evidence is admissible. Rule 702 governs the admissibility of scientific evidence:

> 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.

The Supreme Court held that although Rule 702 does not require "general acceptance," it does require that all scientific testimony be both "relevant" and "reliable."[15] To qualify as scientific, the Court concluded that the testimony must be grounded in "the methods and procedures of science" and be based on more than simply subjective belief or unsupported speculation. The Court offered 4 "pertinent considerations" for federal trial judges to take into account when deciding whether scientific evidence is reliable. The judges must consider, first, whether the hypothesis set forth by the scientific expert is falsifiable or testable and, second, whether the theory or technique has been subjected to peer review and publication. Publication in a peer-reviewed journal is relevant, because it increases the likelihood of detecting substantive flaws in the scientific method used, but publication is not required, because "it does not necessarily correlate with reliability." Third, the judges must consider the potential rate of error in the method used and, fourth, whether the method or theory has gained general acceptance, which "can be an important fact in ruling particular evidence admissible."[15]

The Court concluded by noting that science and law both attempt to find truth but that there are important differences in their methods and goals. In the Court's words, "Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly."[15] The *Federal Rules of Evidence* were designed to promote "a quick, final, and binding legal judgment . . . about a particular set of events in the past . . . not for the exhaustive search for cosmic understanding."[15]

The great strength of *Daubert* is its firm rejection of any single test, such as publication in a peer-reviewed journal, for determining the admissibility of scientific evidence.[16] Peer review is not infallible, and although one hopes that peer review will "screen out work that is clearly invalid and greatly improve the chances that published work is valid, it cannot guarantee scientific validity."[17] In addition, to the extent that the editors of major peer-reviewed journals have expressed their personal opinions on public policy disputes, "their engagement in public disputes may compromise the very image of neutrality that has supported the public credibility of scientific journals and sustained their policy influence."[18]

There is always some danger that lack of a simple exclusionary test will permit the admission of "junk" science or pseudoscience as evidence in the courtroom.[19] But there are generic safeguards against the likelihood that any specific piece of evidence will be the basis of a final decision in court. All expert witnesses who provide scientific evidence are subject to cross-examination under oath, and the defense may present its own experts (and studies) to refute the evidence. The judge may also appoint independent experts to evaluate the evidence for the jury.

US District Court judge Sam C. Pointer, Jr, who oversees all breast implant litigation in the federal court system, exercised this option by appointing 4 independent experts to evaluate existing scientific evidence in 1996. The panel reported in December 1998 that it could find no scientific evidence that breast implants cause immune system illnesses. Testimony of the 4 experts will be videotaped and is admissible in all future breast implant cases tried in the federal court system.[20] To the extent that "hired guns" representing either industry or consumers are a problem, more use should be made of this option.[4,9] The judge will also carefully instruct the jury on the burden of proof. Moreover, the trial judge can refuse to admit even admissible evidence if its probative value is substantially outweighed by the dangers of prejudicing, confusing, or misleading

the jury or just wasting time.[15] Finally, a judge can override a jury's verdict that is not based on reliable evidence, and all verdicts can be appealed.

Despite an ongoing attempt to amend Rule 702 to make it more precise, there are no credible proposals to require judges to admit only peer-reviewed science or "generally accepted" science.[21] The basic mistake of those who want the same standards for evidence admissibility in court as for publication in a peer-reviewed journal "is in thinking that the conclusion sought by the court is the same conclusion sought by the scientist."[22] Courts must decide disputes today in a socially acceptable way; scientists have no time limit, and their work is always tentative and incomplete.[22,23]

It is also worth at least noting that those who favor changing the legal burden or standard of proof based on the breast implant settlement are guilty of the same "mistake" they accuse the courts of: using an anecdote, unsubstantiated by an epidemiological study of how well courts do generally with product liability cases, to "prove" that courts are incapable of making judgments consistent with existing scientific evidence.

Public Health and Consumer Protection

All of this is interesting, but for most public health professionals it must seem largely beside the point. Public health deals with populations and prevention. A much better question than "What scientific evidence should a woman who believes she has been injured by breast implants be permitted to present in court?" is "What evidence of safety should corporations be required to present in a public forum before they are permitted to put their products on the market?" The thalidomide episode helped convince Americans that it is better to present scientific evidence of safety to the Food and Drug Administration (FDA) before marketing than to present scientific evidence of harm to a jury after injury. The goal in premarket testing is prevention of harm, even at the cost of delaying the introduction of beneficial drugs and devices.

The fact that breast implants were on the market before the time that the FDA had jurisdiction over the safety of medical devices explains, but does not excuse, the industry's failure to conduct reasonable premarketing safety trials of their product.[7,24–26] And after the FDA obtained authority over medical devices, Commissioner Kessler properly observed that "the [FDA] law requires a positive demonstration of safety. . . . The FDA was established as a result of a social mandate. Caveat emptor has never been—and will never be—the philosophy at the FDA."[27]

Of course, judges and juries make mistakes. Suppose it ultimately turns out that silicone breast implants do not cause systemic disease; has Dow Corning been treated unfairly? On one level the answer is certainly yes, since the corporation will have compensated at least some women for harm (those compensated for systemic illness rather than localized injuries) that its product did not cause. On a more fundamental level, however, it would be very difficult to conclude that Dow Corning has been treated unfairly. The corporation had many opportunities to conduct studies before any litigation was brought, and it did nothing. It had every opportunity to warn potential users of its product about possible complications (in short, to make sure the surgeons using its implants obtained informed consent from the recipients), and it failed to do this as well.[24] It had the opportunity to do postmarketing surveillance and did none. Finally, it had the opportunity to defend itself in the courtrooms of the United States, most recently with the aid of epidemiological studies to back up its position, but it decided voluntarily to seek the protections of the bankruptcy court to reorganize its business instead.

All of Dow Corning's decisions may strike one as careless, ignorant, or just plain stupid; however, these are all decisions made by Dow Corning, not by the courts, and changing the rules regarding the admissibility of scientific evidence will not make corporations such as Dow Corning wiser or more prudent.

Public Health and Government

Epidemiological evidence is used in a variety of forums and for a variety of purposes. The level of confidence a person or agency will require to make a decision based on such evidence necessarily varies with the goal and the forum. Government acts to protect the public's health primarily through legislation such as occupational health and safety laws, medical licensure, and regulation (e.g., procedures to certify drugs and medical devices "safe and effective" prior to marketing). Congress and state legislatures can use epidemiological evidence to protect the public's health as they see fit, at least as long as the law they enact is "rationally related to a legitimate state interest."[28]

Regulatory agencies are often required by their enabling statutes to examine all relevant data presented to them, and an agency finding or policy decision based in whole or in part on those data will not be disturbed by courts unless the determination is "arbitrary or unreasonable."[29] Congress, for example, recently examined a wide range of epidemiological evidence relating to tobacco and health in its effort to craft a tobacco regulation statute, and should the FDA or another agency ever be given authority to regulate tobacco, it will undoubtedly use epidemiological evidence to bolster its regulations as well. The Environmental Protection Agency also uses its reading of epidemiological studies to make major policy decisions, and its methodology is constantly under challenge and review.[30]

The international environmental movement has enunciated a broader principle—the "precautionary principle"—to apply to all proposed actions that could irreversibly endanger the public's health or the environment. This principle, which has become part of international environmental law, permits protective actions to be taken under conditions of uncertainty (i.e., before there is any conclusive scientific evidence of harm, such as that caused by pollution or the destruction of plant and animal species).[31] It accomplishes this by shifting the burden of proof to corporations to demonstrate that their proposed actions are not likely to cause serious harm to current or future generations before they are permitted to engage in them. This shift in the burden of proof is based on the obvious premise that irreversible and serious harms to the public's health and the environment should be avoided and that society should not have to wait for science to conclusively study the matter before acting to protect itself and the planet.[31,32] Imperfect knowledge is no excuse for governmental or multinational inaction.

Scientific knowledge is essential in developing effective strategies for the prevention of disease and preservation of the biosphere. But science cannot tell us what we should protect and at what cost. These are policy issues that can (and must) be determined long before the scientific studies of causation are even begun. The continuing challenge is to develop effective and democratic forums in which to debate and decide on policies that protect the public's health. □

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Comment: Epidemiology and the New Political Economy of Medicine

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Science, clinical judgment, and money have recently become entwined in American health care in ways that are without precedent in the history of medicine. Among many other changes, the health care industry is joining other sectors of American society in raising the priority accorded to evaluating and communicating about risk.

This paper describes how the new political economy of medical care is creating an unprecedented demand for epidemiological knowledge. First, I summarize the conventional opinion of historians about the use of epidemiology in clinical medicine. Then I explain why the contemporary revision of the social contract between medicine and American society is creating an intense demand for knowledge based on the study of defined populations. Next, I explore implications of this new social contract for physicians, patients, and purchasers.

Finally, I address a paradox. Throughout the 20th century, academic physicians and most practitioners of medicine have taken pride in being at the forefront of scientific progress. Yet, medical care may be one of the last sectors of society in industrial countries to embrace fully probabilistic thinking.

At the request of the editor of this section of the Journal, the present article explores contemporary history relevant to the controversy about silicone breast implants. This controversy offers practical examples of the conflict between the certitudes of a decaying social contract and the implications of another that is emerging.

The Historically Low Salience of Epidemiology for Clinicians

Most physicians during the past century have had low regard for epidemiology as a guide, much less as a standard, for clinical practice. Surveillance of the incidence and prevalence of disease in populations might be a useful basis for public health policy; controlled studies of the effects of a new drug or device were a useful tool of regulatory policy. But physicians made clinical policy—their collective view of appropriate interventions—and treated individual patients mainly on the strength of information they derived from laboratory-based research in biology and chemistry in the context of observation and personal experience.

Most consumers of health care had no basis for challenging either the concepts or the evidence with which physicians made clinical policy. Those who could shop for physicians often inquired about reputations and, frequently, hospital and academic affiliations. When consumers and their lawyers sued for damages as a result of medical care, they expected expert witnesses (for both sides) to offer opinions that were grounded in laboratory science, observation, and personal experience, as well as in epidemiological research. Annas argues elsewhere in this section that "causation in the law is not the same as causation in epidemiology."[1] This is certainly the case, but there is compelling evidence that, over time, the legal system takes account of changes in prevailing views of biomedical science just as it does of changes in economics and sociology.

A recent history of "scientific and therapeutic reform" in the United States[2] concludes that most physicians' appreciation of epidemiology has not improved during the past century. According to Marks, the typical physician "remains blissfully ignorant of the statistical concepts that underwrite the design and interpretation of clinical trials."[2] In 1997 he found no studies challenging a famous

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