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THE FEDERALIST SOCIETY, CONFERENCE: CIVIL JUSTICE AND THE LITIGATION PROCESS: Do THE MERITS AND THE SEARCH FOR TRUTH MATTER ANYMORE?, CONFERENCE DIALOGUE, DAY ONE, ROUNDTABLE: SCIENCE AND CIVIL JUSTICE

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ROUNDTABLE: SCIENCE & CIVIL JUSTICE

OPENING

EDWARD WARREN, DISCUSSION LEADER*

As moderator this morning, my role is to be a gatekeeper, which is an important appellation for this morning's discussion because what I would like to discuss is how science is to be effectively used in the civil justice system. In this discussion, I would like to address both *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[1] and other alternative ways in which science can be used effectively, fairly, and justly in the civil justice system.

About a year after *Daubert* was decided, I wrote a short article emphasizing the breadth and evident purpose of the case as set forth in Justice Blackmun's decision.[2] That evident purpose was for the federal courts, particularly at the trial level, to play gatekeeper regarding the use of science in the courtroom. Three years of appellate decisions after *Daubert*, I think on balance, demonstrate that courts are following that lead.[3]

In *Daubert*, on remand, Judge Kozinski evaluated the plaintiffs' experts in terms of whether or not their testimony constituted scientific evidence under the court's definition. Judge Kozinski found their evidence irrelevant and affirmed summary judgment for the defendant.[4] Other courts have read the decision less broadly. Particularly, Judge Barkett of the Eleventh Circuit said the decision was intended to be a loosening of the rules on scientific evidence in the courtroom.[5]

In preparation for today, I read an obscure article written by a practitioner from Albany, New York, who published the piece in the Albany medical annals in 1900. This piece was then republished in the

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* Partner, Kirkland & Ellis.

1. 509 U.S. 579 (1993).

2. *See* Edward W. Warren, *Judge Leventhal's Revenge: The Courts as "Gatekeepers" of "Good Science" After* Daubert, 1994 PUB. INTEREST L. REV. 93, 94.

3. *See, e.g.*, Borawick v. Shay, 68 F.3d 597 (2d Cir. 1995); Hose v. Chicago Northwestern Transp. Co., 70 F.3d 968 (8th Cir. 1995); McCullock v. H.B. Fuller Co., 61 F.3d 1038 (2d Cir. 1995); United States v. Powers, 59 F.3d 1460 (4th Cir. 1995); United States v. Posado, 57 F.3d 428 (5th Cir. 1995).

4. *See* Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1322 (9th Cir. 1995).

5. *See* Joiner v. General Elec. Co., 78 F.3d 524, 530 (11th Cir. 1996).

Harvard Law Review, revealing the author's name: Billings Learned Hand.[6] Judge Hand had an entirely different conception of what should be done. His view was that the expert represented an exception, and an unwarranted one, to the general rule that witnesses should not be able to testify about the ultimate issues in the case.[7] Generally, a defendant on trial for murder cannot be convicted by witnesses who testify that the defendant intended to kill the victim, but experts are an exception. Expert testimony may be used to show intent in such a case, and such a showing could lead to a conviction. The future Judge Hand concluded this exception was unwarranted.[8] He believed a jury was capable of calling upon its general bank of experience to resolve scientific questions, but for the same reasons was incapable of reconciling competing expert testimony, even though, for hundreds of years, it was normal for juries to hear competing scientific expert testimony.[9]

What Judge Hand advocated instead was really conceptually different from that emphasized in the *Frye*[10] through *Daubert* line of cases.[11] Judge Hand argued that scientific questions should be presented to a scientific panel, which would then present its ultimate conclusions on the general issues—those which fall outside the capability of general jurors and society.[12] The resolutions would then be given to the jury as authoritative determinations of general principle on matters of science. Those determinations could be overturned by the jury only if a reasonable jury under all the circumstances would reasonably conclude there was a basis for rejecting them.[13] He envisioned the role of the trial judge in that scenario as overseeing the jury's acceptance or rejection of those general principles and the jury's use of those principles in resolving the causation issues.[14]

So to recapitulate and to try to give some focus to this morning's discussion, one hundred years ago, Judge Hand was saying, as a practicing lawyer, that we have gone down the wrong road. The road we

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6. *See* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV. L. REV. 40 (1902).

7. *See id.* at 45.

8. *See id.* at 45-58.

9. *See id.* at 51-58.

10. Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

11. *See, e.g.*, United States v. Jakobetz, 955 F.2d 786 (2d Cir. 1992); United States v. Two Bulls, 918 F.2d 56 (8th Cir. 1990); United States v. Downing, 753 F.2d 1224 (3d Cir. 1985); United States v. Williams, 583 F.2d 1194 (2d Cir. 1978).

12. *See* Hand, *supra* note 6, at 55-56.

13. *See id.* at 55-58.

14. *See id.* at 55-57.

have gone down attempts to differentiate among those types of scientific testimony that we will allow to be presented to the jury, and those types that we will not. Fundamentally, that differentiation rests upon an exception to the general prohibition against opinion testimony, which is logically unwarranted and which has all kinds of practical consequences.

Judge Hand's counsel was rejected. We have gone down the road with *Daubert* and *Frye*. But today, I want to pose the question of whether Judge Hand was not right all along. Is not the better approach to think in terms of independent scientific evaluation of key questions with that advice being presented as general propositions? The jury would then consider those propositions in a manner analogous to the judge's charge, although the judge's charge would be conclusive on the jury, whereas the scientific judgments would be only presumptive or advisory.

This obviously poses important questions: Are there independent scientific experts out there? Are there unbiased independent scientific experts? Or, is science simply as politicized as everything else in our society today? Are we simply giving up one form of politicization and embracing another? I think another question is: How do we go about finding those experts if they exist? Is there a mechanism that could be suggested other than a judge calling up his cronies or people from his university or someplace else and saying, "Who do you suggest?"—a process which has an informality that provides no guarantee of fairness, openness, or any other consideration we would think necessary. Lastly, is this process possible notwithstanding the fact that the trial judges themselves are so politicized? Do we have a bench capable of turning these issues over to an objective scientific panel, if one could be found, and then following through in the manner suggested by Judge Hand?

We have six panelists here and, with the exception of Peter Huber and Barry Nace, they are all non-lawyers, so they can speak to the scientific questions here. And, coincidentally perhaps, all four know a fair amount about the breast implant litigation. So I suspect we are going to hear, and I would like to have addressed to the extent possible, some of the questions I posed in the context of the breast implant litigation. However, I ask that with two caveats. Number one, I want to make clear at the outset that my law firm—not me but my law firm—is significantly involved in the breast implant litigation. Secondly, I think many in this room know that some of the issues I have suggested here are issues that are alive today in the context of that litigation, and I do not want my remarks to be interpreted as either an endorsement or criticism of the general concept in the context of that particular litigation.

So I have posed several questions: Are there independent scientists? How do we find them? Can judges be trusted to establish a process which itself is unbiased?

Our first speaker is Barry Nace, a well-known plaintiffs' attorney. He is a former president of the American Trial Lawyers Association of

America and has been involved in many of the contemporary controversial tort issues. He can, hopefully, present a general reaction to some of the things I have addressed and give his opinion on whether or not there are alternatives, other than the two general lines I laid out, for how scientific issues might be resolved in the context of civil litigation.

We will then hear from Dr. George Ehrlich, who was Chairman of the Arthritis Advisory Committee of the Food and Drug Administration and an Adjunct Professor of Medicine at the University of Pennsylvania Medical School. He is a thoughtful critic of the scientific process in the courts and is particularly prepared to speak to the difficulty that jurors and judges alike have in dealing with statistics and questions where numeracy, or the ability to deal with numbers, is at issue.

Then, we have Dr. Norman Anderson of the Johns Hopkins Medical School. Dr. Anderson will speak of the regulatory process and the role that regulatory agencies in that process tend to play and the interaction between the regulatory process and the civil justice system.

We then have Dr. Stuart Schlossman, who is a Professor of Medicine at Harvard Medical School. Professor Schlossman developed a number of the assays used to test for immune system depression and is a critic on how those assays, or alternatives to them, have been used in the court system.

Then we have Gina Kolata, who is a science and medical reporter for the *New York Times*, and who has written extensively about breast implant issues. She is one of our panelists who I think is a little beyond breast implants, although she is very knowledgeable about that, because I think many of us on both sides, plaintiff and defense, recognize that the Heisenberg uncertainty principle[15] certainly applies to the press. The press are not merely observers whose actions do not affect the process; they are very much involved. I would like Ms. Kolata to comment on the press' special responsibility in this area.

Lastly, Peter Huber needs no introduction at all. It is well known that Mr. Huber has written extensively in a variety of areas. I guess I would think of Peter as more than an expert in this area, but, indeed, the leading commentator nationwide today on technical and scientific issues as they relate to the judicial system. He is so well-versed that he turns from one topic to another with great aplomb. But I am sure Peter will have many views on all the subjects I raised and the issues presented by others on the panel.

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15. For a discussion of the principle of uncertainty and its relationship to statistical data as evidence of causation, see Margaret G. Farrell, Daubert v. Merrell Dow Pharmaceuticals, Inc.*: Epistemiology and Legal Process*, 15 CARDOZO L. REV. 2183, 2193-94 (1994).

So with no further introduction, I will turn the panel over to Mr. Nace.

SCIENCE AND CIVIL JUSTICE: A RECENT OXYMORON

BARRY J. NACE, FIRST PANELIST*

I guess I should say that it is nice to be here with a group that most of my friends would refer to as "right-wing radical." When I was asked to be on this panel, I thought, "Well, what do I want to go to that group for?" But, then I realized it is not very often I have the chance to be on a panel with someone who has written about me, who has said I was a poet of the Bendectin litigation,[1] who wrote about my cases but never consulted me about them, and who has quoted me only partially. So I thought that was a good reason to join the panel. Then, I realized that this organization also has a local judge as a member, who once said to me, "Gee, Barry, I had to J.N.O.V. that case because you just tried a better case than the other guy." That sounds fair.

Yet another member of this organization has criticized me, the Bendectin litigation, and even the Supreme Court, for taking *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[2] even though he never had one of the cases himself. He was a judge. There was also the opportunity to speak to an organization that I looked at, and I think that most of my colleagues did too, as one that is dedicated to eliminating jury trials for individuals and to making life as difficult as possible for plaintiffs and their attorneys to ever succeed—an organization that, I think, mostly fears juries. This is also an opportunity to speak in front of a group that is very unusual for me to appear before—a group that does not represent people from time to

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1. Bendectin was a prescription drug prescribed for the treatment of nausea during a woman's pregnancy. *See* Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 582 (1993). Bendectin suits are typically products liability actions for birth defects in children resulting from the mother's ingestion of Bendectin during pregnancy. *See, e.g., id.* at 582; Brock v. Merrell Dow Pharm., Inc., 874 F.2d 307 (5th Cir. 1989); *In re* Bendectin Litig., 857 F.2d 290 (6th Cir. 1988); Watson v. Merrell Dow Pharmaceuticals, Inc., 769 F.2d 354 (6th Cir. 1985). For cases in which Barry Nace has participated, see, e.g., *Raynor v. Merrell Dow Pharmaceuticals, Inc.*, 104 F.3d 1371 (D.C. Cir. 1997); *Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996); *Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir. 1990); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988); *Koller v. Richardson-Merrell, Inc.*, 737 F.2d 1038 (D.C. Cir. 1984); *Merrell Dow Pharmaceuticals, Inc., v. Oxendine*, 649 A.2d 825 (D.C. 1994); *Merrell Dow Pharmaceuticals, Inc., v. Hauner*, 907 S.W.2d 535 (Tex. App. 1994).

2. 509 U.S. 579.

time. This is kind of a unique experience for me, and, as I think about it, maybe I would rather be in Philadelphia. I do not know.

I graduated from law school in Pennsylvania (Dickinson), and I also have a degree in chemistry, which is sort of how I got into this area. But, long before I got involved with this subject, I was trying cases in Washington, D.C., and Bethesda, Maryland, as a personal injury attorney. When you read about me, you would think I am part of a huge law firm and that I have been doing these huge things for all these years. Actually, my law firm has five people in it—probably smaller than most of yours.

I was told that the topic today was supposed to be "science and civil justice." First of all, in the last few years, I have seen little civil justice where science is involved. I have seen people get up, put things in briefs, and argue and write things about such subjects as epidemiology, confidence intervals, "proof," and "no evidence," and do it absolutely wrong and know that they are doing it wrong. I have seen the phrase—a very tricky phrase—"junk science," which was coined somewhere along the line. The phrase has turned into what others have called "junk scholarship." I have known of scientists who have been working with the drug companies and who write articles because they are asked to—and this is something for the scientists here to think about—articles that are approved by drug companies even before they are printed.

I have also read opinions written by judges, such as the second *Daubert* decision referred to earlier.[3] I was involved in that case and I have no idea where the facts in that opinion came from. So I often wonder what is going on. I have to admit that in my stronger moments, I really wonder how some people can sleep out there, and in my weaker moments, I wish it would happen to them. But it does not. Regarding science and civil justice, I think we are in a situation right now where anything goes. Anything goes as far as the "end" of winning is met.

Was Judge Hand wrong? If you think that juries and people are stupid, he was not wrong. If you believe juries are not smart enough to handle these issues, then they should not be presented to the juries. But, I do not agree with that premise and for those of us who actually go into courtrooms and try cases, and actually get down there in the pits and deal with people, Judge Hand was wrong. He was wrong just as those judges are wrong who want to decide that a case cannot get to a jury because the judge wants to decide whether or not the conclusion is right. This violates the holding in *Daubert*—which nobody ever contested by the way—that the judge should be allowed to decide only whether or not there is proper methodology.[4]

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3. *See* Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311 (9th Cir. 1995).

4. *See Daubert*, 509 U.S. at 597.

I recently argued a case in a court of appeals that, if you follow Judge Hand's reasoning, should be affirmed on the basis that juries are too stupid to understand the issue.[5] I disagree. The case has been around for twelve years now, twelve years in front of the same judge. There were two summary judgments granted. Obviously, the first one was ultimately unsuccessful, or there would not have been a second. However, after the first motion, the plaintiff had to expand her affidavits, which were very thick and were accompanied by numerous articles. There were two experts—one had one hundred fourteen articles and one had seventy-seven articles. The defendants filed no response.

The plaintiffs were then asked to bring in its experts for a *Daubert* hearing.[6] Before that happened, however, the judge postponed the hearing three times—twice on the day it was scheduled, with the experts already in town. The judge decided there ought to be something prepared by the plaintiffs in a "question and answer format." So that was done.

The expert witnesses then came back into town and were cross-examined for a day. The defendants offered no affidavits or literature to the contrary. In fact, the defendants' attorneys did no more than stand up and blatantly say, "plaintiffs' experts, who are qualified, are wrong." The judge granted summary judgment again. Imagine the expense to the plaintiffs caused by this judge. And we wonder why our citizens so distrust our system of justice.

Judge Barkett, in *Joiner v. General Electric Co.*,[7] also referred to earlier, obviously would have said that was improper, and I would suggest to you that Judge Hand probably would have thought that was a good idea. I was unfamiliar with the story of Judge Hand before today, but I suspect he would have liked that.

Unfortunately, what we lose sight of is that juries can make good decisions and that, as Justice Blackmun said, there is a need for cross-examination.[8] The traditional way of attacking weak evidence is through cross-examination. Attorneys are trained to do that, and certainly those who represent the drug companies and the manufacturers are usually pretty capable attorneys. I have never found a General Motors, Ford, or drug company that could not afford a good attorney, or two, three, four, or ten or twelve in one case for that matter.

I suspect there may be one or two people on my side in this room today, but for those of you who are out there advocating, we need to do more, such as Judge Hand may have suggested. You probably have not

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5. *See Ambrosini*, 101 F.3d at 129.

6. A hearing in which the trial judge determines whether an expert's testimony rests upon a reliable methodology. *See id.*

7. 78 F.3d 524 (11th Cir. 1996).

8. *See Daubert*, 509 U.S. at 596.

tried too many cases and, thus, have not seen the wisdom that exists in juries and in the jury system. I would suggest that before you go too far in supporting something like that, say to yourself: "What if it were me?" "What if it were my child?" "Would I want that done?" "Would I want scientists to have a blue ribbon discussion about this?" If you could find three scientists to have a panel who were not somehow connected with the situation, I would be surprised.

A judge in Michigan recently decided that she wanted to appoint some scientists, so she gave us a list of five scientists. She never did say why. We were supposed to choose three, but there was not one scientist on the list who was not somehow connected to the company. The judge thought that should not matter since I would have a chance to cross-examine the witness. But, stop and think what you would want. What kind of justice would you want if it were your child or spouse or father or mother? Would you want Judge Hand's philosophy or would you want to rely upon attorneys to do the job they are trained to do in the courtroom and in front of the citizens of this country?

THE PERPETUATION OF ERROR

GEORGE EHRLICH, M.D., SECOND PANELIST*

I will not give you a chronology of the silicone breast implant issue at this point, but I will address some of the things that were just said. Yes, as a parent or as a potential litigant, I would want science to prevail because, unlike what was said, that there is one side or another, science does not take sides. True science has no sides; the only side is true science—good science. False science, pseudo-science, and non-science have no place in the argument. Sheila Birnbaum spoke earlier of computers, copiers, faxes, and the Internet.[1] In her early days, there was only carbon paper, and none of these other things were available. In my early days, when I was in medical school, we still used a textbook by William Boyd,[2] a Canadian pathologist, in which he stated that there are not always answers, but that sometimes we would simply have to ascribe outcomes to a visitation from God. However, that concept no longer works because you cannot sue God.

Somebody must be responsible when something goes wrong or when something happens after another event, which is often faulty reasoning. Recently, on *Today*, they talked about the encephalitis mosquitoes in Rhode Island,[3] about the strongest hurricanes since the 1940s, about floods, AIDS, and the Ebola virus—a great many natural events and diseases. The reports bring to mind Pope Innocent VIII's papal Bull, issued in 1484, entitled, *Summis desiderantes affectibus*, in which he legitimized the work of the plaintiffs' attorneys of the time, Kraemer and Sprenger, who had proclaimed that witchcraft was rife and was the cause of all the bad weather and the plagues—such as the Black Plague, smallpox, and "large" pox, which we today know as syphilis—that were decimating Europe,[4] and the many instances of groups of people behaving

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1. *See* Sheila Birnbaum, *Class Certification—The Exception, Not the Rule*, 41 N.Y.L. SCH. L. REV. 347 (1997).

2. *See* WILLIAM BOYD, A TEXTBOOK OF PATHOLOGY: AN INTRODUCTION TO MEDICINE (7th ed. 1961).

3. *See Today: Killer Mosquitoes* (NBC television broadcast, Sept. 12, 1996).

4. For a brief history of physician Johann Weyer and his work to uncover the mass psychosis of his time, see George E. Ehrlich, *Doctors Afield: Johann Weyer and the Witches*, 263 NEW ENG. J. MED. 245-46 (1960).

strangely or reporting untoward symptoms. Following the issue of the Bull, many went on what was, basically, a legitimized witch hunt. There was a Marcia Angell[5] in those days too, named Johann Weyer, who said that certainly there was disease and natural events, but a lot of what was going on was hysteria, which he uncovered.[6] Weyer, too, wrote a book about it, although it was immediately put on the proscribed list by the Church.

Kraemer and Sprenger worked, and their successors worked, so that during the next hundred years more than a million people in Germany accused of practicing witchcraft were executed under horrible circumstances as prescribed in their book. This witch hunt went on despite scientific evidence to the contrary, because everything that happened was blamed on something and someone. The voices of reason included, incidentally, Dr. Johannes Faust—to be later memorialized in plays and operas—and Hans Sachs[7] of Meistersinger fame, and a few brave others. But that is another story.

The fact is that we have been through all this before, and science has been misused before. The symptoms and signs attributed to silicone implants are almost exactly those that in the 19th Century were ascribed to railways by a British physician, Dr. Ericksen.[8] He called it "railway spine," the symptoms of which included cognitive impairment, poor concentration, sleep disturbance, anxiety, irritability, back stiffness and pain, joint pains, pain on movement, headaches and loss of sexual desire. The plaintiffs' lawyers of the day sued the railroads on that basis and won.

Of course, that diagnosis and attribution disappeared and was replaced by neurasthenia at the turn of the century. Today, we have the silicone breast implant syndrome that, because none of the diseases that were previously alleged turned out to occur in any excess, is said to cause "atypical" disease. Atypical disease, of course, is undefinable, and the so-called "experts" who testify to it use circular reasoning to justify their beliefs. Therefore, the problem arises, whom can you believe. In the courtroom, the plaintiffs' attorneys are extremely persuasive, and they

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5. Executive Editor of the *New England Journal of Medicine* and proponent of the view that there is no scientific evidence linking silicone to any disease. She also believes that the process for presenting scientific evidence in the courtroom should be restructured to eliminate lay jurors from evaluating evidence unless it has been proven to scientific certainty. For more discussion on this view, see MARCIA ANGELL, M.D., SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE (1996).

6. *See* Ehrlich, M.D., *supra* note 4, at 245.

7. *See generally* GREGORY ZILBOORG, M.D., THE MEDICAL MAN AND THE WITCH DURING THE RENAISSANCE (1969) (briefly describing the efforts of Hans Sachs).

8. *See* ROBERT FERRARI, WHIPLASH (forthcoming 1997).

often sound much more credible than defense attorneys. Furthermore, their "experts"—and there are few since not many physicians are willing to testify to this so-called syndrome—have paper credentials that compare favorably to those of the defense experts.

So how does one make a decision? Remember that science cannot prove a negative; science can only prove positives. It can confirm an association but cannot conclusively deny one. That is why we use confidence limits and other statistical terms that tell us the chances of an association are small. If every study comes out the same way, pointing in the same direction, then the chances are even smaller that there is a relationship, even if some of the studies lack power because the control group is too small to be definitive.

When talking about an event that receives media attention or a program like Connie Chung's television show, which gave an unopposed view that silicone breast implants cause disease,[9] people are frightened and tend to remember these things. If I ask anyone in this room what you had for dinner last Thursday, most of you will not remember what you had; but, if it was your anniversary, or some other notable event, and you had a special dinner, you would definitely remember. That is why epidemiology usually finds a slightly increased risk for certain things when they check these out, because people do remember when they are so primed and have a reason to remember. They have more reason to remember. However, we do not even find that slight increase in most of the studies here.

So the problem comes down to innumeracy. Many of the physicians who truly believe what they say are innumerate, innumerate being the mathematical equivalent of illiterate. These physicians do not understand that the people they see are funnelled to them, often by attorneys, who represent a specific "numerator" population, and the physicians do not know what the denominator is—they do not know how often something like this occurs in the general population. The physicians only see the people who come to their offices. Berkson, the originator of epidemiologic studies at the Mayo Clinic, long ago defined this problem to the Mayo physicians. He said that some of the diseases, supposedly rare, appear to be very common, but only because they were seen at the Mayo Clinic, to which they were funneled because of the expertise to be found there. They would not be common in the community-at-large. That is precisely the phenomenon we are dealing with here.

So far, no evidence has emerged to suggest that the silicone used in medical devices is immunogenic, that is, that it can cause immune reactions. In fact, no evidence has emerged to show that it can cause any

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9. *See Face to Face with Connie Chung—Breast Implants: Dangerous Devices?* (CBS television broadcast, Dec. 10, 1990).

of the diseases alleged, especially since most of these diseases are no longer said to result from silicone. So we have this vague group of symptoms and signs that no one can verify.

LAWSUIT SCIENCE: LESSONS FROM THE SILICONE BREAST IMPLANT CONTROVERSY

NORMAN ANDERSON, M.D., THIRD PANELIST*

I am here as an historian who tore up prepared remarks when I heard history being revised by the *Wall Street Journal* and an attorney for Dow Corning in the first panel discussion.[1] To amend those views, I will add my understanding of the evolution of silicone breast implant regulation and litigation. I hope you do not dismiss these comments as pure fancy, for I was a bit player in that drama.

In my mind, the silicone story began in the 1960s when an estimated fifty thousand American women received illicit silicone liquid injections to augment their breasts. The results were disastrous. The women developed inflammatory granulomas. The silicone extruded through holes in the breast and caused massive necrosis and scarring. These women now had breasts that felt like rocks and they often faced breast amputation. By the end of the 1970s, there was hardly a plastic surgeon in the United States who was not caring for some of these women.

In the midst of this debacle, the federal court indicted Dow Corning for misbranding, mislabelling, and transporting liquid silicone across state lines for the illicit injection into these women.[2] A huge legal battle followed. In 1971, Dow Corning pled nolo contendere to eight counts and paid a total of five thousand dollars in fines.[3]

The focus then shifted to gel implants where the same liquid silicone was used to swell a gel matrix contained within a silicone elastomer envelope. These prostheses were introduced in 1963 and gained widespread clinical acceptance without extensive safety testing because none was required for any device before Congress passed the Medical Device Amendment in 1976. After that date, silicone breast implants continued in use under provisions of a grandfather clause which permitted the sale of all devices established in the marketplace before regulatory oversight was mandated—with the added caveat that the Food and Drug Administration (FDA) would require scientific proof of the safety and efficacy for each device at some future date.

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1. *See* Sheila Birnbaum, *Class Certification—The Exception, Not the Rule*, 41 N.Y.L. SCH. L. REV. 347 (1997); Max Boot, *Introduction*, 41 N.Y.L. SCH. L. REV. 337 (1997).

2. *See* United States v. Dow Corning Corp., No. 5381 (E.D. Mich. filed Aug. 6, 1967).

3. *See id.* (E.D. Mich. filed July 15, 1971).

Breast implants first came under scientific scrutiny of the FDA in 1978 when an advisory panel composed largely of surgeons concluded that the implants were safe and recommended these devices be moved into Class II where sound manufacturing practices would suffice to protect the consumer.[4] However, the FDA did not accept that advice and ordered a second review of breast implant safety.

I chaired the FDA advisory panel when this reappraisal was undertaken in 1982-1983. We knew that liquid silicone injections destroyed human breast tissue, so the durability of the envelope surrounding the gel became a primary issue. As liquid silicone injections were also illegal, we were surprised to learn—and I think chagrined to learn—that neither the manufacturers or plastic surgeons submitted any convincing data on the incidence of device failure, implant rupture or gel bleed. There were a host of other problems, but the long-term fate of gel implants was certainly not answered. Accordingly, that advisory panel voted unanimously to keep these devices in Class III—safety and efficacy not proven. The same panel also urged the manufacturers and plastic surgeons to work closely with the FDA in resolving these questions.[5] All parties agreed to this course of action in the public hearing, but that accord disintegrated when the closing gavel hit the table.

In the early 1980s, we began hearing of product liability cases where implant ruptures resulted in fluid gel migration anywhere between the clavicle and groin. Since that extravasated silicone could not be effectively removed from body tissues, these women won substantial damage awards in jury trials and out-of-court settlements. Because all of these cases were placed under court protective orders, only manufacturers, attorneys, and their clients knew the precise outcomes of implant ruptures.[6] But this veil of secrecy began lifting as that decade progressed and FDA concerns over safety heightened when numerous anecdotal stories and case reports began describing clinical problems with breast implants.

In 1988, I again chaired an FDA advisory panel whose purpose was to inform all manufacturers that they would soon be required to provide

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4. *See* MARCIA ANGELL, M.D., SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 51 (1996).

5. *See* HUMAN RESOURCES & INTERGOVERNMENTAL RELATIONS SUBCOMM., COMMITTEE ON GOV'T OPERATIONS, 102D CONG., 2D SESS., THE FDA'S REGULATION OF SILICONE BREAST IMPLANTS 4 (Comm. Print 1992) [hereinafter Committee Print]. The devices were ultimately given Class III status. *See* 21 C.F.R. § 878.3540(b) (1996).

6. *See* ANGELL, *supra* note 4, at 52; *cf.* Greg Rushford, *Senator Takes Aim at Secret Court Settlements*, LEGAL TIMES, May 2, 1994, at 1 (quoting Al Cortese, "the defense bar's chief strategist" on secrecy issues, as stating that "[t]he FDA had all the technical information it needed all along . . .").

scientific proof of the safety of the breast implants which they had been marketing for twenty-five years. That goal was achieved, but it was almost obscured by the public furor created by Dow Corning's long-term toxicity study which showed silicone gel produced sarcomas in rats.[7]

However, I was more shaken by two other events at that meeting. The first issue surfaced when women testified they had reported their breast implant-related injuries to manufacturers. Yet, when they returned to seek further action, there was no record of their complaints in the companies' files. Such failure to recognize, record, and report product-related injuries to the FDA probably occurred because existing regulations gave manufacturers the discretionary authority to decide whether any injury was serious and device-related.[8] Certainly, the testimony of these women indicated that the FDA's prime system for monitoring implant related injuries was both flawed and unreliable.

The second problem highlighted at that meeting came when a California attorney, Mr. Dan Bolton,[9] testified there were serious problems associated with silicone breast implants which could not be discussed because he was under a court protective order.[10] This allegation caused real concerns because the panel knew that Mr. Bolton was a plaintiff's attorney in *Maria Stern v. Dow Corning Corp.*[11] where the jury had given the plaintiff a multimillion dollar award comprised largely of punitive damages against the manufacturer which far exceeded the compensatory damages given for personal injury.[12] Faced with the public intimations that data relevant to implant safety had been withheld from FDA scrutiny by court secrecy orders, the panel urged the agency to use its legal powers to unseal and review all breast implant liability

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7. *See* Committee Print, *supra* note 5, at 9; ANGELL, *supra* note 4, at 57-58.

8. *See* Judy Foreman, *Women and Silicone: A History of Risk*, BOSTON GLOBE, Jan. 19, 1992, at 1.

9. Daniel C. Bolton was the trial lawyer in *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116 (9th Cir. 1994), and *Maria Stern v. Dow Corning Corp.*, No. 83-2348 (N.D. Cal. 1984).

10. *See* Don J. DeBenedictis, *FDA Action Spurs Implant Suits: Evidence Unearthed in Earlier Cases Led to Call for a Moratorium*, A.B.A. J., Mar. 1992, at 20; Gina Kolata, *Secrecy Orders in Lawsuits Prompt States' Efforts to Restrict Their Use*, N.Y. TIMES, Feb. 18, 1992, at D10.

11. No. 83-2348; *see also* Kolata, *supra* note 10 (noting that Maria Stern "brought the first product liability suit against the Dow Corning Corporation . . . contend[ing] that the implants leaked silicone throughout her body and caused a life-threatening autoimmune reaction").

12. *See* ANGELL, *supra* note 4, at 52 (noting "a jury award of nearly $2 million"); *see also* Kolata, *supra* note 10, at D10 (noting that Dow later settled this case for an amount which reportedly "ran to seven figures").

cases under protective order. Regrettably, such actions were never taken and the knowledge gap between regulation and litigation persisted.

In 1991, the FDA called for all manufacturers to present scientific proof of the safety and efficacy of silicone breast implants. However, preliminary reviews of these submissions made it quite clear that none would pass muster. Recognizing these deficiencies, breast implant proponents attempted to override the regulatory process using political pressures, congressional lobbying and public relations campaigns. In the midst of this clamor, a new advisory panel was convened. At its first meeting under the glare of television lights, several manufacturers' representatives stood before piles of boxes which they claimed contained new data on implant safety but could not present because procedural rules required manufacturers to submit all data prior to the panel meeting to permit review by FDA staff. After this tardy submission was denied, I requested that one of the FDA administrators obtain this material for review and was then informed that the boxes were empty for this was simply a public relations ploy. Since I have not seen any semblance of such new information put forward by the manufacturers in ensuing years, it does appear that the action was truly a charade for television.

However, subsequent events were influenced more by revelations from the legal scene. These surfaced in *Hopkins v. Dow Corning Corp.*,[13] where the plaintiff alleged that systemic illness was produced by silicone breast implants and won another multimillion dollar award which included both compensatory and punitive damages. Sealed court documents from this case were given to the FDA by a reporter from the *San Francisco Examiner*.[14] This material included information which the FDA had never seen detailing scientific fraud, shoddy production practices and the rush to market implants which bled gel freely with some rupturing within months to release a fluid gel analogous to liquid silicone. Similar revelations immediately appeared in the lay press describing gel bleed from implants which left grease spots upon velvet display cloths and cited corporate documents urging salesmen to scrub implant surfaces free of gel bleed before marketing these devices to plastic surgeons, etc.[15] I will not cite other allegations posed by these documents, but the sum of this information was very disturbing.

Under the glare of this publicity, the FDA imposed a moratorium on breast implant usage. A bitter public debate followed where breast implant proponents co-opted the feminist term "choice" and accused the FDA of adopting a paternalistic stance which denied women's rights. Others, who had been unable to prove implant safety despite thirty years

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13. 33 F.3d 1116.

14. *See* Committee Print, *supra* note 5, at 45-46; ANGELL, *supra* note 4, at 55-56.

15. *See* Committee Print, *supra* note 5, at 33-35; ANGELL, *supra* note 4, at 57-59.

of opportunity, immediately condemned all research critical of breast implants as "junk science."

The FDA ultimately weathered this storm and limited silicone breast implants to restricted use in 1992. At the same time, plaintiffs' attorneys began their standard approach using case precedent to identify clients with illnesses similar to those cited in *Stern* and *Hopkins*. This effort culminated in mass tort actions which built a settlement upon prorated injury and gave the highest payments to replicas of those two cases.[16] Ultimately, this class action settlement floundered leaving a morass of product liability and bankruptcy suits which are still being argued in the courts today.

However, the discovery process initiated by the multi-District Litigation Group of the American Bar Association did add new insights to this controversy. An in-house advisory panel of the FDA reviewed some of this information and concluded as follows:

> The studies Dow Corning omitted from the [pre-market approval] for their silicone gel-filled breast prostheses . . . do contain information significant to determination of the safety and effectiveness of breast implants.
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> . . . .
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> . . . The FDRL studies, in particular, show toxicologic effects of silicone polymers that the manufacturers, including Dow Corning, had been saying cannot be produced in the animal model.
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> . . . .
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> . . . [T]he more salient question should be "was the withholding of these studies an attempt to deceive." The content of the withheld documents can be said to show a pattern. Intelligent people familiar with this material and anxious to obtain agency approval would recognize that these studies would draw more inquiry and justify further investigation into the safety of these devices. It is reasonable to assume that such people would not want this to happen and, being in the position to control the content of the [pre-market approval application], would leave these studies out to improve the changes for [pre-market] approval. This would be almost impossible to prove without further internal documents from Dow clearly recording a

16. *See* Gina Kolata, *A Case of Justice, or a Total Travesty?*, N.Y. TIMES, June 13, 1995, at D1 (noting that "[w]omen were recruited as plaintiffs by lawyers who traveled the country with medical experts").

> conspiracy. If such documents ever did exist, they certainly do not exist now.[17]

As these events unfolded within the FDA, the Dow Corning Corporation abandoned the manufacture of breast implants, changed its leadership, and began coping with the challenges of mass litigation. When they announced their plans to resolve this controversy by funding new scientific research on breast implant safety,[18] I met with Mr. Keith McKenna, the newly appointed CEO of Dow Corning, his medical officer and his epidemiologist. That meeting can best be described as a screening interview designed primarily to learn what types of illnesses I was seeing in implant recipients. But Mr. McKenna made it clear that Dow Corning was willing to commit twenty to thirty million dollars to resolve questions about implants. In reply, I asked, requested, and literally begged that such monies be administered by a panel outside of Dow Corning, so that impartial scientists could decide which issues should be examined. That wish was not honored, and a small circle within Dow Corning went on to fund research directed at corporate needs.

What has emerged is a sophisticated form of lawsuit science where highly selected research by respected investigators has addressed only the issues chosen by Dow Corning. With thirty million dollars spent in this manner and nothing directed towards plaintiffs' concerns or an impartial look at other implant associated problems, the results were inevitable. Epidemiologic studies selected by these mechanisms and published in the *New England Journal of Medicine* failed to support a statistical correlation between breast implants and autoimmune diseases. Those cautious conclusions were inflated by spin doctors to proclaim breast implants as manifestly safe and free from clinical problems. Certainly that information has influenced court decisions and a recent *Daubert* panel in Oregon.

Today, this panel is discussing tort reform and some members are criticizing scientific experts brought into the courts by plaintiffs. I will not defend abuses of that system, but I want to raise this question: With thirty million dollars being spent on selected research, should we not ask what has been omitted from review—and why? Clearly, the incidence of device failure, the consequences of implant rupture, and causes for the soft

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17. Memorandum from task leader of the Breast Prosthesis PMA Review Team of the FDA to Ronald Johnson, Director of the OCS, June 1992, *quoted in* Deposition of Robert R. LeVier, PhD, *In re* Silicone Breast Implants, MDL-926 (N.D. Ala. 1994).

18. *See* Marcia Angell, M.D., *Shattuck Lecture—Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 NEW ENG. J. MED. 1513, 1515 (1996) (noting that breast implant manufacturers began funding studies of the safety of breast implants).

tissue pain syndromes associated with breast implants have been ignored. Indeed, I submit that if studies from the Mayo and Harvard Women's Group had looked at liquid silicone injections into the breast, they would have concluded no illnesses arose from the injections because of limitations in the study design.

My final point is how can any *Daubert* panel—which does not do its own research, but is dependent upon selected research sponsored by the manufacturer—arrive at a fair and sound scientific opinion. I believe the FDA provides scientific review equal to any *Daubert* panel, but its regulatory intent was defeated by the selective suppression and editing of scientific data in the breast implant controversy. Corporate sponsored research can be good business, but its abuses jeopardize both effective regulation and tort reform. If we are going to push for reforms, these must occur on both sides of the bar. The American judicial system should settle for nothing less.

SOME CONSIDERATIONS ON THE MISUSE OF SCIENTIFIC EVIDENCE IN THE COURTROOM

STUART F. SCHLOSSMAN, M.D., FOURTH PANELIST*

I may be one of those scientists who spends ninety-eight percent of his time doing science and a small percentage of his time dealing with the use and misuse of scientific evidence in the courts. The difficulty is that the courts are being asked to deal with medical and scientific problems which they are largely ill-equipped to handle. Perhaps I can give you a bit of my own experience on this matter.

Over the years, I have developed a number of the tests that are used to assess immunologic function in man. The CD4 test, for example, that deals with AIDS and HIV, was developed in my laboratory many years ago, as were many of the others that have been used by plaintiffs' attorneys and experts to evaluate the immune response. I have also been asked to review data on, for example, toxic spills as well as some of the data on silicone breast implants. In a recent toxic spill case, CD26, an antigen that was discovered in my laboratory, was purported to be abnormal in a very large population of individuals that were exposed to this toxic—supposedly toxic—spill. There were no objective clinical symptoms in this population, nor could any immunologist or internist find objective evidence in these patients that their immunologic system was compromised as evidenced by an increased frequency of infections, autoimmunity, susceptibility to a variety of uncommon infections, or higher incidence of cancer. We could not define a particular clinical condition and much of the case rested on the use and misuse of a variety of clinical assays, the validity of which a jury was going to be asked to judge.

The scientific literacy of juries is very low. I think if you asked most juries whether astrology is a scientific area, they would say, "yes." So to ask them to evaluate the health of people who have eighteen percent CD26 positive cells would be very difficult in my mind. Although I discovered the test, I do not know of any diagnostic or predictive value of the test in any disease. Even if I were to argue with individuals who say that it has diagnostic value or predictive value, it would really be my word against theirs. I am not sure a jury can always distinguish the credibility of someone who discovered the test and is a member of the National

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Academy of Scientists from an expert who happens to be practicing clinical ecology in Northern California.

The point is that I was struck by the fact that I did not understand why the CD26 levels in the plaintiffs were high, but accepted, as a scientist, that the data was correct. The defendants' attorneys did not want to repeat the tests. The plaintiffs' attorneys only did the test once, in a laboratory known to give them results they wished. Thus, I asked to see the primary data, and the two huge cartons arrived that were not ballast but were filled with data—and, as it turned out, the CD26 elevations were fabricated.

So the difficult issue is how to assess a variety of tests that are misused by purportedly reputable scientists. Mr. Nace indicated that if it were your child, it would be a terrible thing. I would say that many of the children in that community, who were told they had chemically induced AIDS, are living with a terrible burden and fear that they may develop this terrible disease when, in fact, there was no scientific data to support their claim.

Regarding the breast implant litigation, I think it is true that perhaps the companies did not do enough in the beginning, but the epidemiologic data indicate right now that there is no evidence of a disease. The plaintiffs' lawyers and experts started by saying that maybe there was a higher frequency of cancer. They looked, but there was no increase in cancer.[1] Then they said there was a higher frequency of scleroderma. They looked, but there was no increased incidence of scleroderma.[2] Then they said there was an increased incidence of lupus, but there was no increased incidence of lupus.[3] There is no increased incidence of any connective tissue disease.[4] Subsequently, they said the real problem was that we have missed an atypical symptom complex, and this is what occurred with CD26. It was not that I did not understand CD26, but I did not know the pattern of CD26, plus CD4, plus CD56 was atypical and this

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1. *See* Jack C. Fisher, M.D., *The Silicone Controversy—When Will Science Prevail?*, 326 NEW ENG. J. MED. 1696, 1697 (1992).

2. *See* Marcia Angell, M.D., *Shattuck Lecture—Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 NEW ENG. J. MED. 1513, 1515 (1996); Jorge Sanchez-Guerrero, M.D., et al., *Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 NEW ENG. J. MED. 1666, 1666-70 (1995).

3. *See* Angell, *supra* note 2, at 1515; Sanchez-Guerrero, *supra* note 2, at 1670.

4. *See* Angell, *supra* note 2, at 1515; Sanchez-Guerrero, *supra* note 2, at 1666; *see also* Gina Kolata, *A Case of Justice, or a Total Travesty?*, N.Y. TIMES, June 13, 1995, at D1 (reporting that many independent immunologists and Britain's Medical Devices Agency have pointed to epidemiological studies which have consistently failed to find links between implants and connective tissue diseases).

was a pattern that only the experts for the plaintiffs could see, but which most scientists could not.

To date, we have a fair amount of epidemiologic data that states there is no evidence of disease in patients with breast implants. These studies have not been carried out by people who are supported by the drug companies. These scientists have done magnificent epidemiologic studies and have found no increased incidence of disease. It is totally unfair to have what they said denigrated by announcing they or their institutions may have received support from drug companies.

A second point to consider is that some of the tests used by the plaintiffs' experts, such as the T-cell response to silicone and antibodies to silicone tests, are tests carried out in these individuals' laboratories and have not been replicated or verified by the scientific community. Also, we have suggested that if a test has been peer-reviewed, then it has a certain level of validity. The difficulty is that we did not anticipate that questionable scientists would start their own journals. And those of us who study science really love to get a paper into *Cell*, *Nature*, or *Science*. We even like to get papers into the *New England Journal of Medicine*. But, in contrast to these journals, there are journals that, I can assure you, nobody has even heard of except the small group of individuals that make up the editorial board, and who make sure their friends are on these boards. Therefore, the concept of peer review, and the belief that a jury can deal with these complex issues, is really very difficult for me to accept. Thus, I really must go back to the principle of having expert panels to help judges and lawyers.

I have a son who is a lawyer. He is the one who did not like chemistry and science and blood as a child. I also have a son, who is a physician, who did like mathematics and the other sciences. I believe that even lawyers who got degrees in chemistry, perhaps twenty years ago, were technologically obsolescent a week after they got their degree, just as most of us in the scientific community would be if we failed to keep up.

We are asking juries who are scientifically illiterate to deal with very complex issues. We are asking judges and lawyers who I also think, to a large extent, are scientifically incapable of dealing with very complicated issues. On the other hand, we have many scientific groups in our society such as the National Academy of Medicine, the Institute of Medicine, the American Association of Immunologists, for example, which I think could provide expertise or a panel of unbiased individuals who could help assess the validity of some of the scientific claims that are presently being made.

SCIENCE AND CIVIL JUSTICE

GINA KOLATA, FIFTH PANELIST*

I had the same funny feeling that Mr. Nace had about being in front of a radical right-wing group, because as soon as I got involved in the breast implant controversy and some other stories, I suddenly became the darling of conservative groups. That is a very funny position for me. I never thought of myself as being aligned with one side or another, and it indicated to me how polarized people's opinions get and how much people want you to say what they think fits into their political view of things.

I went at the story as a science reporter, and I am one of those people who does like science. I have a master's degree in mathematics, and I studied molecular biology in graduate school as well. So I like all this stuff, and I consider myself "quantitatively literate," which is the new catch word for people who like to look at this kind of thing. Yet it was not an easy thing for me to report on.

At first, I was not reporting on this topic at the *New York Times*. Somebody else was handling these stories, and we stake out our own claim for things. It was not that somebody told me not to do it; rather, it was that I never said I particularly wanted to do it.

I first became aware of some of the problems with breast implants when I did a story on secrecy in the courts and on court orders that seal information one might want to know.[1] I spoke to Dan Bolton, who told me about a judgment that I believe was in the *Maria Stern* case.[2] He also told me about this incredibly damning evidence that Dow Corning knew, and knows, concerning how dangerous breast implants are and about how they willfully hid their material from the Food and Drug Administration

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1. *See* Gina Kolata, *Secrecy Orders in Lawsuits Prompt States' Efforts to Restrict Their Use*, N.Y. TIMES, Feb. 18, 1992, at D10.

2. Daniel C. Bolton was the trial lawyer in *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116 (9th Cir. 1994), and *Maria Stern v. Dow Corning Corp.*, No. 83-2348 (N.D. Cal. 1984).

(FDA).[3] He also told me that he could not disclose what he knew because of the secrecy order.

That stuck with me. However, I thought that the evidence I had to that point was anecdotal, and as a quantitatively literate science reporter, I was really skeptical of anecdotal evidence. I saw it in the Bendectin case[4] and I was skeptical then. I was skeptical when I saw people coming forward saying that they had scleroderma and breast implants, and, therefore, the breast implants caused the scleroderma. That is like saying, I drank coffee this morning and I have scleroderma; therefore, the coffee caused the scleroderma. You really cannot simply draw that kind of a conclusion, and I think most of us who have been in this business learn not to jump to those conclusions. I was not persuaded by the anecdotes, but I still had my doubts because of the stories that there were secret data that were not provided to the FDA—secret data that were in the hands of Dow Corning, and which the FDA did not have.

Then the scientific evidence started coming out and nothing seemed to be supported.[5] The epidemiology did not seem to be supporting what the plaintiffs' attorneys said. I still kept thinking there might be another piece to the picture. Some data that we did not have—secret data that the FDA saw—prompted the FDA to ask the Justice Department to get involved.[6] It was years later before I found out what came of this. Dow Corning told me, but I checked with the FDA just to be sure.

It turned out, I believe it was during the multi-district litigation, that Dow Corning's lawyers were going through a storeroom with all types of

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3. *See* HUMAN RESOURCES & INTERGOVERNMENTAL RELATIONS SUBCOMM., COMMITTEE ON GOV'T OPERATIONS, 102D CONG., 2D SESS., THE FDA'S REGULATION OF SILICONE BREAST IMPLANTS 29-30 (Comm. Print 1992) [hereinafter Committee Print]; Phillip J. Hilts, *Panel to Consider What Sort of Rules Should Control Gel Implants*, N.Y. TIMES, Feb. 18, 1992, at D10 (stating that an expert "panel was convened by the Food and Drug Administration after the recent disclosure that manufacturers of silicone implants disregarded evidence of possible safety problems for years").

4. *See* Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

5. *See* Marcia Angell, M.D., *Shattuck Lecture—Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 NEW ENG. J. MED. 1513, 1515 (1996); Jorge Sanchez-Guerrero, M.D., et al., *Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 NEW ENG. J. MED. 1666, 1666 (1995); *see also* Gina Kolata, *A Case of Justice, or a Total Travesty?*, N.Y. TIMES, June 13, 1995, at D1 (reporting that many independent immunologists and Britain's Medical Devices Agency have pointed to epidemiological studies which have consistently failed to find links between implants and connective tissue diseases).

6. *See* Kolata, *supra* note 5, at D1 (noting that "the F.D.A. and the Justice Department cleared the company of allegations of withholding data").

documents and came upon something from the FDA and the Justice Department. It said that they had looked at all the information that Dow Corning had not given them and decided that there was nothing new that was not also in the information that Dow Corning did give them. In fact, it could reasonably be argued the information Dow Corning did not give them was of a lesser quality but generally supportive of the information they did give the FDA and Justice Department.[7] So it made sense for Dow Corning not to have necessarily provided the FDA with this other information. It is not that anything was hidden; it was simply that there was nothing new there. It was just information that was not of as high a scientific quality.

I thought that was amazing. Neither the FDA nor the Justice Department ever told Dow Corning; they never mentioned it to anybody; it just went away. I called the FDA, told them I had the document, and asked if it was genuine. I thought perhaps it was an interim report that was later refuted or proven wrong. The FDA told me it was their final report. The Justice Department contacted Dow Corning and said that it was dropping its case, and they never commented on anything else. So as far as we know, there was nothing else. But, as a reporter, this placed a doubt in my mind. The epidemiology never showed anything, but there was always the question of whether the studies were to be trusted.

One suspicious study was conducted by Charlie Hennekens at Harvard.[8] He told me the story behind his study. Dow Corning was asked by the FDA to conduct some studies, and Dr. Hennekens thought he had the perfect population. He had some data and thought he could look back at his study population and ask some of the necessary questions. He thought they could get these data in an unbiased way because the women were part of a different study. The women filled out questionnaires but were not specifically asked whether they had breast implants, if they felt tired, or if they had headaches.[9]

Dr. Hennekens went to David Kessler, the head of the FDA, and told him he had a problem. He explained that he wanted to do the study, but if he did it and Dow Corning paid for it, there was no way to protect the results from future claims of contamination. Dr. Hennekens asked what he might do to maintain his scientific integrity and yet take the funding.

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7. *See* MARCIA ANGELL, M.D., SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 57-60 (1996) (noting that documents indicated "how little was known, how inadequate the studies had been, and how relentlessly the company pursued its marketing goals").

8. *See* Charles H. Hennekens, M.D., et al., *Self-Reported Breast Implants and Connective Tissue Diseases in Female Health Professionals: A Retrospective Cohort Study*, 275 JAMA 616 (1996).

9. *See id.* at 617.

They decided that the best thing to do was to get something in writing from Dow Corning, which stated that it would fund the study but not require disclosure about interim findings. Dr. Hennekens could also say and publish what he wanted, and Dow Corning would not know what he said until he decided to tell them. That is exactly what occurred.

However, when the study came out, people claimed that the results could not be believed because the study was funded by Dow Corning. The results did not show what the plaintiffs' attorneys had hoped they would show. It was simply another one of those studies that did not show much.

When I went to report on these stories—and this comes back to the central question of whether independent scientific experts can be found—I had the same problem that I had with the breast implant stories. Everybody that cared about the data seemed to be associated with one side or another—they were a consultant, an expert witness, or they were something else. When you do a story, and you write, "Dr. So-and-So, who is a consultant for Dow Corning, said he thinks there is nothing there," or "Dr. So-and-So, who is an expert witness for the plaintiffs," people discount it immediately. How do you find independent people? Although it is not simple, it is not, on the other hand, impossible.

When I was reporting on doctors who had deals with lawyers, and who I thought were running women through mills and coming out with the disease they wanted to find and the treatment they wanted to give, I found something else instead. I found doctors who were specialists in those diseases, who had nothing to do with breast implant litigation, and who were more than willing to discuss the issue with me and give some very strong statements. I did not have trouble finding very credible people with very good scientific reputations who were not making any money on this. At first, some people were hesitant to even get involved for fear of being drawn into the litigation as an expert witness. But, many of these doctors felt so strongly about what they were seeing that they decided that they should talk about it anyway.

When I wanted to write about Charlie Hennekens's story, I thought that I should use the same approach. I decided to find epidemiologists who had experience evaluating large studies like this, had never had anything to do with breast implant litigation, had never made any money from it, and who had never consulted for anybody and did not want to, and then ask if they would look at the results and tell me what they thought. I found several people. It did not take a month-long search; it took about a day or so. It was not impossible.

So from my own experience, I agree that it can be difficult to find lay people who understand these complexities. I think that we are talking about a method of reasoning that many people do not understand. They are not used to thinking the way that scientists think and they are not used to evaluating evidence. However, I do not think it is that difficult to find

scientists. We have bodies like the National Research Council that can help us find independent experts to objectively look at studies and evaluate results. This might help to avoid repeating situations like the Bendectin and breast implant litigation, in which we had competing experts.

WHOSE GORE IS STALKED?

PETER HUBER, SIXTH PANELIST*

With only one glaring exception, "junk science" is politically neutral. It is the nature of science and junk science alike that they do not care who they help or hurt. Whoever wrote the laws of science was indifferent to human and social outcomes.

An earlier speaker mentioned my name in connection with tobacco and referred to me, I believe, as an "expert" for one side in these cases. This illustrates, I think, how casual some plaintiffs' lawyers are about who they will designate as an "expert." I have written one *Forbes* column in which I mentioned the economic impacts of tobacco[1] and appeared on two television debates on the subject. This, I now learn, is enough to qualify me as a "leading expert" on the matter.

Well, then, here is my expert opinion. There are three facts about tobacco that richly illustrate how politically neutral facts can be. As a non-smoker with no involvement at all in tobacco litigation, I take none of them personally. I don't get indignant about them. I don't even much care if anybody believes them or not. I take consolation in the knowledge that they are objectively true.

The first is that tobacco companies sold cigarettes in Mississippi. The second is that those sales caused a lot of premature death in Mississippi. And the third is that those deaths saved the State of Mississippi money. Call me the "Angel of Darkness" if you like. It won't change the facts.

Notice that two of those three facts are vigorously contested by lawyers. Most tobacco companies would like to suggest that tobacco did not, in fact, cause premature death. The plaintiffs' lawyers would like to suggest that Mississippi saves a lot of money when its citizens live to a ripe old age. Both sides deserve to lose. We are watching, here, a spectacle in which two packs of liars go after each other. They are just lying about different clusters of facts.

The tobacco packs aren't alone, of course. I watched with great interest when *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[2] went up to the Supreme Court. Both sides wanted experts and professional associations to file amicus briefs on their sides. Steven J. Gould, a renowned paleontologist who teaches at Harvard, allowed his name to be

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1. *See* Peter Huber, *Health, Death and Economics*, FORBES, May 10, 1993, at 172.

2. 509 U.S. 579 (1993).

attached to one of those briefs.[3] I don't know him personally, but politics aside, I admire and like him. Many of you have read his columns and books.[4] Mr. Gould allowed his name to be associated with a brief that supported the plaintiffs, and argued for a lenient definition of "scientific knowledge" for legal purposes. Sharp lines, the brief argued, could not be drawn between good science and junk in court.[5] A curious position, I thought, for a man who, in his other life, has argued so long and hard for maintaining a sharp line between evolution, on the one hand, and "creation science" on the other.[6] Mr. Gould is clear enough on the differences between science and junk in his own field, when such lines coincide with his own political preferences. I wish he had been equally clear when they did not.

But if Steven Gould was right in his *Daubert* brief, what could possibly be wrong with the State of Mississippi legislating, for instance, that its public schools teach only creation science, and not Darwin? If there are no real lines, if one expert is as good as the next, if anybody we hire is as believable as anybody else, how could it possibly be an "establishment of religion" to have one brand of biological "science" taught rather than another? If you believe the *Daubert* plaintiffs, you also have to believe there is no difference between religion and science for First Amendment purposes. After all, there are perfectly solemn and properly dressed, properly credentialed people out there—they don't live under bridges or anything like that—who call themselves "creation scientists." They probably even have their own peer-reviewed journal.

Before *Daubert*, as you know, federal courts applied a standard first articulated in a case called *Frye v. United States*.[7] *Frye*, you will recall, was a criminal case that involved lie-detector evidence.[8] But how many of you remember whether it was the prosecutor or the defendant that submitted the lie detector evidence that the *Frye* court excluded? I won't tell you; if it matters to *your* views about *Frye*, then you will have to go and look it up.[9] It doesn't matter to *mine*. I can tell you that only one

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3. Brief Amici Curiae of Physicians, Scientists, and Historians of Science in Support of Petitioners at 8-11, 14-19, *Daubert*, 509 U.S. at 579 (No. 92-102).

4. *See, e.g.*, STEVEN JAY GOULD, DINOSAUR IN A HAYSTACK (1995); Steven Jay Gould, *Life on Mars? So What?*, N.Y. TIMES, Aug. 11, 1996, at 13; Steven J. Gould, *No More 'Wretched Refuse,'* N.Y. TIMES, June 7, 1995, at A27.

5. *See* Brief Amici Curiae at 8-11, 14-19, *Daubert* (No. 92-102).

6. *See Schools Brief: The Missing Links of Evolution*, ECONOMIST, May 23, 1987, at 86.

7. 293 F. 1013 (D.C. Cir. 1923).

8. *See id.* at 1013.

9. *See id.* at 1014.

side won. But what difference does that make to the accuracy, such as it is, of a lie detector? Either lie detectors work reliably or they don't.

The same goes for DNA evidence. We saw, recently, the spectacle of Barry Scheck advising one side in a much-publicized trial involving a great deal of blood.[10] Now, the science of DNA fingerprinting is what it is, whoever's gore it stalks. It is equally reliable or unreliable, whether submitted by somebody who has been on death row for ten years on a rape-murder charge, and who can now prove that it was not his semen, after all, or whether submitted to put another man on death row in his place. The science is either good or it is bad; it is not just good when you want it to be and bad when that better serves your private ends. Mr. Scheck appears to be yet another prominent lawyer who hasn't fully grasped that point.

Before *Daubert,* the Supreme Court took a case involving a certain "Dr. Death"[11]—a psychiatrist who travels in southern courts testifying about the "future dangerousness" of capital defendants.[12] "Future dangerousness" is a factor that is weighed in capital sentencing in many states.[13] Now, if psychiatric evidence of that kind is reliable, then it should be admitted. And, if it is unmitigated junk—which, in fact, it is—then Dr. Death should not be testifying in court. It is, indeed, abominable that he is ever allowed in the door. Even if for the purpose of sending Ted Bundy to the electric chair.[14] Ted Bundy deserves to go. But no self-respecting legal community deserves Dr. Death. This is just a matter of proper sanitation in court.

Finally, it is rare that I agree with Mr. Nace, but I am happy to agree with him on one small point today. He asked, if I understood him correctly, how any parent of a daughter could wish on the world the kinds of rules of evidence that I support. As it happens, I have three young children, and I have their interests very much at heart. And I cannot possibly believe that any father could wish his children to grow up in a world in which junk science proliferates, and is accepted, not merely in astrology columns that run next to the comics, but in courtrooms called

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10. *See At Simpson Trial, Blood Tests and Bafflement*, N.Y. TIMES, May 23, 1995, at A14.

11. *See* Barefoot v. Estelle, 463 U.S. 880 (1983); *see also* Peter Applebome, *'Blue Line' Aftermath: New Trial Is Possible*, N.Y. TIMES, Dec. 8, 1988, at C19.

12. *See Barefoot*, 463 U.S. at 885.

13. *See, e.g.*, Simmons v. South Carolina, 512 U.S. 154 (1994); Johnson V. Texas, 509 U.S. 350 (1993); Ake v. Oklahoma, 470 U.S. 68 (1985); *Barefoot*, 463 U.S. at 896.

14. *See* Bundy v. State, 455 So. 2d 330 (Fla. 1984).

upon to decide the difference between truth and falsehood.[15] If I imagine all my children as future plaintiffs with completely invalid claims, then of course I might wish for them the kinds of rules that Mr. Nace espouses. But perhaps they will some day be future plaintiffs with *valid* claims, and face junk science from the other side. Or perhaps they will some day be future defendants. Or future prosecutors. In my current state of ignorance, the best I can hope for them is a truthful society, that knows how to maintain good lines between science and the alternatives. The only time you favor junk science is when the facts are against you.

If my child has cancer, and I am suing, I might well want junk science. But if my child has cancer and I am trying to get her treated, I want the Mayo Clinic. Yes indeed, if my child is represented some day by Mr. Nace, I may want every possible edge in her favor. But then, she might instead be one of Mr. Nace's targets, in which case I'd much prefer rules that promote truth and accuracy.

Which brings me to my last point. If you believe that science exists, and that true facts are ascertainable—that belief leads you to a certain view of ordered society. Most people, most of the time, are best served by that view. Only one particular community frequently is not. Only one particular community consistently grows and prospers by rules that blur all the lines between good science and bad. That's the legal community. I do not mean just the plaintiffs' lawyers or the American Trial Lawyers Association. I mean symmetrically, plaintiff and defense lawyers alike. The more uncertainty there is, the more we can pretend that known facts are not known; then the more we can hire legions of lawyers to stage great circus-like battles between hired experts. Defense lawyers are usually not quite so open about their own interests in this regard, because their clients might protest. The fact is, lawyers on both sides of the aisle are served by scientific anarchy.

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15. *See* Barry J. Nace, *Science and Civil Justice: A Recent Oxymoron*, 41 N.Y.L. SCH. L. REV. 393, 396 (1997).

ROUNDTABLE:
AUDIENCE DISCUSSION

EDWARD WARREN: It is the prerogative of the chair to ask one question, and, in a sense, it is the question that I began with: If we accept, as I do, that Judge Hand is right—that a rule that tries to say "this comes in, this doesn't come in, this does, doesn't," based on some *Frye* or *Daubert* standard is illogical and inconsistent with the view that the jury, rather than the witnesses, ought to be addressing the ultimate issues and ought to be addressing the grand and general premises—then it seems to me the question, which I tried to pose initially, is nonetheless still a question. That is, whether there is a way to get "good science" into a decisional status in litigation.

Now, let me say that it may very well be that witnesses for the plaintiffs and the defendants appear each to be carrying his or her own biases, but this does not mean that all scientists are liars or that all scientists are dishonest. That seems to be an example of the very innumeracy that we are talking about.

My hypothesis would be that the scientific community, in general, subscribes to what Peter Huber just said, and that is that science is apolitical, that there really is scientific truth, yea or nay.[1] So the question is whether that apolitical, truthful science is accessible in the judicial process. I would also say, hypothetically, that if it is accessible to Gina Kolata, it also ought to be accessible to federal judges or state judges if they choose to attempt to find it. However, fundamentally, the question seems to be: Will they attempt to find it? So the question—and this is the kind of question that lawyers and judges of good faith must address—is whether there is a mechanism that will permit them to find it in a fashion that is appropriate and reviewable.

I would like at least the scientists here to tell me if they think that Peter Huber is right, that there is something about the truth of science. I would also like to know if Gina Kolata is right, that there is a community—maybe it is ninety-eight percent of the scientific community—that would like to wash its hands of the courtroom, but not of science, and if asked to participate in a way that was consistent with their own self-image and principles, would aid in this process. I would like at least the three scientists and perhaps Barry Nace to just briefly comment on whether they think that those premises have any validity.

DR. GEORGE EHRLICH: I think that there is some validity. I think that we can, and should, get that kind of science; or, if we do not, I do

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1. *See* Peter W. Huber, *Whose Gore Is Stalked?*, 41 N.Y.L. SCH. L. REV. 419 (1997).

not think that this committee—that outsiders—necessarily need to judge the facts of the case. But they should judge the validity of the kind of testimony and the validity of the kind of evidence that is being brought to bear, and also the validity of the people who are going to provide this testimony.

In the case we have been discussing—the silicone breast implant case—I must take issue with what Dr. Anderson told you.[2] Dr. Elizabeth Connell, who was the Chairman of the Advisory Committee in the last instance, has told me that there were serious distortions of what was presented to the committee and the decision that came about. She said that the outcome was not how the committee felt as a whole; and, additionally, that there was nothing hidden from the committee, there were no secret documents, and that the sarcomas that were found in the animals are inherent in that particular species and have never been duplicated in humans.[3]

I also know that there are more than 100,000 different kinds of silicone and that the contents of the envelopes in the silicone breast implants changed several times by the various manufacturers, so there was no single compound.[4] There was also the so-called "adjuvant disease"—which was originally reported in Japan, by the way, not in the United States—where reactions to injections of industrial, not medical, silicone accompanied by paraffin, and some other substances, produced horrible disease in some of the women,[5] which have been incorrectly extrapolated to breast implants. It reminds me of Tom Stoppard's play, *The Real Thing*, where one of the characters says, "There's something scary about stupidity made coherent."[6]

I do not think that you can do that. There is absolutely no evidence to suggest that the device or that the kinds of silicone used in the device—not just in breast implants, but for other purposes in the body, such as in joints, for leads, for pacemakers, or for various other purposes that are absolutely essential, such as shunts—is in any way immunogenic or causes any of the diseases. Furthermore, there are no longer any

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2. *See* Norman Anderson, M.D., *Lawsuit Science: Lessons from the Silicone Breast Implant Controversy*, 41 N.Y.L. SCH. L. REV. 401 (1997).

3. *See* MARCIA ANGELL, M.D., SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 54-58 (1996).

4. *See* John R. Easter et al., *Medical "State of the Art" for the Breast Implant Litigation*, *in* BREAST IMPLANT LITIGATION: CURRENT MEDICAL AND LEGAL THEORIES 18-21 (1993).

5. *See id.* at 29-32; Nachman Brautbar et al., *Silicone Breast Implants and Autoimmunity: Causation or Myth?*, 49 ARCHIVES ENVTL. HEALTH 151 (1994).

6. TOM STOPPARD, THE REAL THING act 2, sc. 5 (rev. 1983).

diseases being alleged. There is just a vague group of symptoms, none of which can be verified, and suspect laboratory tests.

DR. NORMAN ANDERSON: Anybody who has worked in this arena believes in science and believes that this is the only way we will achieve effective, fair, and rational decisions. I believe in the Food and Drug Administration (FDA). I believe in regulation, and I think the FDA has to have full access to all relevant material to make appropriate and fair decisions.

The problem is that when that data is edited, suppressed, or delayed, you can make, with the best intent, the wrong scientific decision. So one has the ideal premise that has been put forward with *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[7] that in a real world we can identify good science and go through in a very critical manner to resolve these questions.[8]

I would like to remind you, again, not only that the *Daubert* panel does not generate the data, but to question what kind of data is being given to it. I have not said that, for example, the epidemiology failing to link silicone with scleroderma is wrong. I only question what was not looked at. What was ignored were reports that these devices rupture anywhere between five and fifty percent of the time after they have been in the body for ten years.[9]

Another point that stands out, when looking at the history of peer review for silicone breast implants, is that ninety percent of all the literature up until 1991 came from plastic surgeons and representatives of the silicone manufacturers. If you were going to use publication for expertise, it would come from vested interests. You would see that virtually none of the early publications about breast implants were in the *New England Journal of Medicine*; they were in the specialty plastic surgery journals.

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7. 509 U.S. 579 (1993).

8. *See id.* at 597.

9. *See generally* PAMELA SCOTT-KENDALL, TORN ILLUSIONS: ONE WOMAN'S TRAGIC EXPERIENCE WITH THE SILICONE CONSPIRACY 113 (1994) (citing a Baylor College of Medicine study that estimated that 70 percent of silicone implants rupture and suggested that all implants will rupture with time and age); O. Gordon Robinson, Jr, M.D., et al., *Analysis of Explanted Silicone Implants: A Report of 300 Patients*, 34 ANNALS PLASTIC SURGERY 1 (1995) (noting that a study of 300 patients with implants indicated a rupture rate of 71 percent); *cf.* ANGELL, *supra* note 3, at 21 (stating that the best estimates of implant ruptures are around five percent); *Council Report: Silicone Gel Breast Implants*, 270 JAMA 2602, 2604 (1993) (suggesting that four to six percent of implants rupture); Joanne Jacobs, *Hysteria Is Easier Than Science, and it Pays Better*, BALTIMORE SUN, Aug. 7, 1996, at 19 (stating that implants rupture in as much as five percent of women).

In the days of silicone injections, the plastic surgeons denied that silicone could destroy the breast. Editors added notes in press stating that this destruction of the breast was not due to silicone, but was produced by adulterants used in the sakurai formula.[10] It took them twenty years to admit that this was not true.

You can also look at the history of what I am worried about and what my panel was worried about—rupture. A literature review of silicone breast implants in 1988 reported forty cases of rupture, while, in 1991, a single surgeon reported ninety-one cases.[11] This simply meant that no one published bad results. Records were not kept; but no one wanted to publish bad results. When you have that situation, how do you find the truth?

I also want to tell you that these decisions are not made in the abstract. The plastic surgeon, who first raised the sword against silicone injections in Las Vegas, had his practice destroyed, his referral base taken away, and was disciplined for taking this stance. One of the members of my FDA advisory committee who voted to say, "Keep these at class III," had his professional career threatened and never returned to an FDA advisory panel. The second-in-command of the Canadian FDA was critical of the polyurethane-coated breast implants and was fired. We can even go on and talk about other kinds of discipline brought by professional societies more recently in the implant dispute. In this highly charged arena, with these kinds of pressures, it is one thing to talk about idealism, but trench warfare can be very dirty.

DR. STUART SCHLOSSMAN: We have heard of a conspiratorial approach. The fundamental issue, however, is that we really cannot go back and look at what was to be done. Plainly, the breast manufacturers did not do epidemiologic studies. But, now that they have supported some, we are being told that it is bad that they have supported them. You cannot have it both ways.

On the other hand, we must deal with individuals who represent themselves as experts in the courts, who in reality are not experts. They ask the courts to evaluate tests that are not well established, not

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10. *See* Fernando Ortez-Monasterio, M.D., & Ignacio Trigos, M.D., *Management of Patients with Complications from Injections of Foreign Materials into the Breasts*, 50 PLASTIC RECONSTRUCTIVE SURGERY 42, 42-47 (1972).

11. *See* Blaine Andersen, M.D., et al., *The Diagnosis of Ruptured Breast Implants*, 84 PLASTIC RECONSTRUCTIVE SURGERY 903, 903-05 (1989); Norman D. Anderson, M.D., & Wendie A. Berg, M.D., *Impact of Recent Advances for Detecting Failed Breast Implants*, *in* 1 MEDICAL & LEGAL ASPECTS OF BREAST IMPLANTS 3, 3-4 (1992); Charles Vinnik, M.D., *Migratory Silicone*, *in* CLINICAL ASPECTS SILICONE IN MEDICAL DEVICES 59-67 (Food & Drug Admin. Ctr. for Devices & Radiologic Health 1991).

recognized by the FDA, and in many cases not recognized for the purposes for which they are being used. Additionally, the tests are being used to support the notion that silicone, or some toxic substance, produced a terrible effect on the plaintiffs. How can these tests be evaluated when many of them have been published in journals that are not available to the rest of the immunologic community, and have not received true peer review by scientists in that field? I think for that purpose you need some form of an expert panel or group to review much of the scientific data that is being presented to the courts.

As Gina Kolata indicated, the National Academy of Sciences, through the Institute of Medicine and Medical Research Council can convene panels to investigate a number of important scientific issues.[12] Additionally, there are reputable scientists who do not sell out to companies when grants come into their universities from these companies. Personally, I do not have a grant from Dow or from anyone else involved in breast litigation.

There is institutional oversight in this area. For example, even if a pharmaceutical company supported research—and keep in mind that perhaps twenty percent of research in this country is supported by pharmaceutical companies, while the vast majority is still supported by National Institutes of Health and other agencies—the rules and regulations that involve the pharmaceutical industry support are very stringent. As was the case was with Dr. Hennekens and the School of Public Health,[13] the regulations prevent the Dow company from influencing the data prior to its publication.[14] I think that this is the case in all the universities in this country that I am aware of and that accept pharmaceutical industry support, which is a valuable mechanism to support research in the country.

BARRY NACE: Let me start off by saying Stephen J. Gould is somebody that I do not know, have never met, have never talked to, and have never had anything to do with. I did represent the plaintiffs in the *Daubert* case, and I can assure you that Mr. Gould was not retained, hired, or anything else, by any plaintiff in that case.

We hear a lot of rhetoric going around, but, you know, it still comes down to the fact that I am not willing to accept everything you say. I am not willing to accept everything that these people say, and, perhaps, my clients are not willing to accept it either. I think we would feel much more comfortable if we could get you under cross-examination and ask

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12. *See* Gina Kolata, *Science and Civil Justice*, 41 N.Y.L. SCH. L. REV. 413, 417 (1997).

13. *See id.* at 415-16.

14. *See* ANGELL, *supra* note 3, at 95.

questions, and then the people could decide what weight and what credibility they want to give to you. I am not singling you out; that was just an example. Since I have never met you before—and contrary to everybody else in this room, I do not do breast implant cases—I do not know what is going on there. It is very interesting, though, to listen to it.

The bottom line is that I would disagree with these blue ribbon panels; we do not need blue ribbon panels. What we need are attorneys who properly know the subject and can cross-examine these people. If these people are so bad, and I hear that these witnesses are so bad, I am absolutely convinced that those good attorneys can cross-examine the hell out of them and show how bad they are, to the point that their testimony is either going to be stricken or totally disregarded.

It comes down to the fact that I would much rather rely on someone who is a citizen of this country making decisions after they have heard all of the evidence and testimony, rather than some blue ribbon elitist group deciding what they want as evidence, or how they think the evidence will be interpreted. I do not believe that cloaking individuals with science degrees or black robes elevates them to a higher plane over neighbors and fellow citizens when deciding on credibility and weight issues.

QUESTION: I want to ask a very specific question, which I think is along the lines of what Mr. Warren has been trying to get at, and I will ask Dr. Anderson because of his expressed faith in the FDA. If the FDA finds a product to be safe and effective, which it has to do by statute, and if the company has committed no fraud, would you support a rule and law that precludes any court or jury from finding the product to be dangerous and defective?

DR. ANDERSON: I would like to answer that in the affirmative, but I cannot, because of the realities and practical experience. First, there are the limitations in the data. The FDA does not conduct the science; it is at the mercy of what it is given. Second, there is the problem of long-term follow-up and how accurate or good it is. Ultimately, the testing is in the marketplace and in the outcome. The FDA is not infallible.

Another argument in favor of product liability is the fact that the regulatory agency is subject to a great deal of political pressure. I have watched Congress and the Executive Branch influence the direction of FDA investigation. So the fact is that the regulatory agency is not run on hard science. It is politically sensitive, and I think we have a reason for not making it infallible in view of the law.

MR. NACE: In the very first Bendectin case that I tried—and everybody in this area would agree with me, there was an extremely conservative trial judge handling the case—the defense counsel got up and

said, "Hey, the drug has been approved. It's on the market. The FDA said it's okay." This extremely conservative judge looked at them, pointed to the jury box and said, "There's your FDA." Based upon what I have learned about the FDA and scientists over the years, I would much rather rely on the jury to decide than the FDA.

QUESTION: Mr. Warren, regarding the proposal to set up panels to evaluate expert testimony, there is a consequence that I do not know if you have addressed. I was looking through the old records of one of my former law firms, and I noticed the courts used to give trials within sixty to ninety days after the complaint was served; however, that was in the 1890s. But, we had a couple of experiments in New York, one of which called for medical malpractice panels. Another experiment was called something like "mandatory conciliation." What is wrong in the civil justice system today is complexity, not excessive simplicity. What are the unintended effects of turning two lawyers loose on this additional panel before you even impanel your jury. Additionally, think of the effects of allowing the insurance companies to hold the money a few more months while they attempt to abuse this additional step before they get to the real thing.

MR. WARREN: Let me say, as Learned Hand said, that these are issues that will be worked out in different ways, at different times, and at different places.[15] But, the principle that I believe he was advocating, nonetheless, has much to recommend it.

If we allow expert witnesses to testify to opinion, because those are general premises that are outside the kin of normal jurors, then it follows logically that jurors who do not have specialized expertise cannot decide between two experts who say competing things. So I believe this leads logically to the conclusion that those issues, in the first instance, need to be resolved by someone who can make those kinds of judgments, and that general knowledge needs to be conveyed to the jury in a form in which it can be used at trial.

Now, I would anticipate that if, in fact, my hypothesis, that there are at least some unbiased scientists, were true, I suspect that those individuals—most of whom do not have, and do not want, anything to do with the courtroom, but perhaps could be persuaded to play a role if their principles and discipline were accepted—would find that much of the cross-examination by both sides in these cases was hogwash and a waste of time. I suspect what they would want to do, as Dr. Schlossman

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15. *See* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV. L. REV. 40, 56 (1902).

suggested, is to say, "Let me see your underlying data, or let me address how you got to the conclusions that you propose to testify to in this case."

I do not say these things are easy; I think the system is exceedingly complex. I do think, however, that there is an important role for lawyers, even under a system like that. But, I suspect it is quite a bit different from the role that the lawyers are playing today.

You must pose questions that are of concrete value in a case. You simply cannot let this be an open-ended process. Lawyers are good at this. Judges are good at this. What I am suggesting is analogous to the process that is employed when lawyers suggest alternative charges to a jury on questions of law. There are certainly differences in point of view, but it seems to me that the disputed issues of law for the judge to decide become very clear. Those issues need to be posed to persons of expertise who have the ability to address them in a manner that will provide general and useable advice to the jury.

Again, let me just say that I do not want to be a great advocate for this; I think there are immense complexities to overcome, and you have to take things one step at a time. I only suggest that, logically, it has advantages over the present system. As Judge Hand said, and I do believe as Ms. Kolata said, we have scientific organizations of real merit in this country, such as the National Research Council, the Council of the National Academy of Sciences, and many professional organizations and boards. I may think they are dilatory in their role in this process, but I think persons of good faith, and judges of good intention, could approach them, and I believe they would be able to persuade those organizations to participate in experiments along the lines that we are talking about. So no speeches ordered, but it seems to me, logically, that there is much to be said for that point of view.