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Introduction to the Symposium

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SCIENCE FOR JUDGES VI INTRODUCTION

*Margaret A. Berger**

Once again, the *Journal of Law and Policy* is publishing papers relating to science and law that had their inception at a *Science for Judges* program for federal and state judges.¹ The program, held at Brooklyn Law School on November 4 and 5, 2005, was the sixth in a series of conferences funded by the Common Benefit Trust established in the Silicone Breast Implant Products Liability Litigation. These programs have been presented under the auspices of Brooklyn Law School's Center for Health, Science and Public Policy in collaboration with the Federal Judicial Center, the National Center for State Courts, and the Committee on Science, Technology and Law of the National Academies of Science.

November's program conference was devoted to an exploration of evidence-based medicine. Understanding the methodology that evidence-based medicine brings to an evaluation of medical research seemed highly compatible with the objectives of these programs for judges because medical experts are among the most commonly used experts in court proceedings. They testify frequently in a wide variety of cases, such as toxic tort cases,

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¹ Papers from previous *Science for Judges* programs can be found in 12 J.L. & POL'Y 1, 1-53 (2003) (papers discussing the practice of epidemiology and the science produced by administrative agencies); 12 J.L. & POL'Y 485, 485-639 (2004) (papers discussing toxicology and epidemiology); 13 J.L. & POL'Y 1, 1-179 (2005) (papers discussing the integrity of scientific research and forensic evidence in criminal proceedings); 13 J.L. & POL'Y 499, 499-647 (2005) (papers discussing Agent Orange and human behavior research); 14 J.L. & POL'Y 1, 1-209 (papers discussing risk assessment and data disclosure and protection). All papers are available in electronic form at <http://brooklaw.edu/centers/scienceforjudges/papers.php>.

medical malpractice actions, and insurance coverage disputes. The articles that follow have two major objectives: 1) to examine the role of evidence-based medicine in improving decision making by policy makers in a number of different arenas, and 2) to provide the reader with an understanding of the statistical concepts and technical vocabulary that researchers use when they employ the methodology of evidence-based medicine in reaching a conclusion about a disputed medical intervention, or in deciding that no conclusion is as yet warranted.

The Fox-Greenfield article, *Helping Public Officials Use Research Evaluating Health Care*,² provides background information by tracing the history of the evidence-based medicine movement and its progress in bringing information about outcomes to the attention of policy makers. It suggests that the judiciary too will benefit from knowing how to access systematic reviews and make use of their findings. Gibson's article, *When Good Information Truly Matters: Public Sector Decision Makers Acquiring and Using Research to Inform Their Decisions*,³ follows up on the Fox-Greenfield discussion by examining a trend on the part of public officials to inform themselves rather than relying solely on information that others provide. This trend is leading public officials to seek, commission, and evaluate research needed to make decisions in the public interest. As an example, he then explores the Drug Effectiveness Review Project (DERP), a collaboration of fifteen states and two other organizations that commissions and uses systematic reviews of global research to inform drug purchasing decisions in their Medicaid, corrections, workers' compensation, general health care, and employee benefits programs. In addition to explaining DERP's process, he analyzes the criticisms that have been voiced about this initiative.

Bero's article, *Evaluating Systematic Reviews and Meta-Analyses*,⁴ begins by explaining the strengths and importance of

² Daniel M. Fox & Lee Greenfield, *Helping Public Officials Use Research Evaluating Healthcare*, 14 J.L. & POL'Y 531 (2006).

³ Mark Gibson, *When Good Information Truly Matters: Public Sector Decision Makers Acquiring and Using Research to Inform Their Decisions*, 14 J.L. & POL'Y 553 (2006).

⁴ Lisa A. Bero, *Evaluating Systematic Reviews and Meta-Analyses*, 14 J.L.

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systematic reviews, and by providing an example of a meta-analysis that showed that a widely-used treatment had no effect. She then turns to the complex question of how systematic reviews are evaluated for bias. After discussing how to set up protocols before a study begins, to ensure that researchers cannot adjust their analysis midstream if they are disappointed by the conclusions that are emerging, she turns to defining various types of bias and how bias can be detected and eliminated. Judges and lawyers should find her exposition extremely useful in evaluating studies on which expert witnesses seek to rely. Her discussion also points out, however, how difficult it may be to arrive at a definitive answer. Although evidence-based medicine seeks to arrive at statistically significant research results that are true, Bero's paper acknowledges the many different obstacles that may have to be overcome.

The Lerner-Robertson article, *When There Are No Randomized Controlled Trials: A Case History of a Controversial Procedure for Metastatic Breast Cancer*,⁵ is a fascinating and troubling account of the use of bone marrow transplants to treat advanced cases of breast cancer even though the technique's effectiveness had not been studied. Lerner and Robertson paint a vivid picture of the various forces that combined to demand the transplant procedure despite the lack of scientific information, the huge cost, and deaths that resulted from the treatment. This cautionary tale of oncologists, politicians, scientific fraud, and advocates for women provides a remarkable glimpse of the various players, including the courts which became involved because of suits by women denied insurance coverage. The article also explains how ultimately the ineffectiveness of the transplants was shown despite the absence of randomized controlled trials by using an approach that combined data from uncontrolled trials. Certainly, the value of evidence-based approaches is validated by this experience.

But there is a limit to how useful evidence-based medicine can be in judicial proceedings. Much will depend on the question

& POL'Y 571 (2006).

⁵ Jeffrey C. Lerner & Diane C. Robertson, *When There Are No Randomized Controlled Trials: A Case History of a Controversial Procedure for Metastatic Breast Cancer*, 14 J.L. & POL'Y 597 (2006).

before the court. Systematic reviews of randomized controlled studies are the gold standard in determining whether an intervention is efficacious and may therefore be extremely useful in malpractice cases and insurance disputes. However, observational studies are much more likely to play a role in assessing causation in toxic tort cases.

It is, however, not only the issue that will determine the usefulness of an evidence-based medicine approach. This approach evaluates the strength of existing evidence. Often, of course, in legal proceedings there will be no studies that satisfy the standards of evidence-based medicine. What does the judge do then? How should gaps in knowledge be treated? Can inferences be drawn against a party that possesses information which it failed to supply, such as negative trials, or that failed to conduct additional research? Can one combine other kinds of evidence with studies that are insufficient in themselves to prove the issue in controversy? How does one synthesize these different types of evidence? What is the applicable standard of proof that scientific evidence must meet—is it the rigorous standard that the practitioners of science-based medicine use when they decide a conclusion is warranted, or is it the lower preponderance of evidence standard that applies in civil litigation? What role do conflicts of interest or bias play? These are all fascinating questions that are beyond the scope of this *Science for Judges* program. Some have been discussed at previous programs and at the *Science for Judges VII* program which was held in March 2006. Papers from that conference will be published in a forthcoming issue of the *Journal of Law and Policy*. The oral presentations made at the March program are available now at the *Science for Judges* website.⁶

The articles that follow provide rich food for thought for all those interested in the interaction of science and law and the role of public policy in decision making. The *Science for Judges* program and the *Journal of Law and Policy* wish to thank Dan Fox for

⁶ Brooklyn Law School, Center for Health, Science and Public Policy, Science for Judges, <http://www.brooklaw.edu/centers/scienceforjudges/events.php>.

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assembling the authors of these important and timely pieces.