Neutral Science Panels: Two Examples of Panels of Court-Appointed Experts in the Breast Implants Product Liability Litigation

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Acknowledgments

In gathering information for this report we are indebted to many individuals for their comments and suggestions on the courts' appointment of neutral experts in the silicone breast implant litigation. First and foremost, we thank Judge Robert E. Jones (*Hall v. Baxter Healthcare Corp.*) and Judge Sam C. Pointer, Jr. (ret.) (*In re Silicone Gel Breast Implants Products Liability Litigation, MDL-926*) as well as the participants in these two cases, including the technical advisors, selection panel members, Federal Rule of Civil Procedure 706 experts, special counsel, and attorneys. Their insights enriched our report. We also acknowledge the indispensable assistance of Judge John Koeltl (S.D.N.Y.), who served as our liaison to the Court Administration and Case Management Committee. Among Center staff we thank Donna Stienstra for her comments on earlier draft reports and Kristina Gill for her research assistance.

I. Introduction[1]

On June 25, 1992, the Judicial Panel on Multidistrict Litigation (J.P.M.L.) designated Chief Judge Sam C. Pointer, Jr. (N.D. Ala.), as the transferee judge to manage pretrial proceedings in *In re Silicone Gel Breast Implants Products Liability Litigation, MDL-926,* 793 F. Supp. 1098 (J.P.M.L. 1992) ("*MDL-926*"). In August 1996 the Judicial Conference of the United States agreed to fund from judiciary appropriations an experimental national science panel of independent experts appointed by Judge Pointer. The Conference's Committee on Court Administration and Case Management was assigned oversight responsibility for this program. At its December 1996 meeting, the Court Administration and Case Management Committee asked the Federal Judicial Center to evaluate the use of this panel and compare it to a panel appointed by Judge Robert Jones (D. Or.) in *Hall v. Baxter Healthcare Corp.,* 947 F. Supp. 1387 (D. Or. 1996) ("*Hall*"). This report describes these expert panels in sufficient detail to permit others to understand the procedures that were used, the benefits that resulted, and the problems that arose.[2]

The use of such panels of appointed experts represents a marked departure from the traditional means of presenting and considering expert testimony. Judge Pointer's and Judge Jones's innovations were stimulated by the complex scientific evidence being introduced to prove that silicone gel breast implants cause a number of systemic connective tissue diseases. Evaluation of such evidence requires consideration of emerging research

1. This publication is substantially similar to the report delivered in November 1999 to the Judicial Conference Committee on Court Administration and Case Management. This version differs in that it incorporates comments from study participants, and it describes how the National Science Panel's report is being used in federal and state cases.

2. This report is consistent with the recommendation of the Federal Courts Study Committee that "for instances in which a high number of injuries may have been caused by a single product or event, the Center should 'analyze and disseminate information about tailored procedures to avoid undue re-litigation of pertinent issues and otherwise facilitate prompt, economical and just disposition of claims.'" Report of the Federal Courts Study Committee 46 (1990).

in a number of areas of science, including epidemiology, toxicology, immunology, and rheumatology.

While the two panels share a common impetus, they differ markedly in their purpose, context, and application.[3] In *Hall,* Judge Jones used the expert panel's reports to assist him in resolving twenty-five joint motions in limine that sought to exclude the testimony of plaintiffs' expert witnesses (i.e., motions based on *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)). Judge Pointer was the transferee judge assigned to handle pretrial proceedings in the multidistrict litigation. He used the expert panel to develop videotaped testimony on various scientific issues; this testimony will become part of the record when the cases are returned to federal district courts across the country for trial.[4] As a result of these distinct purposes, the two procedures differed in the selection of the appointed experts, the services the experts provided, the extent of deposition and cross-examination of the appointed experts, and the expense. Table 1 summarizes how the two programs differed.

3. *See* Karen Butler Reisinger, *Court-Appointed Expert Panels: A Comparison of Two Models*, 32 Ind. L. Rev. 225 (1998).

4. We may prepare an additional report for the committee on the use of the videotaped testimony by the transferor courts when the cases are returned to the local district courts for trial if the amount or nature of such activity warrants such a report.

Table 1. Comparison of the Two Uses of Panels of Appointed Experts in Silicone Gel Breast Implants Litigation

	Hall v. Baxter Healthcare Corp., Judge Robert Jones (D. Or.)	*In re* Silicone Gel Breast Implants Products Liability Litigation, MDL-926, Judge Sam Pointer, Jr. (N.D. Ala.)
Purpose of Appointment of Expert Panels	Aid single district court in resolving defendants' motions in limine to exclude plaintiffs' expert scientific testimony in context of cases consolidated for trial	Develop testimony by court-appointed experts regarding general causation as part of a multidistrict litigation proceeding for presentation at trial
Authority for Appointment	Appointed as technical advisors under authority of Fed. R. Evid. 104 and on the inherent authority of the court	Appointed as court-appointed experts under authority of Fed. R. Evid. 706
Primary Product of Expert Panel	Individual expert reports that informed the court as it considered the motions in limine	Videotaped testimony that will be presented at trial or at preliminary hearings
Subsequent Use of Primary Product	Uncertain	Videotaped testimony will become part of the record of each case when the case is returned to the transferor court
Number of Cases in the Proceeding	≈ 70	≈ 27,000
Time from Start of Selection to Completion of Duties of Expert Panel	Approximately 4 months	3 years
Source of Funding	Cost shared by the parties	Judiciary appropriations with party payment of discrete components
Total Cost of the Panel and Related Expenses	≈ $76,000	≈ $1,000,000 for the expert panel > $1,000,000 for special counsels to represent the experts

Research Methods

Our approach in gathering information differed for the two programs. Since the experts in the Oregon program had delivered their reports before we began the study, our analysis was based on interviews in which participants recounted events that in some instances occurred months in the past. The participants were aware of Judge Jones's ruling in the case,[5] which may have influenced their assessment of the procedure. Most interviews were conducted in-person during a three-day visit to the Oregon district court. Interviews with the attorneys were conducted in Judge Jones's chambers at a conference he convened upon our arrival.

Since the multidistrict litigation (MDL) program in Judge Pointer's court was in its early stages when we began our study, we were able, over a two-year period, to attend a number of hearings and to have ongoing discussions with some participants regarding the development of the program. As a result, we have much more detailed information on the implementation of Judge Pointer's program. Members of the selection panel discussed activities that had taken place before the beginning of the study. Interviews with experts, special counsel, and attorneys were delayed until the completion of the videotaped trial deposition of the appointed experts. Most of the formal interviews were conducted by telephone.

Summary of Suggestions for Future Use of Panels of Appointed Experts

Both science panels produced expert reports that proved to be consistent with later findings of independent panels of scientific experts who examined related issues. Despite the high quality of the information developed by the expert panels, interviews with participants in the two programs revealed a number of difficulties that are likely to arise if such panels are used in future litigation. Judges who consider using such expert panels may wish to consider the following suggestions, which we derived from the comments of the participants. These suggestions are discussed in

5. Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387 (D. Or. 1996).

further detail in the final section of this report (see *infra*, section X, Suggestions for Use of Panels of Neutral Experts).

- Appointment of such a panel should be undertaken only in extraordinary cases. The cost, time, and difficulty of finding appropriate candidates who are willing to serve, and the problems of administering the work of the panel, limit the role of such panels to only those cases with an exceptional need.
- The role of the expert panel should be specified in advance of the appointment. The conditions of the appointment should then be tailored to fulfill this role, with the experts informed of the nature of their obligations at the time they are invited to serve. More specifically, the experts should be informed of the extent of depositions and cross-examination if those things are to be part of the experts' service.
- Areas of expertise should be sought that will match the evidentiary issues. Specifying such areas may prove surprisingly difficult where expertise in a combination of subjects is required. Considerable effort may be required to find appropriate candidates who are willing to serve.
- Conflicts of interest should be defined with specificity, since science and law appear to recognize different standards for identifying a conflict. A screening questionnaire that requires written certification of the absence of conflicts will help convey the standards appropriate to the case. A screening procedure for conflicts of interest should also be developed for colleagues who will provide direct assistance to the expert panel members. A procedure should be created for experts to report or obtain guidance about possible conflicts of interest that arise during their service.
- A procedure for organizing the work of the panel should be specified soon after the panel is appointed. This procedure should indicate how the panel members should communicate with one another, as well as the extent and circumstances under which they may seek assistance from colleagues outside the panel.
- The duties and functions of the experts should be specified in a written order, which should include the issues to be considered, the form of the panel's final report, and the procedures for providing

information to the court. A mechanism for clarifying the instructions should be developed.

- The court should establish a budget, with input from the experts and parties, once the duties of the experts have been determined.
- The court must maintain administrative oversight of the work of the panel to ensure it proceeds in a prompt and efficient manner.
- The court should consider appointing special counsel to represent the interests of inexperienced witnesses who are going to be deposed or cross-examined. Care should be taken in defining special counsel's role and compensation.

Overview of the Report

The next two sections of the report offer an overview of the role of the panels of experts in *Hall v. Baxter Healthcare Corp.* and *In re Silicone Gel Breast Implants Products Liability Litigation, MDL-926.* Subsequent sections contain more detail, comparing and describing the procedures used to select the experts for appointment to the panels, the instruction of the expert panels in their tasks, the preparation of the reports by the panels, the depositions and testimony of the experts, and the costs of the two programs. The penultimate section summarizes participants' overall reactions to the procedures and offers a number of issues for judges to consider when appointing such panels in the future. A final section looks at how the National Science Panel report is being used in recent federal and state cases.

II. Summary of Oregon Breast Implant Litigation (Hall v. Baxter Healthcare Corp.)

In January 1996, Judge Pointer remanded to the District of Oregon approximately seventy cases that had been transferred from that district as part of the MDL process. These cases were ultimately consolidated for trial before Judge Robert E. Jones, who promptly held several status conferences with counsel.[6] Later, at plaintiffs' request, Judge Jones convened a "science day" tutorial so he could learn more about the basis of the scientific testimony that the parties planned to introduce at trial. Shortly thereafter, defendants filed twenty-five joint motions in limine to exclude the plaintiffs' experts' testimony on causation of systemic connective tissue disease.

Procedures Used to Determine Admissibility of the Scientific Evidence

Seeking assistance in ruling on these motions for the first group of cases scheduled for trial, Judge Jones scheduled an evidentiary hearing under the authority of Federal Rule of Evidence 104(a) to consider the admissibility of the scientific evidence. This hearing, according to Judge Jones's order, was to serve two purposes:

6. Judge Jones divided the seventy cases into three trial groups with common characteristics such as implant type, manufacturer, and expert witness. One of the trial groups chose not to participate in the pretrial hearing and, consequently, was not bound by the court's ruling. Judge Jones ordered the other two trial groups to provide a list of all lay and expert witnesses to be called at trial, together with a narrative statement of each witness's proposed testimony. He also ordered counsel to summarize each expert witness's opinion, to identify all the materials upon which each expert would rely for his or her opinions, and to submit transcripts of any testimony given by the witness in similar cases. *Hall,* 947 F. Supp. at 1392. These materials were filed in July 1996.

- "the court must determine whether plaintiffs' experts' testimony reflects 'scientific knowledge,' 'constitutes good science,' and was 'derived by the scientific method'"[7] and
- "the court must ensure that the proposed testimony 'fits,' that is, the testimony is 'relevant to the task at hand' in that it logically advances a material aspect of the proposing party's case."[8]

In May 1996, prior to the Rule 104(a) hearing, Judge Jones appointed a medical school professor as special master to help identify suitable neutral experts. The court sought to appoint advisors in the fields of immunology, epidemiology, rheumatology, and toxicology. But technical advisors in only three of the disciplines—immunology, epidemiology, and rheumatology—were selected prior to the hearing. Following the hearing, the court appointed a fourth expert specializing in biochemistry. The special master briefed the last advisor on events that had occurred prior to his appointment.

Because Judge Jones wished to use the appointed experts to advise him rather than offer testimony at trial, he appointed the experts as "technical advisors"[9] under the court's inherent authority rather than as court-appointed experts under Fed. R. Evid. 706, "which requires court-appointed experts to act, in effect, as additional witnesses subject to depositions and testifying at trial."[10]

Judge Jones structured the evidentiary hearing according to subject matter, with plaintiffs presenting their experts in a particular field, fol-

7. *Id.* at 1396 (quoting Daubert v. Merrell Dow Pharm., Inc. 43 F.3d 1311, 1316 (9th Cir. 1995)).

8. *Id.* (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597, 113 S. Ct. 2786, 2798–2799 (1993) [hereinafter *Daubert I*]).

9. An early statement of this authority is found in *Ex Parte Peterson*, 243 U.S. 300, 312 (1920) (finding that "[c]ourts have (at least in the absence of legislation to the contrary) inherent power to provide themselves with appropriate instruments required for the performance of their duties"). For a more recent statement of this authority, see *Reilly v. United States*, 863 F.2d 149, & n.4 (1st Cir. 1988) (concluding that a district court has inherent authority to appoint an expert as a technical advisor).

10. *Hall,* 947 F. Supp. at 1392, n.8.

lowed by defendants' witnesses in the same field.[11] Judge Jones thought the relaxed evidentiary rules of Rule 104(a) were "remarkably effective, both in permitting the parties to focus on presenting their evidence and in expediting the proceeding."[12]

In response to a plaintiff's motion following the evidentiary hearing, Judge Jones amended the procedure to include a number of procedural safeguards mentioned in Rule 706 but not required under Rule 104. Among the changes, he agreed to provide a written charge to the technical advisors, to communicate with the advisors on the record, and to allow the attorneys a limited opportunity to question the advisors regarding the content of their reports. Then, with input from the parties' counsel and the technical advisors, Judge Jones set forth a schedule for post-hearing procedures that required parties' counsel to submit, within a week, their proposed questions for the written charge to the technical advisors. Parties also were instructed to present videotaped arguments, which included plaintiffs' submissions, defendants' submissions, and plaintiffs' rebuttals. After reviewing these materials, Judge Jones submitted the following questions to the advisors:

- Is the expert's opinion supported by scientific reasoning and methodology, generally accepted in the expert's particular scientific community, or is it otherwise qualified?
- Is the expert's opinion based on scientifically reliable data?
- If epidemiological studies have not been done or are inconclusive, what other data—such as animal studies, biophysical data, clinical experience in the field, medical records, differential diagnosis, preliminary studies, general scientific knowledge, and medical literature—can justify, to a reasonable medical probability, a conclusion concerning the cause of the syndrome or disease at issue?
- Do the methodology and data support the expert's conclusions?

11. Judge Nely Johnson of the Oregon state court also presided at the hearing. At that time, she had yet to rule on the admissibility of the scientific evidence in the state court breast implant proceedings.

12. *Hall*, 947 F. Supp. at 1393, n.11.

- Do the scientific data relied on by the expert apply to the syndrome or disease at issue in these cases? For instance, are epidemiological studies directed at other typical or classical diseases relevant to an atypical disease?

In September 1996, approximately four months after their appointment, the technical advisors submitted their separate reports to the court. Three of the technical advisors found little scientific support for the contentions of the plaintiffs' experts. Specifically, the court's immunologist stated that the plaintiffs' experts' positions were not well supported by the data available in the published scientific literature, nor were they derived from valid conclusions of the studies.[13] Similarly, the rheumatologist criticized plaintiffs' experts on the basis that their methodology was not scientifically valid. The biochemist concluded that the chemical studies were based on appropriate methods, but that some of the "work was inadequately documented and of clearly debatable value. . . ."[14] The epidemiologist generally thought that the plaintiffs' epidemiologists' opinions were supported by scientific reasoning and methodology generally used in the field of epidemiology.[15] However, Judge Jones excluded the epidemiological testimony on other grounds, finding plaintiffs' two experts' testimony to be unreliable.[16]

Judge Jones expressed satisfaction with the experts' reports and thought all the reports, taken together, had reached essentially the same conclusion: that scientific evidence showing silicone gel breast implants cause disease is unreliable, though in different ways.

Three days after the advisors had submitted their reports, the court held a hearing at which the parties questioned the advisors on their findings and conclusions. During this hearing, Judge Jones limited counsels' inquiries to the scientific basis of the advisors' reports.

After the hearings the court expressed concern that plaintiffs' position could not be sustained and asked defense counsel to submit pro-

13. *Id*. at 1461.
14. *Id*. at 1475–76.
15. *Id*. at 1451.
16. *Id*. at 1405–07.

posed findings of fact and conclusions of law. Plaintiffs' counsel responded by filing objections and proposing alternative findings, to which the defendants then filed a response.

On December 18, 1996, Judge Jones issued his decision granting defendants' motions in limine to exclude plaintiffs' scientific evidence of a link between silicone gel breast implants and autoimmune disorders or atypical connective tissue disease. Judge Jones ruled that the proffered evidence did not meet acceptable standards of scientific validity.[17] He stayed his summary judgment order pending the report of the panel of national experts in Judge Pointer's multidistrict litigation.

Funding the Technical Advisors

The costs associated with appointing a special master and the four technical advisors totaled approximately $76,000. Securing funds to compensate the technical advisors was problematic. Initially, at Judge Jones's request, the parties agreed to pay a total of $20,000 toward creation of the neutral panel with the understanding that they would later be reimbursed by the judiciary. Judge Jones requested federal funding because he anticipated that his advisors' reports would be useful in resolving numerous silicone gel breast implant cases pending in federal and state courts. Judge Jones's request for funding was denied by the Judicial Conference and the parties were not reimbursed for the funds they paid the technical advisors.

17. *Hall,* 947 F. Supp. at 1394. In part, the court held that "none of the 16 epidemiological studies relied on showed that women with implants faced relative risk of disease sufficient to establish causation under Oregon law." *Id*. at 1389. The court stated that the expert testimony "had not been subject to peer review and conflicted with general consensus of [the] scientific community" and did not have the required "fit" with the scientific issues in the litigation. *Id.*

III. Summary of Multidistrict Litigation (*In re* Silicone Gel Breast Implants Products Liability Litigation, MDL-926)

Judge Pointer's appointment of a national panel of four experts in the silicone gel breast implant litigation came about because of actions taken by Judge Jack B. Weinstein (E.D.N.Y.) and Judge Jones (D. Or.), and as a consequence of sophisticated legal strategies employed by plaintiffs' and defendants' attorneys in this high-stakes national mass tort litigation.

Origin of the National Science Panel

On June 25, 1992, the Judicial Panel on Multidistrict Litigation designated Chief Judge Sam C. Pointer, Jr., as the transferee judge to manage pretrial proceedings in the breast implant products liability litigation. By October 1999, more than 27,000 cases had been transferred to Judge Pointer's docket.[18] In 1994, one of the defendants informally proposed that Judge Pointer appoint a national panel of experts to consider scientific causation issues. Judge Pointer declined, expressing concern that the procedure would be expensive and that the fast pace of scientific change would complicate the process and limit the impact of any results.

The idea lay dormant until 1996 when Judge Pointer began to remand cases to their original courts after the conclusion of MDL pretrial proceedings. A number of cases were remanded to the Eastern and Southern Districts of New York. At a pretrial hearing for those cases, Judge Weinstein indicated that he had questions about the validity of some of the plaintiffs' science claims. On April 3, 1996, Judge Weinstein and Judge Harold Baer (S.D.N.Y.) created a three-person selection panel

18. In addition, approximately 440,000 silicone gel breast implant claims were filed with a claims facility developed as part of a conditional national settlement. For a discussion of the history and implications of that settlement, see Jay Tidmarsh, *Mass Tort Settlement Class Actions: Five Case Studies* 75–89 (Federal Judicial Center 1998).

of special masters to help identify suitable experts for court appointment to the science panel.

At about the same time, as discussed above, Judge Jones decided to appoint a panel of technical advisors to assist him in ruling on *Daubert* motions. To aid in the search for suitable experts, he also named a special master.

Before the New York selection panel and the Oregon special master could complete their work, the *MDL-926* national Plaintiffs Steering Committee (PSC) urged Judge Pointer to consider appointing a national panel of experts. The PSC was apparently motivated by concerns that local appointments of experts could proliferate and that such a turn of events might allow national defense attorneys to overwhelm the resources of local plaintiffs' attorneys. They preferred a national process that would use the resources and expertise available to the PSC.

Plaintiffs' attorneys also feared the consequences of local proceedings using appointed panels of experts. Some saw the local efforts as designed to exclude plaintiffs' expert testimony through *Daubert* hearings. One plaintiffs' attorney described the PSC's desire to have a national panel as an act of desperation. "It was clear that we would not get jury trials otherwise. It was our last chance to keep the right to jury trials alive." Another plaintiffs' attorney expressed a concern that defendants would "judge shop." Such distrust apparently led the PSC to prefer that Judge Pointer control the court-appointed expert process. In the words of one plaintiffs' attorney, "we had confidence that Judge Pointer would handle such a panel fairly and would not bring an agenda to the process."

Defendants opposed the PSC initiatives to create a national panel primarily on jurisdictional grounds.[19] They argued that appointment of experts whose testimony would be used in trials exceeded the power of an MDL judge in managing pretrial proceedings. Judge Pointer addressed these concerns in part by providing notice to local counsel in the form of

19. Given the defendants earlier support for appointing a national panel, Judge Pointer indicated some surprise at their opposition. *In re* Silicone Gel Breast Implants Prods. Liab. Litig., MDL-926, Order 31, n.3 (N.D. Ala. May 30, 1996) ("It is unclear whether defendants [in objecting to the appointment] are mimicking Br'er Rabbit or are concerned about courts receiving testimony from impartial experts.").

a conditional order detailing the proposed process and allowing attorneys or parties to register any objections they might have. In the end, Judge Pointer ruled that "[t]he short, but correct, answer is that any implementation of Rule 706 procedures must be commenced during the pretrial stage of a case and that many, if not most, of the pretrial activities of a transferee judge under § 1407—such as supervision of depositions and production of documents—are undertaken for the very reason that such matters may be needed at a trial."[20] Defendants who had invested time and expense in supporting the New York and Oregon processes also expressed concern about the costs and delays a national procedure might entail.

Appointing and Instructing the Selection Panel

After consulting and receiving encouragement from Judges Baer, Jones, and Weinstein, as well as other state and federal judges, Judge Pointer on May 30, 1996, conditionally granted the PSC motion for a national panel of court-appointed experts under Fed. R. Evid. 706.[21] Judges Baer and Weinstein deferred to Judge Pointer's action and terminated their own efforts to appoint a panel. Judge Jones proceeded with his cases and appointed four technical advisors during the summer of 1996, but ultimately linked a conditional summary judgment in his cases to the findings of Judge Pointer's national panel of court-appointed experts.[22]

In May 1996, Judge Pointer appointed a selection panel to commence the process of screening individuals to serve as members of the National

20. *Id.*, Order 31B (N.D. Ala. June 13, 1996).

21. *Id.*, Order 31 (N.D. Ala. May 30, 1996). The conditional nature of the order was removed by Order 31B.

22. Judges Baer and Weinstein also conducted *Daubert* hearings, but in October 1996 ruled that it would be premature to decide defendants' motions for summary judgment before the national panel reported and the judges had an opportunity "to complete their threshold inquiry into the admissibility of plaintiffs' expert testimony." The judges granted plaintiffs' motion to sever the local injury claims (e.g., contracture, rupture, foreign body reaction) from the claims of systemic injuries (e.g., connective tissue and autoimmune diseases) on the theory that they could probably only recover on local injury claims. All claims have been settled with the help of a special master Judge Weinstein appointed.

Science Panel. Judge Pointer was interested in having impartial persons with relevant expertise serve. Judge Pointer invited the selection panel to consider nominating up to three candidates from each of the following disciplines: immunology, epidemiology, rheumatology, and toxicology. After some disagreement on that point, the selection panel decided that one nomination per specialty would suffice. Based on recommendations of the selection panel, Judge Pointer appointed three panel members on August 23, 1996, and a fourth member on September 17, 1996. The appointments tracked the specialties that Judge Pointer had identified as central to the breast implant litigation: immunology, epidemiology, rheumatology, and toxicology.

In the end, the national MDL process controlled the selection and appointment of experts for all the courts except the District of Oregon.

Instructing the Expert Panel Members

Soon after the panel's appointment, Judge Pointer instructed the panel members orally and in writing. His written instructions, framed in consultation with the parties, asked the panel to review the scientific literature and indicate whether the literature provides a scientific basis for concluding that silicone gel breast implants cause a number of diseases and symptoms. He also directed the national panel to inform the court about whether reasonable scientists might disagree with the panel's conclusions.

Judge Pointer delivered oral instructions at a conference designed to orient the panel members to the issues in the litigation. He discussed the panelists' roles as expert witnesses, the procedures they should follow in seeking advice or information from nonparties, the ground rules about contacting representatives of other parties, and the procedures that would be involved in the discovery and trial depositions. This informal discussion was on the record, but later events suggest that some panel members may not have understood the issues and guidelines framed by Judge Pointer.

Communication with the Expert Panel

Several months after appointing the panel, Judge Pointer appointed a private attorney as special counsel to the national panel of experts and provided that any communication between the special counsel and the panel members would be covered by the attorney–client privilege. This appointment generally forestalled the need for direct communication between the judge and the panel members and provided an indirect and relatively open channel for such communications. The special counsel attempted to channel all communications among panel members through his office. Panel members, however, found such efforts to be cumbersome and ultimately communicated directly with each other to prepare their final report. Eventually, when the panel members reported difficulties communicating with the special counsel, Judge Pointer appointed a second special counsel to represent the interests of panel members during the depositions.

Use of special counsel also insulated panel members from communications with parties to the litigation. Nonetheless, a troublesome incident occurred late in the process when one of the panel members had contact with representatives of a defendant on a matter unrelated to the litigation. In this instance, the two special counsel were not in a position to know about or control the communications.

While preparing their report, panel members sought and received specialized assistance in areas such as statistical analysis from colleagues who were not on the panel. On several occasions, such assistance was provided on a formal basis through the special counsel or through the court's funds. As noted above, during an orientation conference Judge Pointer established guidelines for communicating with colleagues and others who were not parties to the litigation. These guidelines became the source of confusion among the panel members and inhibited consultation with colleagues, including authors of studies being reviewed. Screening for colleagues who could give assistance appears to have been less rigorous than screening for the initial appointments.

The lack of a central administrative mechanism created difficulties in producing a single report. Members of the panel found various ways to

integrate separate electronic chapters into a single report with common formatting.

Report of the Expert Panel

In November 1998, the panel members produced a report consisting of four chapters, each written by one panel member, linked by a common introduction, conclusion, and executive summary. There was considerable consensus among the panel members with respect to causation issues and the possible effects of exposure to silicone gel. Specifically, the toxicologist concluded that "[t]he preponderance of data from [animal] studies indicate that silicone implants do not alter incidence or severity of autoimmune disease."[23] "Considering the broad range of testing systems that have been used in the study of silicone effects, the toxicologic and immunologic responses are few in number and questionable in significance."[24] The immunologist found that many of the studies available for analysis were methodologically inadequate with ill-defined or inappropriate comparison subjects or unorthodox data analyses.[25] Because of these limitations, among others, she concluded from existing studies that women with silicone breast implants do not display a silicone-induced systemic abnormality in the types or functions of cells of the immune system. The epidemiologist found "no association between breast implants and any of the individual connective tissue diseases, all definite connective diseases combined, or the other autoimmune/rheumatic conditions."[26] Finally, the rheumatologist found problems with many of the studies. For example, "the same complaint appeared in more than one disease category; self-report was not verified; timing of the complaint in relation to the implant was not known; indication for the implant was ignored; and in individual studies, the number of affected women was

23. Betty A. Diamond et al., *Silicone Breast Implants in Relation to Connective Tissue Diseases and Immunologic Dysfunction: A Report by a National Science Panel to the Honorable Sam C. Pointer, Jr., Coordinating Judge for Federal Breast Implant Multidistrict Litigation*, Executive Summary at 4 (Nov. 17, 1998).

24. *Id.* at 5.

25. *Id*. at 5–6.

26. *Id.* at 6.

small. Furthermore, many of the rheumatologic complaints reported are common in the general population and . . . in physicians' offices. No distinctive features relating to silicone breast implants could be identified."[27]

Discovery Depositions

In February 1999 in Atlanta, Judge Pointer presided over discovery depositions of the four panel members. By prior order, he established ground rules that required the parties to submit written questions and attach related articles in advance. He also limited each side to three hours to examine each witness.

Before the discovery depositions, the plaintiffs' attorneys requested copies of all notes kept by panel members and all records of their communications with each other. Defendants and special counsel objected and the parties briefed the issues. Judge Pointer ruled, in the context of a specific request during the first deposition, that generally the work of panel members is a proper subject of inquiry and production. Panel members, he ruled, are not protected by a "decisionmaking privilege." Judge Pointer's early instruction that the panel members were free to communicate with each other did not mean, he said, that such communications were privileged.

Judge Pointer also ruled that the panel members' personal notes had to be disclosed, including notes in the margins of articles. He ruled that notes on conversations between panel members, even if conducted at the direction of special counsel, were not covered by the attorney–client privilege. On the other hand, Judge Pointer indicated that many of the documents requested could be expected to have little value to the litigation, and he directed that panel members spend no more than a few hours looking for such materials.

An inquiry into allegations of conflict of interest and bias against a panel member arose out of the discovery depositions. Plaintiffs' attorneys found that a panel member had several contacts with one of the parties about matters unrelated to the litigation. The panel member, as chair of a

27. *See* Diamond, *supra* note 23, at 7.

medical school, solicited funds from a defendant to support a professional conference on a topic not related to silicone gel breast implants. The conflict-of-interest screening form used by the selection panel instructed the panel members to report any changes in that expert's conflict-of-interest situation to the selection panel, but gave no guidance on how to proceed after the selection panel finished its work and dissolved.

As a consequence of the revelation, an additional discovery deposition was taken. The media obtained some of the resulting information and publicized it widely. Plaintiffs moved to disqualify the panel member and withdraw the joint report of the panel. Judge Pointer denied the motion on April 19, 1999, the day before videotaped depositions were to begin. Judge Pointer ruled that the panel member's work was objective and unbiased and that the failure to communicate additional contacts with a defendant was understandable given the ambiguities in the instructions. Judge Pointer made clear that he had intended to authorize communications by panel members with party representatives on matters unrelated to silicone gel breast implants. Even though the special counsel, on behalf of the panel member, filed a motion in limine to bar further examination of these allegations, Judge Pointer ruled that he could not restrict the right to cross-examine the witness on this subject and permitted plaintiffs' attorneys to conduct a lengthy cross-examination regarding these matters.

Trial Depositions

Prior to the trial depositions, Judge Pointer ordered counsel for the parties to provide each panel member with topics of inquiry and references to pages in books and articles. The parties provided lengthy lists and a host of new articles.

Depositions lasted a total of eight consecutive days, April 20–27, 1999. Proceedings were videotaped and transcribed by a court reporter. Problems in preparing the exhibits for viewing as part of the videotape have hindered the editing and a complete tape may not be available for some time. Work on editing the depositions was ongoing as of March 2001.

Each trial deposition opened with a direct examination by special counsel, during which the witness generally gave a background lecture, with slides or other visual aids, on the scientific foundation for the report and its conclusions. Defendants were then allowed to cross-examine, followed by plaintiffs. Redirect and recross were also permitted. Trial depositions were cross-noticed to attorneys in all the breast implant litigation so that the depositions might be used in all trials in state and federal courts. One attorney from outside the Plaintiffs Steering Committee appeared and was given a limited opportunity to examine the first panel member who testified.

Objections were, for the most part, preserved for resolution by each trial judge on remand. Judge Pointer generally denied objections as to form, but sometimes underscored a defect. Most of the testimony focused on scientific standards and the details of scientific studies discussed—or not discussed—in the final report.

Cost of the MDL Pretrial Process

Overall, the process of selecting, instructing, informing, reporting, and deposing the four panel members in the MDL pretrial process before Judge Pointer's panel covered a period of more than three years and cost almost $1 million. The federal judiciary provided approximately $734,000, the balance consisted of fees and expenses shared equally by the parties.

More than $1 million was paid by the parties in fees and expenses to special counsel to represent the panel members. As of December 2000, the costs related to the editing of the National Science Panel video depositions totaled approximately $165,000. Because the videotaped testimony is not yet available for use in trials, we cannot at this time assess the full impact of the report beyond looking at its reported effects on the settlements of claims and its citation in written opinions. However, early indications are that the existence of the report has encouraged settlement of many of the remaining cases.

IV. Identification and Selection of Experts

Identification and selection of appropriate individuals present an initial barrier to the use of court-appointed experts and technical advisors.[28] The difficulty of finding qualified candidates was compounded in each of these two cases by the need for specialized experts, and for each expert to be knowledgeable in multiple areas of research. To identify suitable candidates, both Judge Jones and Judge Pointer decided to seek the assistance of individuals with contacts in the science community. A number of unexpected problems arose during this process, suggesting that finding appropriate candidates may be more difficult than generally believed. For this reason, the identification and selection process is discussed in some detail.

Hall v. Baxter Healthcare Corp.

After examining the pleadings and responses of the parties, Judge Jones identified four relevant areas of scientific expertise to guide the appointment of experts: epidemiology, immunology, toxicology, and rheumatology. He then appointed Dr. Richard Jones as a special master to help identify scientists to serve as technical advisors. Judge Jones was aware of Dr. Jones's qualifications in part through their relationship as first cousins.[29] Judge Jones indicated that he selected Dr. Jones because he knew that Dr. Jones, as a prominent member of the science community,[30] could

28. In general, federal judges have tended to appoint experts with whom they were familiar. "[I]t is far more common for judges to appoint experts that they have identified and recruited, often based on previous personal or professional relationships, than for judges to appoint experts nominated by the parties." Joe S. Cecil & Thomas E. Willging, Court-Appointed Experts: Defining the Role of Experts Appointed Under Federal Rule of Evidence 706, at 31 (Federal Judicial Center 1993).

29. Judge Jones indicated that he did not believe his familial relationship with Dr. Jones caused any problems. No such concerns were brought to his attention by counsel.

30. Dr. Richard Jones, M.D., Ph.D., is professor emeritus of the Department of Biochemistry and Molecular Biology, Oregon Health Sciences University; the former acting

help him identify experts fairly quickly in the relevant fields and also help him understand much of the scientific evidence. A number of other interviewees confirmed that Dr. Jones is prominent in the biomedical research community and would be a likely resource for any judge who wished to identify local experts in such areas of science. Prior to Dr. Jones's appointment, Judge Jones confirmed that Dr. Jones had no prior contact with any plaintiffs or defendants or their respective attorneys and had not taken a position concerning the health effects of silicone gel breast implants. Counsel did not object to his appointment.

After examining the submissions of the parties to learn about the technical issues in dispute,[31] Dr. Jones "sought the names of potential experts from senior faculty at the Oregon Health Sciences University in each specialty area"[32] and from other professional scientific and academic colleagues. Dr. Jones narrowed the initial pool of approximately seventy-five potential candidates, to "nine epidemiologists, two immunologists, fourteen rheumatologists, and six toxicologists."[33] He then contacted these potential candidates to determine their level of interest and availability, as well as the existence of any bias or conflict.[34] Most of the individuals contacted expressed an interest in serving but were unavailable to serve because of preexisting commitments. If a candidate expressed an interest and was available, Dr. Jones requested a "copy of [the candidate's] curriculum vitae and a statement indicating absence of any previ-

president of Oregon Health Sciences University; and former chair of the university's biochemistry department.

31. "The court also instructed counsel to summarize each expert witness's opinion, to identify all the materials upon which each expert would rely for his or her opinions, and to submit transcripts of any testimony given by the witness in similar cases." Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1392 (D. Or. 1996).

32. Richard T. Jones, Silicone Breast Implant Litigation: Process Used to Identify and Recommend Neutral Scientific Experts for Federal Rules of Evidence 104(a) Hearings Before the Honorable Robert E. Jones, U.S. District Court, District of Oregon 1 (Jan. 14, 1996) (unpublished manuscript on file with authors).

33. *Id.* at 2.

34. Screening for availability and bias was accomplished through telephone conversations.

ous or current involvement with people or matters related to silicone breast implant litigation."[35]

At the conclusion of the screening process, Judge Jones appointed three technical advisors:

- Merwyn R. Greenlick, Ph.D. (epidemiology), professor and chair, Department of Public Health and Preventive Medicine, Oregon Health Sciences University;
- Robert F. Wilkens, M.D. (rheumatology), specialist in immunology and toxicology, Seattle, Washington; and
- Mary Stenzel-Poore, Ph.D. (immunologist/toxicologist), assistant professor, Department of Molecular Microbiology and Immunology, University of Oregon Health Sciences Center.

After the evidentiary hearing, Judge Jones made one additional appointment:

- Ronald McClard, Ph.D. (biochemistry), professor of chemistry, Reed College.

The variation in the manner in which each of these experts was selected indicates the difficulties that can be encountered in selecting a panel of experts. Dr. Merwyn Greenlick, who served as the technical advisor in epidemiology, initially assisted Dr. Jones in screening epidemiologists as candidates for appointment. When the initial nominee withdrew from consideration owing to a conflict of interest,[36] Dr. Jones contacted Dr. Greenlick about serving on the panel. Dr. Greenlick agreed to serve out of respect for Dr. Jones and because, he said, he was curious how the process would work. Dr. Greenlick's only previous experience with breast implants was minor, having consulted on the design of an epidemiology

35. Jones, *supra* note 32, at 3. Dr. Jones confirmed that potential candidates had not expressed a position on whether silicone gel breast implants cause certain types of medical ailments.

36. After the initial screening, Dr. Jones learned that the candidate had reviewed silicone studies for a course in trial advocacy taught by one of the plaintiffs' attorneys. Also, this candidate had developed an epidemiology research proposal regarding effects of exposure to silicone. This research had been supported by both the Center for Disease Control and National Institutes of Health. Both agencies had discouraged his participation on the panel, and as a result the candidate removed himself from consideration.

study that was undertaken by persons in his academic department and funded jointly by both plaintiffs and defendants.

Identifying a technical advisor with knowledge of immunology and toxicology was especially difficult. There are few immunologists and toxicologists relative to other specialties, and many candidates had research and consulting relationships with defendant companies. None of the local toxicologists was able or willing to serve.[37] Dr. Jones then contacted Dr. Mary Stenzel-Poore, an immunologist at the University of Oregon Health Sciences Center, who is an expert in inflammatory response. She agreed to serve as an advisor because, she said, she welcomed the opportunity to provide a valuable service to the court. Dr. Stenzel-Poore was unfamiliar with judicial processes and reluctant to participate in cross-examination regarding her findings. She believed that such an examination would require her to maintain detailed records regarding how she arrived at her findings and conclusions in a manner that was inconsistent with scientific practice.[38] At the time Dr. Stenzel-Poore agreed to serve on the panel, Judge Jones assured her he did not plan to hold a hearing at which the experts would be questioned about their reports.[39]

Public statements by many local rheumatologists regarding the breast implant litigation complicated the task of identifying a candidate who met the standards for neutrality. A prominent local rheumatologist had published an article in the editorial page in the local newspaper stating that there was no relationship between silicone gel breast implants and connective tissue disease. Most of the other rheumatologists in Oregon then endorsed the statement, thereby removing themselves from consideration. Dr. Jones sought recommendations from some of the local

37. Dr. Jones initially contacted Nancy Kerkvliet, Ph.D., an immunologist/toxicologist, but she declined to serve on Judge Jones's panel of technical advisors because of preexisting commitments. Later she agreed to serve on Judge Pointer's national panel of court-appointed experts.

38. Compare with the comments of Dr. Barbara Hulka, who served as the epidemiologist on Judge Pointer's panel, suggesting that the legal system discourages the kind of record keeping that science requires. *See generally infra* § VII, Discovery and Depositions of the Experts.

39. *See infra* § VII, Discovery and Depositions of the Experts.

rheumatologists for candidates outside the area. As a result of this search, Dr. Jones nominated Robert F. Wilkens, M.D., a rheumatologist who has a clinical practice and an appointment as adjunct professor of medicine at the University of Washington School of Medicine. Dr. Wilkens thought serving as a technical advisor would be intriguing and an attractive alternative to the party-sponsored expert role in which he previously served in unrelated litigation. He also welcomed the opportunity to conduct a review of the scientific evidence regarding the effects of silicone gel breast implants.

The inability to identify a suitable toxicologist caused Judge Jones to reconsider the nature of the expertise required on the panel. Since much of the toxicological evidence depended on the chemistry of silicone and its conversion products, Judge Jones determined that a biochemist would be able to meet this need. He intended to ask Dr. Jones, who also was trained as a biochemist, to serve on the panel.[40] However, following the evidentiary hearing, Dr. Jones was asked to serve as a special master on Judge Pointer's national selection panel, a position that would not permit him to serve as a technical advisor for Judge Jones. Dr. Jones then urged Dr. Ronald McClard, a biochemist with experience in polymer chemistry, to serve on the panel of technical advisors. Dr. McClard agreed to serve because of his personal acquaintance and respect for Dr. Jones as a scholar and medical school administrator.[41] In addition, Dr. McClard was intrigued by the prospect of participating in a novel procedure and was interested in learning more about the process of litigation, "the evidence and its intrinsic merit."[42]

Several plaintiffs' and defense attorneys expressed concern that they had little or no opportunity for input into the selection of the technical advisors. Most troubling was the fact that they knew very little about the background of the advisors and the positions they had taken on issues related to the litigation. One attorney indicated that although the parties

40. *See* Jones, *supra* note 32, at 3.

41. Dr. McClard volunteered that Dr. Jones would be the logical choice to assemble such a panel of experts because of his stature among his colleagues.

42. Marilyn Musick, *Science Reclaims Integrity in Court*, The Reed Magazine, May 1997, at 6 (describing Dr. McClard's participation on the panel of experts).

had been supplied with the advisors' curriculum vitae, this meant little since Judge Jones had allowed almost no communication between the attorneys and advisors prior to the advisors submitting their reports to the court. Judge Jones, on the other hand, says he restricted interaction between counsel and the technical advisors to protect the advisors' independence.

In re Silicone Gel Breast Implants Products Liability Litigation

The selection panel used in the national breast implant litigation was initially developed by Judge Jack B. Weinstein for use in breast implant litigation in the Eastern and Southern Districts of New York. In April 1996, Judge Weinstein appointed Professors Margaret A. Berger, Joel E. Cohen, and Alan Wolf as special masters to serve on the selection panel. Judge Weinstein had worked professionally with each member of the panel prior to the appointment. He had collaborated with Professor Berger, a professor at Brooklyn Law School, over the years on a variety of professional activities. Judge Weinstein had designated Professor Berger as a court-appointed expert in the Johns Manville bankruptcy reorganization proceedings and, among other duties, had asked her to identify scientists to serve on a separate panel of court-appointed experts that developed forecasts of the volume, type, and timing of future claims from asbestos-related injuries.[43] Professor Berger agreed to serve as a special master in the breast implant litigation, she said, because it presented the challenge of assessing the existence of causal relationships between silicone gel and systemic diseases. Professor Berger also welcomed the opportunity to interact with members of the scientific community and to continue developing her interest in the interdisciplinary subspecialty of law and science.

Professor Joel Cohen, a mathematician and head of the Laboratory of Populations at Rockefeller University in New York, was among the scientists selected to serve on Judge Weinstein's panel of experts that prepared forecasts of future asbestos claimants in the Johns Manville bankruptcy

43. For a discussion of Professor Berger's role after her appointment, see *In re Joint E. & S. Dist. Asbestos Litig.*, 129 B.R. 710, 763–64 (E.D.N.Y. 1991).

reorganization. He agreed to participate, he said, because of his respect for Judge Weinstein and because he perceived a public duty to assist in the thoughtful resolution of this litigation. Professor Cohen's earlier service as a court-appointed expert and his national reputation among scientists were expected to help persuade well-qualified scientists to serve on the breast implant panel and to help in reviewing their credentials.

Professor Alan Wolf, a professor in the Department of Physics of the Cooper Union, and a graduate of and adjunct professor at the Benjamin N. Cardozo School of Law in New York, had served as a student intern for Judge Weinstein while in law school and later clerked for Judge Lawrence McKenna (S.D.N.Y.). Following his internship, Professor Wolf served as an expert for a private party in the Johns Manville bankruptcy reorganization and reviewed the report prepared by Professor Cohen and other members of that panel of experts. Professor Wolf participated because of his interest in strengthening the judiciary's ability to consider scientific information.

In May 1996, after granting a motion by the Plaintiffs' Steering Committee to appoint experts under Fed. R. Evid. 706, Judge Pointer received Judge Weinstein's permission to adopt his procedure and selection panel as part of his multidistrict litigation process.[44] Judge Pointer then added three additional members—Dr. Judith L. Craven, of Houston, Texas; Dr. Richard Jones, of Portland, Oregon; and Dr. Keith Marton, of San Francisco, California—to give the selection panel broader geographic representation and to aid in the identification of candidates with national reputations.[45]

Dr. Richard Jones had recently served as a special master for U.S. District Judge Robert Jones (D. Or.) in the Oregon breast implant litigation, as described above. Dr. Jones agreed to serve, he said, because he was familiar with the issues and problems in recruiting scientists to serve as experts for the court, and because he had found his previous experience identifying technical advisors to be both challenging and rewarding.

44. *See supra* § III, Summary of Multidistrict Litigation.

45. *In re* Silicone Gel Breast Implants Prods. Liab. Litig., MDL-926, Order 31 (N.D. Ala. June 13, 1996).

Dr. Judith Craven is a medical doctor and has a master's degree in public health. Dr. Craven was recommended to Judge Pointer by a federal judge who was familiar with Dr. Craven's role in the public health community. She had recently served as dean of the University of Texas Health Science Center in Houston and was prominent in discussions of public policy regarding health care issues. She agreed to serve on the selection panel because she regarded the use of court-sponsored experts as a sensible way of presenting scientific knowledge in the context of litigation.

Dr. Kenneth Marton is a medical doctor and a fellow of the American College of Physicians, and he has a background in epidemiology. Dr. Marton was recommended to Judge Pointer by a federal judge. Dr. Marton agreed to serve on the selection panel because of the importance of resolving the scientific questions in the silicone gel breast implant litigation. He also wanted to participate in this novel procedure, which was designed to improve the presentation of scientific information in litigation.

The experience of Professors Berger and Cohen in serving on the panel of experts in the Johns Manville bankruptcy reorganization guided the development of procedures for selection of candidates for the science panel. Soon after their appointment by Judge Weinstein, Professors Berger, Cohen, and Wolf met to discuss their roles, procedures, and standards for evaluating candidates. This was the primary in-person meeting of the original panel members. These panel members met again briefly after a hearing at which the parties presented the research supporting their claims and offered suggestions for possible experts. All other communication was by telephone, electronic mail, conventional mail, and fax. The three panel members identified by Judge Pointer never met with other members of the selection panel or those they nominated for inclusion on the science panel.

Identifying candidates for appointment

At the initial meeting, the three selection-panel members appointed by Judge Weinstein agreed that they would seek scientists with national reputations who had no significant ties to the litigation, no significant current or close past relationship with parties to the litigation, and no

significant involvement in research that likely would be introduced as evidence.[46] After considerable discussion the panel devised a conflict-of-interest form and required each expert to sign a copy before being appointed. A copy of the form is found *infra* at the Appendix.[47]

After extensive discussions with Judge Pointer and input from the parties, the selection panel recommended that four fields be represented by the experts appointed to the science panel—epidemiology, toxicology, immunology, and rheumatology.[48] As a minimum standard, they agreed

46. In general, the selection panel sought candidates who were knowledgeable about a specific scientific area but not intellectually committed to a position regarding disputed issues in the breast implant litigation. This standard excluded from consideration those who had conducted research on exposure to silicone breast implants or testified at congressional hearings regarding the regulation of such implants. Such scientists were sometimes asked to suggest suitable candidates.

47. After reviewing the claims of the parties, the selection-panel members also agreed at this meeting on two standards regarding their own conduct. First, the selection panel agreed to be open in describing its activities, roles, and meetings, while at the same time being cautious about attributing specific statements to identifiable individual scientists whom they contacted. Second, they agreed to hold themselves to a conflicts-of-interest standard that is similar to that they set for the scientists they reviewed. As a result, the members of the selection panel divested themselves and their immediate families of all financial interests in the twenty or so corporations involved in the litigation (exclusive of any interests that arose from holdings in undifferentiated mutual funds) and paid capital gains taxes on the income from such sales. The selection panel also agreed that Professor Berger should field any press inquiries and speak on behalf of the group.

48. These are the same areas of expertise originally established by Judge Jones for his panel (in the end, Judge Jones did not appoint a toxicologist but did appoint a polymer chemist). The selection panel considered but decided not to include in its recommendation experts in polymer chemistry, psychiatry, and oncology. The panel initially planned to recommend that a statistician be included on the panel, but the need for such expertise became less urgent in light of the statistical skills possessed by the experts appointed to the panel. Judge Pointer's order appointing the selection panel notes that those appointed to the science panel are expected to have "such familiarity with statistics as may be needed or desirable to perform their functions and responsibilities." *In re* Silicone Gel Breast Implants Prods. Liab. Litig., MDL-926, Order 31 (N.D. Ala. June 13, 1996). At its initial meeting, one member of the National Science Panel inquired about the possibility of regular consultation with a statistical expert while reviewing existing studies. Judge Pointer left open the possibility of hiring a statistical consultant. The selection panel determined that an expert in polymer chemistry was unnecessary given the narrow issues that arise concerning polymer chemistry and the breadth of expertise in related areas on the science panel. They also determined that an expert in psychiatry was unnecessary in

to consider only those candidates who were actively conducting scientific research, thereby excluding most treating physicians. In addition, the selection panelists agreed that they would prefer to nominate academic scholars, since the skeptical and independent perspective traditionally associated with academia was expected to be especially valuable in this inquiry.[49] They also preferred scholars who had achieved the level of full professor, a standard thought necessary to ensure that the experts relied on by the court were of equal stature with those relied on by the parties. The selection panel viewed its task as identifying the best four candidates available to serve on the science panel. Qualifications as a scientist were given the greatest weight in screening of candidates, reflected in part by the preference for researchers with strong ties to the academic community. Expertise in more than one relevant area was especially valued. In addition to scientific excellence, the committee placed great weight on the ability of the candidate to communicate findings to a lay audience and the ability to work well in a committee setting. Telephone conversations with candidates and conversations with those who knew the candidates were useful in assessing communication skills and collegial styles.

The screening panel also sought candidates who were open-minded about whether there is a causal relationship between the silicone gel in breast implants and the systemic diseases raised in the complaint. A candidate's previous experience testifying as a party's expert in the breast implant litigation weighed against him or her because of the possible ap-

evaluating a causal relationship between exposure to silicone breast implant and organic disease, because such a relationship was thought to be tenuous at best.

Judge Pointer's order permitted the selection panel to recommend "one or more persons with special expertise in the interrelationship between the forensic sciences and legal process and procedures, for appointment as Chair of the Science Panel" to "perform administrative, coordinating, and consultative services" (and not to "submit findings, be deposed, or present testimony"). The idea that a forensic specialist would be appointed to chair the panel and address its administrative needs ran into objections from the parties and was eventually abandoned. The absence of this position created a void that was later filled by appointment of special counsel and, later, a second special counsel.

49. However, in the Oregon litigation a number of attorneys expressed concerns that a Ph.D. immunologist would be reviewing scientific studies conducted by immunologists with medical degrees and training. In the MDL process, the screening panel found an immunologist who had research skills, medical training, and an active clinical practice.

pearance of bias. Researchers who had studied the effects of breast implants, including those who served as technical advisors in the Oregon federal litigation, were not considered since selection of a candidate with a stated position, no matter how qualified the candidate, would appear to prejudge the issue.

The selection panel divided its tasks along the following general lines. Professor Berger served as chair of the panel and overall coordinator. All six of the panel members used their professional and institutional contacts to identify candidates for the panel to consider and review curriculum vitae, contact professional references, and gather other sources of information about candidates. Professor Wolf then searched public sources, including those on the Internet, for background information about candidates. Professor Wolf also spoke by telephone with nominees to gather information to support their applications and explore possible conflicts of interest. He later sent promising candidates a copy of the conflict-of-interest form for their signature. Once all information was received, the selection panelists conferred by telephone conference call to discuss viable candidates. Nominees for the science panel were approved by unanimous agreement of the selection panel. Serious and unresolved misgivings about an individual candidate were enough to block further consideration.

Several selection-panel members found that the lack of face-to-face meetings impeded the efficient working of the selection panel. As one member explained, the absence of face-to-face contact delayed the identification of individual preferences and values held by members of the selection panel. Such issues were explored in a somewhat awkward fashion in extended telephone conference calls involving the entire panel. The panel did not meet because of the time and expense required for such a meeting.

Identifying candidates for the science panel involved telephone conversations with hundreds of scientists over a six-month period. Professors Berger, Cohen, and Wolf began identifying potential candidates prior to Judge Pointer's appointing additional panel members. Professor Berger sought input from scientists she knew through her previous work in recruiting court-appointed experts and through her contacts with professional organizations. A staff member of the National Academy of

Sciences (NAS) who directed a panel on which Professor Berger had recently served provided a valuable list of candidates from members of NAS committees and special study panels. Apart from the assistance provided by the NAS, efforts to identify candidates by contacting professional societies and scientific organizations proved fruitless.[50]

Professor Cohen reviewed the parties' background papers on scientific issues and then used computerized scientific reference services to identify researchers who were active in examining the general topics that would arise in the litigation but who were not committed to a position on a disputed issue. Professor Cohen then relied on his network of scientific and academic colleagues to identify other potential candidates and obtain information on the standing of candidates in the scientific community.

Professor Wolf also called on professional colleagues to suggest candidates. He then supplemented these suggestions with promising candidates identified through telephone conversations with leaders in major medical schools and through library research for scholars prominent in relevant areas.

The three additional selection-panel members were appointed while the initial members were still collecting names of potential candidates and before any nominations were made, so the transition to a larger panel was uncomplicated. The new members of the panel used approaches similar to those of the others when identifying candidates.

The biomedical training of the additional members proved helpful in identifying candidates and assessing professional achievement. Dr. Jones also suggested candidates based on his experience in developing the panel of technical advisors who served in the Oregon federal breast implant litigation. In general, scientists with academic ties were found to be most suitable as candidates since they had a high degree of technical skill and

50. The selection panel was wary of seeking nominations from those professional associations that had taken stands on issues subject to dispute in the breast implant litigation. For example, the statement by the American College of Rheumatology that studies show no relationship between exposure to silicone implants and systemic disease made that entity inappropriate to nominate candidates for the science panel. The selection panel was also concerned that officers of a professional association might not be currently active in scientific research.

were less likely to have a preexisting relationship with a party. On occasion the same scientist was recommended by several persons with different positions on the breast implant litigation. Such a convergence of suggestions was given great weight.

Two members of the selection panel noted the important role played by personal relationships throughout the selection process. The members of the selection panel were known by Judge Weinstein or were referred to Judge Pointer by other federal judges. Nominees for the science panel were identified by pursuing extensive networks of professional relationships, to the point that some finalists in the process were three or more steps removed from the person initially contacted by the selection panel. Personal relationships also played an important role in assessing the scientific reputations and collegiality of prospective nominees. Selection-panel members asked those who were likely to know a candidate about the candidate's professional standing and temperament.

Screening for conflicts of interest

Once a promising candidate was identified and he or she indicated an interest in serving, the candidate was asked to submit information that would be required of testifying experts under Fed. R. Civ. P. 26(a)(2) (i.e., all publications authored by the witness within the preceding ten years and a listing of any cases in which the witness had testified as an expert at trial or by deposition during the preceding four years). Telephone calls were made to others in the field to learn of the candidate's reputation for scientific rigor and objectivity. Extensive searches of the Internet and electronic databases were used to identify publications, professional affiliations, public controversies in which the candidate had participated, and litigation in which the candidate may have served as an expert.[51] A number of candidates had posted their curriculum vitae on the Web sites maintained by their universities, eliminating the need to request copies. Databases of publicly available information regarding

51. For example, such searches revealed an article that described one candidate who had testified as an expert witness as "incendiary" and "difficult to work with." Such assessments were then examined through conversations with other colleagues.

property and financial assets were also examined for potential conflicts of interest. While the members of the selection panel were uneasy about inquiring into such matters, they did so because they knew that counsel for the parties would conduct similar investigations of the science panel appointees. Over 100 hours were spent conducting electronic network searches of potential candidates.

The most difficult part of the screening process was identifying candidates who met the panel's exacting tests for impartiality and freedom from conflicts of interest. During the initial telephone call, candidates were informed that a previous association or financial relationship with any of the defendants or a close relationship with a potential plaintiff in the litigation would be regarded as a conflict of interest that would render the candidate unsuitable for service on the panel. Interested candidates were sent a letter that set forth the concerns of the selection panel in greater detail and that asked them to sign a form certifying that no such conflict existed.[52] When we asked later about this screening, those panel members who were selected to serve said they did not object to it.

To screen candidates for conflicts of interest, the selection panel created a form modeled on one used by the National Academy of Sciences. The form proved to be a crucial part of the screening process. The form asked the candidate to certify that he or she did not have a close relationship with anyone who could be defined as an "interested party." An "interested party" was defined broadly to include, among other things, such factors as

- having a stake in the outcome of the litigation,
- having the potential to be a litigant in this case,
- having close friends or attorneys who were involved in the litigation,
- having a financial interest in one or more corporate defendants,
- having a family member or friend working for a party,
- conducting prior research on breast implants,
- receiving funding for research from one of the parties,
- making public statements regarding the disputed issues, or

52. *See infra* Appendix: Conflict and Bias Screening Questionnaire.

- working as an expert with any party or attorney for any party, or maintaining close associations with colleagues with ties to a party.

While candidates for the science panel were not asked to disclose financial assets, they were given a list of defendants in the litigation and informed that any significant current or past relationship, financial or otherwise, with any of the defendants might raise a conflict-of-interest question.

If candidates expressed an interest in serving on the science panel during the initial telephone conversation and presented no obvious conflicts of interest, they were sent a cover letter describing the opportunity in greater detail.[53] Professor Wolf then followed up with a telephone call. He served as the primary contact for most candidates, spending from three to four hours in telephone conversations with those who were selected as candidates to serve on the science panel. In the initial conversation, Professor Wolf followed an outline prepared by the selection panel, explaining the nature of the task, the importance to the court of having qualified scientists serve on the panel, and the importance of avoiding conflicts of interests.

Almost everyone contacted was curious about the science panel. Some candidates declined almost immediately, indicating that they did not wish to become involved in the legal system or in this particular area of litigation. One selection-panel member commented that a few candidates saw little prestige working with the judicial system; they would have preferred if the request have come from the National Research Council, an organization regarded highly by scientists. This member stated that if science panels are going to succeed, the scientific community must encourage scientists' participation in the judicial process. Others expressed concern about the amount of time such service would require. Many qualified candidates said they had commitments that stretched out for years and were too busy to serve on short notice. Candidates often were concerned about the uncertain nature of the time commitment and re-

53. There was considerable variation from this standard pattern of contact. Some candidates were sent the cover letter by fax as an initial matter. Others learned about the panel through an E-mail message from Professor Wolf.

quired assurance that they would be able to remain productive in their professions. Candidates were told that the commitment would not extend beyond four to six hours per week for approximately one year and that Judge Pointer would relieve them of their obligation if necessary because of unforeseen circumstances. All of those ultimately appointed to the science panel at least once declined to serve and were persuaded to reconsider.

Screening for conflicts of interest was difficult and time consuming. Many of those contacted had worked in some capacity for one or more of the defendant corporations, either conducting research, serving as a consultant, or serving as an expert witness. This was especially true of toxicologists. Often such associations were not mentioned in the extensive telephone conversations. Requiring signatures on the conflict-of-interest form yielded much useful information that had not been forthcoming through less formal methods.[54] A number of candidates appeared to give full consideration to the issue only when presented with the form and a request for written certification of the absence of a conflict as defined in the form.

Identifying candidates who were knowledgeable regarding the scientific specialties, yet open-minded regarding the issues in dispute in the litigation, required a number of difficult choices. Many of those most knowledgeable about research on the effects of breast implants were committed to positions that were disputed in the litigation, thereby removing them from consideration. The selection panel attempted to identify scholars who were knowledgeable about relevant areas without having participated directly in the research or debate over breast implants. For example, one scientist who was ultimately appointed to the National Science Panel was familiar with epidemiological studies of breast cancer but had not reviewed the epidemiological literature regarding alleged problems with breast implants.

54. One candidate indicated in the telephone conversation that no conflicts existed, then declined to sign the form after revealing that he had testified on behalf of one of the defendants six months earlier and received payment in the five-figure range.

Another example of the selection panel's concern about the appearance of commitment to a disputed position is the scrutiny given to participation of one panel member on a committee of rheumatologists seeking to revise the position statement of the American College of Rheumatology (ACR) on the effects of breast implants. In October 1995, the ACR issued a statement that concluded that "studies provide compelling evidence that silicone implants expose patients to no demonstrable additional risk for connective tissue or rheumatic disease." In April 1996, Dr. Betty Diamond, at the request of ACR, agreed to serve on a panel to reexamine and possibly update the October 1995 statement. After reviewing the statement, the panel recommended revising the statement by adding the following "and that additional information could be expected with regard to non-traditional diseases." The ACR decided not to accept the panel's revision. Because the contents of the statement, which Dr. Diamond assisted in formulating, appeared to take no position on the causation issue with regard to breast implants, the selection panel believed she met the standard for impartiality. The panel concluded that her advocacy of a neutral wait-and-see policy for the ACR was consistent with her role of assessing the evidence on scientific grounds.

In general, members of the selection panel reported (and members of the expert panel confirmed) that those who accepted the invitation to serve on the science panel seemed curious about the process and viewed such service as an opportunity to strengthen the presentation of scientific information in a judicial forum. They also placed great weight on the fact that they would be furthering a public interest by serving as an expert for the court. None seemed motivated by traditional professional research interests, since service on the science panel would very likely limit the opportunity for traditional scientific achievement during the time of service. Panelists were given assurances that they would be able to write about their experiences on the science panel upon completion of their service.

Even though the selection panel was permitted to nominate multiple candidates, the panel decided to nominate only one scientist for each po-

sition.[55] In each case the selection panel was unanimous in its belief that the nominated individual was the best available person for the job. Most of those nominated were separately identified by more than one member of the selection panel, thereby strengthening the confidence of the panel in the candidate. The court accepted each of the four nominations.

Those nominated by the selection panel and accepted by the court as the members of the National Science Panel were

- Dr. Betty A. Diamond (immunology), professor, Department of Microbiology and Immunology, Albert Einstein College of Medicine, Bronx, New York;
- Dr. Barbara S. Hulka (epidemiology), Kenan Professor, Department of Epidemiology, School of Public Health, University of North Carolina, Chapel Hill, North Carolina;
- Dr. Nancy I. Kerkvliet (toxicology), professor and extension toxicology specialist, Department of Agricultural Chemistry, Oregon State University, Corvallis, Oregon; and
- Dr. Peter Tugwell (rheumatology), professor and chairman, Department of Medicine, University of Ottawa, Ottawa, Ontario, Canada.

55. One expert-panel member wished two people had been appointed from each scientific discipline so each finding would have been based on the consensus of two experts. Had this proposal been accepted, it would have had a significant impact on the cost of the process, perhaps doubling it.

V. Instructions to the Expert Panel

Producing a written report was an important objective of both *Hall* and *MDL-926*. In *Hall*, the report was the primary product of the expert panel. In *MDL-926*, the report served to give focus and structure to the experts' videotaped testimony.

The courts' instructions to the expert panel members in both proceedings were intended to define the experts' tasks and set out a procedure to assist them in carrying out their charge. Judge Jones's instructions to his advisors were designed to guide the experts in producing a report that would help him make a decision about whether to exclude plaintiffs' scientific evidence at the pretrial stage. Judge Pointer's instructions were designed to assist the experts in reviewing the scientific literature, producing a written report, and providing testimony for federal and state breast implant trials nationwide. The instructions differed in several ways, including timing, the definition of the experts' duties, and the extent to which the initial instructions were supplemented. As both the Oregon and multidistrict litigation processes unfolded, clarification or elaboration of several instructions or questions became necessary. During interviews, participants in both processes emphasized the need for clearer instructions and more guidance from the court. In this section we describe the scope of those instructions, consider similarities and differences, and highlight issues and concerns raised by the participants in both cases.

Hall v. Baxter Healthcare Corp.

In the Oregon litigation, Judge Jones instructed the technical advisors after a pretrial hearing he convened to assist him in making a determination of whether the parties' expert testimony rested on reliable scientific methodology. At this hearing, Judge Jones, the special master, and three of the technical advisors asked the parties' expert witnesses questions

about the basis of their testimony.[56] Following the hearing, Judge Jones asked counsel to submit proposed questions for the technical advisors. After reviewing the submissions he drafted the following five questions:

- Is the expert's opinion supported by scientific reasoning and methodology that are generally accepted in the expert's particular scientific community or otherwise qualified?
- Is the expert's opinion based on scientifically reliable data?
- If epidemiological studies have not been done or are inconclusive, what other data (e.g., animal studies, biophysical data, clinical experience in the field, medical records, differential diagnosis, preliminary studies, general scientific knowledge, and medical literature) can justify, to a reasonable medical probability, a conclusion concerning the cause of the syndrome or disease at issue?
- Do the methodology and data support the expert's conclusions?
- Do the scientific data relied on by the expert apply to the syndrome or disease at issue in these cases? For instance, are epidemiological studies directed at other typical or classical diseases relevant to an atypical disease?

The questions were intended to guide the advisors as they considered issues of relevancy, fit, and validity of plaintiffs' experts' evidence. The court included, in addition to its five questions, all but one of counsels' proposed twenty or so questions and instructed the advisors to respond to any of those questions they thought would be helpful to the court in discharging its gatekeeping role.

Several plaintiffs' attorneys said they wished they had had better direction from the court as to the scope of the advisors' tasks before drafting their questions. For example, one attorney thought Judge Jones should have submitted to the parties a list of issues he wanted the advisors to address before commencing the Rule 104(a) hearing.

56. The three technical advisors were Dr. Greenlick (epidemiologist), Dr. Wilkens (rheumatologist), and Dr. Stenzel-Poore (immunologist). Dr. Jones observed the hearing as an expert in biochemistry. When he resigned as an expert from the panel he briefed Dr. McClard, his replacement, about the hearing.

The special master indicated that he and the advisors would have welcomed more definitive instructions from the court earlier in the process, especially since they were unfamiliar with judicial procedures and the operation of the court. One advisor said: "The most difficult part was knowing the assignment." Another called for "better instructions as to our specific duties." A third observed that "the lack of guidance regarding the task created confusion," and the fourth found that "changing expectations regarding what was expected of us complicated our assignment." The special master also noted that providing such instruction was made more difficult because of the evolving nature of the process.

The fourth instruction—"Do the methodology and data support the expert's conclusion?"—generated considerable commentary from the advisors as well as parties' counsel. This instruction reflected the Supreme Court's caution in *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* that in assessing whether the basis for expert testimony is scientifically valid, the court must focus "solely on methodology, not on the conclusions that they generate."[57]

Some of the advisors found this question confusing. From a scientist's perspective there is no clear delineation between methodology and conclusion; the methods frame the conclusion, which then leads to alternative methods for the next study. One advisor commented that the attorneys created more confusion with their attempt to clarify the distinction between methodology and conclusion. One attorney, for example, urged the advisors "to consider only the methodology, not the conclusions," but went on to discuss the conclusions. These mixed signals from the attorneys made the advisors' task more difficult.

Judge Jones agreed that the methodology/conclusion distinction under *Daubert I* presented a difficult issue. Judge Jones anticipated the Supreme Court's resolution of this issue when, in his opinion, he indicated that

> [t]here appears to be no clear demarcation between scientific methodology and the conclusions it generates. *Daubert I* acknowledged this much, recognizing that science is a process, not an encyclopedic

57. 113 S. Ct. 2786, 2799 (1993).

> body of knowledge. "This court need not and should not ignore any step in the process, but must ensure that in each step, from initial premise to ultimate conclusion, the expert faithfully followed valid scientific methodology. In other words, this court need not accept, as scientifically reliable, any conclusion that good science does not permit to be drawn from the underlying data but which instead constitutes 'unsupported speculation'. . . ."[58]

The special master commented that distinguishing between methodology and conclusion is difficult when the findings involve a chain of reasoning that is tied to research methods. He believes that scientists should be permitted to comment on the validity of inferences and conclusions because a valid method may be applied inappropriately.

Communications between experts and the court

Judge Jones asked Dr. Richard Jones to continue to serve as special master following appointment of the expert panel. Dr. Jones served on occasion as an intermediary, fielding questions from the panel members and bringing questions to Judge Jones or the parties if appropriate. This approach reduced instances of ex parte communication[59] and allowed for instruction of the experts while permitting Judge Jones to maintain suffi-

58. Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1401 (D. Or. 1996) (citation omitted). *See also* Joiner v. General Elec. Co., 118 S. Ct. 512, 519 (1997) ("But conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.").

59. In general, case law and canons of judicial ethics discourage any type of ex parte communication regarding substantive matters during the course of the litigation between the judge and the court-appointed experts offering testimony as a witness. *See* Cecil & Willging, *supra* note 28, at 39–43. When the expert serves as a technical advisor, and therefore as a consultant to a judge, ex parte communication with the judge sometimes occurs. But even here appellate courts have cautioned that judges should follow certain procedural safeguards. Reilly v. United States, 863 F.2d 149, 158–60 (1st Cir. 1988) (holding that ground rules governing communication with a technical advisor included advising parties if an expert ranged into an area not discussed in briefs; appellate court recommends inclusion of a comprehensive job description on the record and submission of an affidavit of the expert's compliance with the ground rules at the end of the appointment).

cient distance from the work of the panel. We are aware of no instances of direct communication regarding matters of substance between Judge Jones and the panel experts. In one instance an expert sought clarification of a statement regarding the precision of a certain measurement that had been relied on at the preliminary hearing. This expert's concern was relayed to Judge Jones through Dr. Jones. When Judge Jones declined to reopen the record to obtain clarification of this issue, the expert on his own initiative contacted the manufacturer of the laboratory instrument to determine if it was capable of making the disputed measurement, an approach that amounted to an indirect form of ex parte communication with the judge.

In re Silicone Gel Breast Implants Products Liability Litigation

Judge Pointer provided written instructions to his panel of experts soon after they were appointed.[60] Following issuance of the written instructions, Judge Pointer held a two-day conference where he provided an orientation to the experts. The orientation included, among other things, an overview of events that had led to the experts' appointment and a description of their roles and responsibilities. He stressed that the experts were not being asked to perform independent research or examine patients. Rather, he said, they were being called upon to look at the various scientific studies and reports and to make professional judgments as to whether there exists a reliable scientific basis within their disciplines for drawing certain conclusions (i.e., whether implants cause or exacerbate specified conditions).

Judge Pointer had previously discussed the duties of the experts with parties' counsel, and the attorneys had reviewed and commented on a draft of the court's proposed instructions. Judge Pointer included many of the parties' suggestions, but limited the number of systemic injury symptoms for the experts to consider to around twenty-five.[61]

60. Fed. R. Evid. 706(a) requires written instructions or a conference with the court's experts.

61. Listed in the appendix of the court's order were various diseases, symptoms, conditions, or complaints that have sometimes been asserted as possibly associated with sili-

In his written instructions Judge Pointer asked the court-appointed experts to respond to these questions:[62]

> (a) Issues. To what extent, if any, and with what limitations and caveats do existing studies, research, and reported observations provide a reliable and reasonable scientific basis for one to conclude that silicone-gel breast implants cause or exacerbate any of the conditions described in (b) below? If, in the process of making these findings, you believe that there are related or subordinate issues that should be separately addressed, please do so.
>
> (b) Scope. You are asked at this time to consider the relationship, if any, between implants and the following:
>
> i) "classic" connective tissue diseases, such as systemic lupus erythematosus, Sjögren's syndrome, etc.
>
> ii) "atypical" presentations of connective tissue diseases or symptoms
>
> iii) immune system dysfunctions
>
> (c) Contrary Opinions. To what extent, if any, should any of your opinions referenced in (a) above be considered as subject to sufficient genuine dispute as would permit other persons, generally qualified in your field of expertise, to express opinions that, though contrary to yours, would likely be viewed by others in the field as representing legitimate and responsible disagreement within your profession?

During the conference, the experts were given an opportunity to review and comment on the court's proposed instructions. They were asked to point out any issues that were not clear and to indicate whether they felt comfortable performing the tasks as outlined in the instructions. The experts expressed no reservations regarding the instructions during the conference.

Judge Pointer delivered oral instructions to the panel members on the procedures to be followed regarding consultation among themselves, consultation with authors of studies, obtaining special assistance or advice from other experts, preparation of reports, and potential procedures

cone gel implants. The experts were encouraged to comment on the scientific bases, if any, for any such claimed linkage. They were not asked to consider purely local complications, such as breast disfigurement, tenderness, or capsular contracture.

62. *In re* Silicone Gel Breast Implant Prods. Liab. Litig., MDL-926, Order 31E (Directions to National Science Panel Under Rule 706) § 1(a)–(c) (N.D. Ala. Oct. 31, 1996).

for presenting testimony through depositions. As reported below, some of these oral instructions proved to be unclear to the experts and counsel.

Communications with and among panel members

Throughout the process, issues arose about the proper methods for communication between the judge and panel and among panel and non-panel members. In an early order, litigants and implant recipients, their counsel, and their potential lay or expert witnesses, were enjoined from directly communicating with any of the members of the National Science Panel regarding issues in the breast-implant litigation.[63]

Judge Pointer initially anticipated appointing a fifth panel member to serve as an administrator and coordinator of the panel activities. He also anticipated communicating directly with the panel members. But defense counsel objected to direct communications, fearing that such communication would compromise the work of the panel.[64] Also, it soon became clear that the experts' lack of familiarity with the legal process, and the deposition process in particular, made it necessary to appoint counsel to represent their interests in those proceedings. Consequently, in January 1997 Judge Pointer appointed John M. Kobayashi of Denver, Colorado, to act as "special, independent, and private counsel to the members of the National Science Panel."[65]

Following appointment of the special counsel, Judge Pointer instructed that all communication with the panel was to be made through Mr. Kobayashi.[66] Mr. Kobayashi was authorized to contact parties, their counsel, and the court, singly or in combination, "mindful, however, of the obligation not to engage in communications that might be viewed as inappropriate ex parte communications involving substantive matters."[67] Judge Pointer ordered that all communication between panel members

63. *Id.*, Order 31D (Appointing Additional Member of National Science Panel and Precluding Ex Parte Communications with Panel Members) (N.D. Ala. Sept. 17, 1996).

64. *See* Edgar v. K.L., 93 F.3d 256 (7th Cir. 1996).

65. *In re* Silicone Gel Breast Implant Prods. Liab. Litig., MDL-926, Order 31F (Appointment of Special Counsel to National Science Panel) (N.D. Ala. Jan. 13, 1997).

66. *Id.*

67. *Id.*

and special counsel would be subject to attorney–client privilege.[68] Mr. Kobayashi also served as a channel of communication from the expert panel members to Judge Pointer, including communications regarding administrative matters such as billing, payment, and scheduling of hearings.

The few instances of direct communication between Judge Pointer and the experts serving on his panel arose when communication between the experts and special counsel appeared to break down. When several of the experts had difficulty contacting Mr. Kobayashi, they called Judge Pointer's chambers directly with their questions and requests. On occasion, when discussing administrative matters with a member of Judge Pointer's staff, an expert would raise a question of substance. Judge Pointer would then report these contacts and the substance of his response to the parties. Attorneys for the defendants, who had initially objected to a proposal to permit ex parte communications between Judge Pointer and the expert panel members, reported that this process worked well. Attorneys for the plaintiffs, who did not object to the proposal for direct communications, also expressed no concerns about ex parte communication between Judge Pointer and the experts.

Mr. Kobayashi was active in conveying to the parties the needs of the panel in terms of the format and structure of information the panel wished to consider. In the one known instance of direct contact between a panel member and a party, the panel member appeared on a symposium panel unrelated to breast implants that was organized and sponsored by one of the defendants. This interaction became the topic of an extended hearing, which is discussed in section VII, *infra*.

Participants' comments on the instructions

Participants provided a range of comments about the court's oral and written instructions. Generally, the panel expressed some confusion as to how to conduct their work, frustration about restrictions on their day-to-day activities, and concern about the confidentiality of their notes and conversations. One expert commented that the oral instructions seemed

68. *Id.*

fine at the time, but the panel later realized that all instructions should have been written and affirmed by all involved.

With respect to the court's written instructions, one panel member commented "they were precise from a legal standpoint, but the panel had to work hard to figure out what the questions really were. Only then could [the panel] decide who would cover what area. There were a lot of options for organizing the work, and the way we did it is only one of many possibilities. What we ended up with, though, was appropriate and it was appropriate for the court to leave it to us to figure out how to organize our work."

Another panel member commented that the panel had been told to be careful about drafts, but she was not aware that this would extend to scribbling notes on articles. At the outset, Judge Pointer had advised the panel members to revise their computer-based drafts as he does, without saving the old ones. However, Judge Pointer said he could not advise them whether or not earlier drafts would or would not have to be produced.

All of the experts thought the initial screening for conflicts of interest had been done in good faith but that the screening did not anticipate issues that arose later. One expert commented that the court should have had written instructions on conflicts of interest. Having such instructions, the expert believed, would have minimized a lot of the confusion surrounding appropriate communications with parties and nonparties. Several experts noted that as time passed the definition of what seemed to be a conflict of interest changed.

On reflection, Judge Pointer concluded that it would have been better to have provided written instructions on conflicts of interest rather than oral instructions. He said he should have clarified and reasserted the conflicts screening initially performed by the selection panel. He also said he should have spent more time preparing special instructions on conflicts of interest and periodically reemphasizing these issues. At the same time, Judge Pointer said he had been concerned that more detailed instructions regarding conflicts could overstate the problem of communication with representatives of the parties and might have discouraged the selected experts, and perhaps it might have made it even more difficult to get candidates to serve. In fact, Judge Pointer noted that had a more re-

strictive definition of conflicts of interest been in place, at least one expert would have chosen not to serve on the panel. When asked about using the conflicts of interest standard for judges, Judge Pointer said he did not think it would have been practical because the issues are different.

One plaintiffs' attorney thought Judge Pointer's oral instruction implied that the experts were entitled to keep their opinions, correspondence, and other communications secret. This attorney thought the experts should have had no more right to secrecy and should have had no more court protection than any other party's expert. This attorney also thought it was inappropriate for the court to allow the experts to work together as a group, with their deliberations being secret.

One plaintiffs' attorney thought the instructions were clear except for the standard-of-proof question. The attorney noted that Judge Pointer had instructed the panel to apply the standard of proof used in their respective fields. As a result, panel members used the scientific standard, which requires greater certainty than the legal standard of a preponderance of the evidence. This attorney thought the scientific standard was the wrong standard to use.

Several defendants' attorneys thought the question concerning causation issues was fine, but that the question regarding acceptable minority views was not as clear as it could have been. These attorneys thought the court was asking the panel to do something the panelists would not normally do—that is, to be critical of other scientists and their methods.

Finally, several of the experts thought their report would be the major product and were surprised to learn that they would have to be deposed, even though the court's Order 31, which preceded their appointment, clearly states that videotaped depositions would be the ultimate products. All of the experts in both cases noted that many of their concerns should have been expected given the participation of "naïve" scientists or physicians, without previous experience as experts, in a judicial process with which they were not familiar.

VI. Collecting Scientific Information and Producing the Reports

In this section, we discuss the information on which the reports were based, the form of the reports, the experts' division of labor, needs for assistance and expertise, administrative matters relating to the production of the reports, and perceptions of the attorneys about the usefulness of the reports.

Hall v. Baxter Healthcare Corp.

In the Oregon litigation, the advisors received scientific information in three ways. First, Judge Jones structured a four-day pretrial hearing on the admissibility of expert evidence; each day was devoted to one of the four subject-matter areas (biochemistry, epidemiology, immunology, and rheumatology). At the hearing, the expert advisors and the special master listened as the parties' experts presented their views in narrative form. Opposing counsel then cross-examined the experts, but without evidentiary objections. Judge Jones limited the questions to those addressing science issues, ruling out, for example, questions regarding bias and funding of the research. Judge Jones and the technical advisors also asked questions of the parties' experts about the basis of their proffered testimony.

Second, following the hearing the parties provided the panel of advisors with numerous boxes of articles and other written materials. All of the technical advisors in the Oregon litigation indicated that they were initially overwhelmed by the amount of material they had to review in a brief period of time. One advisor noted that the material submitted by the parties should have been better organized. The advisors believed that they should have received guidance about how to undertake their review.

Third, Judge Jones ordered the parties to prepare videotaped summations for the technical advisors, allowing each side thirty minutes per discipline and allowing plaintiffs forty minutes for rebuttal.

To assist the technical advisors in carrying out their charge and to minimize ex parte communication, Judge Jones asked Dr. Jones, the special master, to continue to serve following appointment of the expert panel. Dr. Jones assisted the technical advisors by (1) offering guidance regarding their tasks, which in some instances included interpreting the court's instructions, (2) contacting Judge Jones with advisors' questions about communications with others not on the panel, and (3) reviewing drafts of some of the reports to ensure they were responsive to the court's questions and written in a way that would be understandable to a nonscientist.

As a result of Dr. McClard's (the biochemist) late appointment, he had only a few weeks to prepare his report. Understandably, he had a great number of questions about the evidentiary hearing and report preparation. Consequently, Dr. Jones worked more closely with Dr. McClard than with the other technical advisors. He assisted Dr. McClard by responding to general questions, such as how to locate items in the court record. Dr. Jones indicated that he offered no opinion or judgment regarding the merits of the issues in dispute, but that he did help focus Dr. McClard's inquiry on the relevant issues. Further, he also reviewed a draft of Dr. McClard's opinion and suggested minor revisions to several phrases that Dr. Jones thought might be misunderstood.

Judge Jones's questions provided some structure for developing the report. However, since he required the advisors to prepare separate reports and not exchange reports prior to submission to the court, the advisors had little need to communicate beyond deciding how specific topics would be divided among the panel members, some of whom had overlapping areas of expertise. Two of those experts consulted on how they should divide certain overlapping issues of immunology and rheumatology and then proceeded to work independently of each other and the rest of the panel. The technical advisors almost never consulted with scientists who were not part of the panel, in part because of the short time available for preparing their report. One panel member did ask a senior researcher in her department to clarify some technical issues and outdated language in some of the older reports submitted by the parties to make sure she interpreted this information correctly. We are not aware

of any other contacts between the panel members and outside colleagues regarding this litigation.

All of the advisors found the lack of specific guidance regarding the relationship between methodology and conclusions and the treatment of minority viewpoints especially problematic. In the end, the advisors produced separate reports that included inconsistent views.

In re Silicone Gel Breast Implants Products Liability Litigation

In the MDL proceedings the experts also received information in three ways. First, Judge Pointer arranged a two-day conference at which the party experts presented their views and engaged in informal discussions with the panel members. Subsequently, the panel members, with the assistance of special counsel, convened a conference in Washington, D.C. The panel members directed the discussion at that conference, with Judge Pointer sitting in the audience. These two hearings are described in greater detail below.

Second, the experts reviewed articles and other written materials that were transmitted through the special counsel's office. In all, the parties submitted over thirty-five linear feet of written material. At Judge Pointer's urging, the parties formulated priority lists of forty articles per expert for each side and a "top 100" listing overall. The panel of national experts also expressed concern about the volume of material it received and the length of time it took to review such documents. Initially, the panel was given eleven large boxes containing thousands of documents. Most of the panel members thought the court's later directive that the parties prioritize articles helped tremendously. One expert thought the priorities gave them a starting point, but the experts continued to discover important facets of the issues until the end of the process. On the other hand, another expert commented that the prioritized material was not that useful since it was arranged based on the parties' arguments.

Third, each of the experts conducted his or her own searches. Such searches rarely turned up information that the parties had not provided at some point as part of their submissions. At the trial deposition stage, the parties listed hundreds of additional articles as possible bases for cross-examination. Nevertheless, this independent search gave panel

members confidence that their opinions were based on a thorough review of the literature.

Individual versus joint reports

In his initial instructions to the MDL selection panel, Judge Pointer expressed his "present contemplation" that each expert would prepare an individual report after drawing on other panelists' expertise and after the expert finished all or a discrete portion of the assignment and was prepared to make a finding.[69] This instruction was intended to create an identifiable body of work linked to each panel member as a way of framing his or her direct testimony and focusing any cross-examination. As the work evolved, the panelists combined their individual efforts into a single report after they all reached the same conclusion: There was no reasonable and reliable scientific basis for one to conclude that silicone gel breast implants cause or exacerbate the specified diseases. To satisfy the need for individual accountability and responsibility, each panelist wrote a separate chapter. All four panelists signed the final report, and their findings were linked by an executive summary that included an introductory section on the common background for the report. The executive summary concluded with a joint statement responding to Judge Pointer's question about opinions that were contrary to those of the panel members. Each chapter contained its own background, definitions of problems, analyses, and conclusions, as well as its own references, tables, and appendices.

There was considerable overlap in the qualifications of the panel members. Dr. Diamond was appointed as an immunologist and Dr. Kerkvliet was appointed as a toxicologist, but both dealt in essence with immune system responses to foreign substances. They divided the labor by agreeing that Dr. Diamond would consider research on human immunology and Dr. Kerkvliet would examine animal studies. Dr. Hulka was appointed as an epidemiologist and Dr. Tugwell as a rheumatologist. To address rheumatological issues, Dr. Tugwell relied primarily on epi-

69. *In re* Silicone Gel Breast Implant Prods. Liab. Litig., MDL-926, Order No. 31 (Appointment of Rule 706 Expert Witnesses) § 3(b)(3)(b) (N.D. Ala. May 30, 1996).

demiological methods. Each wrote separate chapters that reflected similar methods and analyses.

Communications among panel members and with colleagues

Judge Pointer indicated that the panel members were free to communicate with each other as needed.[70] Mr. Kobayashi was concerned that the subject of such communication could become a topic for discovery and attempted to bring such communications into the protection of attorney–client privilege by setting up a special telephone line and urging the panel members to communicate with each other only when an attorney from his office was on the line. The experts found this restriction both awkward and inconvenient and soon began to engage in direct telephone and E-mail communications. The experts reported that such communication was necessary to coordinate their work on a single comprehensive report. One expert expressed frustration that they had very few opportunities to meet in person as a panel. All the panel members agreed that the open communication among panel members was essential in preparing the report.

Another point of tension between Mr. Kobayashi and panel members involved the opportunity for the court-appointed experts, as they reviewed the literature and prepared the report, to communicate with colleagues not serving on the panel. Such consultations are a common practice among scientists, especially where a scientist is attempting to master a new area of research. Since the panel members had not conducted research on the effects of silicone gel breast implants, they wanted to consult with others who were experienced in this area. At the first meeting in Birmingham, Ala., one of the panel members asked Judge Pointer about consultation with colleagues who were not involved in the litigation—the panel member was told that such consultations were appropriate if she kept a log of the inquiry. If a panel member wished to ask questions of an author of one of the papers being reviewed for the litigation, the inquiry could involve questions to clarify an understanding of data in a research

70. Transcript of National Science Panel Hearing Held Before the Honorable Sam C. Pointer, Jr., at 27 (Oct. 24, 1996) (on file with authors).

study, but not an interpretation of the data, a distinction that proved difficult to make. After Mr. Kobayashi became special counsel, he established a phone line for such communications and kept a log of such contacts.

The experts in Judge Pointer's litigation found that such constraints discouraged occasional consultation with colleagues.[71] One panel member did go through the preclearance process to contact two persons in her academic department, but was surprised to learn that their identities were then reported to the attorneys for the parties. From that point on she was reluctant to approach colleagues for fear of getting them involved in the litigation. Other panel members did not contact colleagues, either because they were concerned or confused about the conditions governing such contacts or because they wanted to develop an independent judgment of the issues. One panel member suggested that the panel would have benefited from clearer rules and from a document that panel members could have sent to colleagues setting forth the ground rules governing the panel member's constraints and the possible consequences of responding to an inquiry.

Need for special assistance

Apart from occasional consultation with colleagues, the panel members in Judge Pointer's litigation also required several forms of specific assistance in preparing their report. For two panel members the assistance took the form of assembling a team of two or three other researchers to assist with review of published studies, to develop sophisticated statistical reanalyses of data from those studies, and to review and edit the panel members' contributions to the final report. The individual panel member directed the work and communicated freely with the members of his or her research team. These interactions were the topic of inquiry at the discovery depositions and at trial.

Two other members of the panel required more limited assistance. One panel member asked two colleagues from her department to review her section of the report and offer technical and editorial suggestions.

71. The need for such contacts was mitigated by the Washington, D.C., hearing.

Another panel member used an information specialist to identify relevant articles and prepare brief summaries from the boxes of materials that the parties sent to the panel members. Some of those colleagues appear to have been paid through the judiciary account while others were paid by the parties through the special counsel. Each panel member testified that the report represented his or her independent assessment of the evidence.

The need for a polymer chemist was raised at various times by the panel members. Late in the process special counsel contracted with a polymer chemist to consider questions raised by panel members, but by the time the chemist reported the experts had completed their own reports and were about to begin the discovery depositions. The polymer chemist's report apparently had no influence on the experts' conclusions. At least one of the panelists thought that the chemistry issues were moot because their findings did not indicate any perturbation of the immune system that would have required an assessment of various chemical explanations. One panelist expressed concern that the panel did not have a neurologist or someone with expertise in neuropsychiatric assessments to give a critical evaluation of some of the assessment tools used in epidemiological studies.

Dividing the administrative labor was another problematic area. The parties objected to Judge Pointer's original plan to appoint an administrative chair of the panel, and he did not implement that plan. None of the panel members was designated as a chair or convenor and no one had responsibility to initiate communication about matters of mutual concern, such as the division of labor or the production of a report. By default, this role came to be filled by special counsel and by the individual panel members who offered to undertake particular activities. One panelist, for example, volunteered to draft an executive summary to the final report.

The absence of a chair and of central administrative support resulted in a number of difficulties in producing the final report. More than one panelist found a need to have his or her section of the report read—for clarity and editorial precision—by someone not familiar with the subject matter, but there was no provision for central editing.

Similarly, there was a need for central production of an electronic version of the report. The panelists produced their chapters using their

own word processing systems and formats. Melding these efforts into one central document became necessary, and one of the panelists took responsibility for preparing the final manuscript. This panelist found some resources at the university, but still found it difficult to get the report out in a unified electronic format. Another panelist, while generally satisfied with the level of administrative assistance, felt constrained to do the photocopying rather than ask the departmental secretary to do so.

Report of the expert panel

In November 1998, the National Science Panel issued its report. The report consisted of four chapters, each written by one member discussing the issues in her or his area of expertise, an introduction, conclusion, and executive summary. There was general consensus among the panel that they had found no scientific basis to support the claim that silicone gel breast implants cause connective tissue diseases or immune system dysfunctions. For a more detailed description of each panel member's conclusions, see *supra* page 18, Report of the Expert Panel.

Attorneys' views of the usefulness of the report

Attorneys' views about the usefulness of the report are directly related to the extent to which the report supports the attorneys' claims. In general, attorneys for defendants find the report and the videotaped testimony extremely useful and they expect to use them in any trials about systemic issues and in any *Daubert* hearings that might precede such trials. On the other hand, attorneys for plaintiffs think the report and testimony are worth very little and expect to challenge their use at every juncture. Attorneys on both sides have doubts about the life expectancy of the report and testimony.

All defendants' attorneys and even one plaintiffs' attorney found that the report matched well the issues of the litigation. Other plaintiffs' attorneys identified a number of gaps in the report. One argued that the experts simply ignored significant studies. Others considered the absence of views from a pathologist or a polymer chemist to be fatal. Another focused on the absence of clinical findings, arguing that the report by its terms addressed the general causation issues in terms of existing scientific research only and could not be used to exclude clinical evidence that ill-

nesses arose following the implants and were cured when the implants were removed.

All agree that, except in extraordinary circumstances, the report itself will not be independently admissible as evidence. Plaintiffs' attorneys expect to argue that the report "is not the type of information that an expert would ordinarily rely on." One plaintiffs' attorney said "an expert relying on the report would have to answer some very difficult questions."

Another attorney noted that a limitation on the utility of the report and videotaped testimony is that it relates entirely to evidence of systemic injuries and simply does not consider local injuries; plaintiffs plan to emphasize local injuries, which they believe are present in many, if not all, of the cases that remain in the system.

VII. Discovery and Depositions of the Experts

Candidates for appointment as experts often express concern about the extent to which their opinions will be subject to deposition and cross-examination. Scientists tend to view a proper inquiry as limited to the opinions and information expressed in the research report. This is especially true where the experts are appointed by the courts and are unlikely to have been influenced by contact with the parties. Such scientists tend to regard inquiry into factors not directly related to the report, such as the personal motivations of the researcher or opinions on matters outside the report, as unnecessary attacks on the integrity of the individual. The legal system, of course, tends to be more skeptical and traditionally permits a more searching inquiry into the basis of expert testimony and opinion. In both *Hall* and *MDL-926*, the court found it necessary to fashion a compromise procedure that permitted the attorneys to inquire into the basis of the expert panel members' opinions while constraining the inquiry short of its traditional scope. As the MDL judge presiding over a national docket of cases, Judge Pointer had to be concerned that any rulings or other limitations on cross-examination might render the deposition testimony inadmissible at trial. Multiple standards might apply in various trial courts in which the testimony might be used.

Hall v. Baxter Healthcare Corp.

In the Oregon litigation, Judge Jones did not contemplate having depositions of the experts because their role was to serve as technical advisors, not witnesses. Judge Jones appointed them pursuant to a court's inherent authority to seek technical advice and assistance and, thus, concluded that the requirements of Fed. R. Evid. 706 relating to depositions, testimony, and cross-examination did not apply. After plaintiffs filed a motion to apply Rule 706 protections to the process, Judge Jones gave the parties a limited opportunity to question the experts about the scientific bases for their reports.

Three days after the technical advisors submitted their reports, the court conducted a hearing at which parties' counsel questioned the advisors. Judge Jones made clear that this hearing was not to be a deposition, but rather a chance for the attorneys to ask questions about the bases of the advisors' reports. Almost all of the plaintiffs' attorneys and a number of defense attorneys thought that this hearing did not provide an adequate opportunity to question the advisors about their findings and conclusions. Similarly, one technical advisor believed the hearing was not a true "cross-examination" and thought that he and the other advisors should have been deposed. Upon reflection, Judge Jones thought that having advisors provide testimony in open court may have created some confusion regarding their role, since advisors who serve as consultants to the court are not generally deposed. Still, he was satisfied with the way the process worked.

In re Silicone Gel Breast Implants Products Liability Litigation

Judge Pointer, the parties, and special counsel for the court-appointed experts created a hybrid deposition process that was adapted to the needs of the litigation and that attempted to balance the interests of the parties, the experts, and the court. Judge Pointer sought to create an informal atmosphere that would be comfortable for the experts while giving the parties the opportunity to discover information relevant to the videotaped trial depositions that were to follow a couple months later.

Discovery deposition format

Discovery depositions were conducted in Atlanta, in February 1999, under ground rules established by Judge Pointer in orders issued during December 1998 and January 1999. Judge Pointer presided at the depositions, which were held in a law firm's conference room. Depositions were transcribed by a court reporter, but not videotaped. Each side was allowed a maximum of three hours to conduct its examination, with one attorney from each side permitted to question a given panel member. Time limits were applied flexibly. All of the panelists were allowed to be present while the others testified.

Flexible informality describes the deposition process. Some questions, especially those dealing with the process of preparing the report, were posed to more than one panelist in an informal "joint deposition" format. Once in a while, if a panel member did not know the answer to a question, he or she referred it to another expert. Sometimes special counsel would whisper to the expert after a question was asked. No one objected to a practice that, in other deposition contexts, has been known to lead to contentious battles.

Before the depositions, counsel were ordered to submit general wording of all questions to be asked each witness, and copies of these questions were provided to the witnesses in advance of the hearing. If a question referred to an article not cited in the report, a copy of that article was to be attached to the request. Additional questions were permitted only to the extent that a panelist appeared prepared to respond to the question despite the lack of prior notice.

In all, counsel asked the experts hundreds of questions, ranging from detailed questions about particular studies to general questions about the panelists' backgrounds. Questions typically were related to the process of conducting the research and to the substance of the science issues. In general, plaintiffs' questions were more in the style of a cross-examination and defendants' questions were more expository.[72] Judge Pointer tried to separate out the common issues and structure a joint dis-

72. Some examples of plaintiffs' attorneys questions give a flavor of the confrontational questions the panelists faced. Plaintiffs' background questions included: "Are you an expert in the following areas: toxicology, pathology, polymer chemistry, neurology, or epidemiology?" and "Have you conducted any original research on silicone or breast implants?" Plaintiffs' process questions included: "In preparing for your testimony today, please tell us what you reviewed, who you met with, what was said, who else was present, and what else, if anything, did you do?" and "Did the panel adopt any procedures for reviewing the materials and preparing the report?" Plaintiffs' questions addressing the science issues included: "Do you find granuloma in healthy individuals or is that an indication of a disease process?" or "What criteria did you use to determine if the elevation of risk in the studies referenced on Page IV-7 are substantial or consistent, and what epidemiological literature do you rely on for your criteria?" As one plaintiffs' attorney indicated to us, the Plaintiffs' Steering Committee attorneys were representing plaintiffs' attorneys across the country and accordingly felt pressure to be especially thorough.

cussion, but for the most part the depositions were conducted on an individual basis.

Plaintiffs' requests for documents

In December 1998, plaintiffs' attorneys requested, among other items, copies of the experts' notes and any other evidence of communications among panel members concerning preparation of the report (including communications with counsel), as well as drafts of the report or any outlines. Defendants and special counsel objected. After the parties were unable to resolve the issues in dispute, Judge Pointer directed the parties to brief two issues: "(1) whether communications among panelists may be discovered; and (2) whether the parties are entitled to discovery of the panelists' drafts and working notes."[73]

Plaintiffs argued that their right to obtain notes, drafts, and other material was a central part of their right under Fed. R. Evid. 706 to cross-examine a court-appointed expert and that the materials sought were clearly within the scope of discovery as set out in Fed. R. Civ. P. 26. Defendants claimed that the request delved into material that was privileged because it was used in the decision-making process, analogizing to cases involving arbitrators, hearing examiners, and other decision makers. Plaintiffs countered that the panelists are witnesses, not adjudicators.

Special counsel participated in a conference call with Judge Pointer and the defendants' attorneys considering the plaintiffs' request, but did not file a brief or other written argument relating to the request. In response to the request, one special counsel produced documents from two of the experts. One of those experts produced a record of all telephone calls from her office during a two-year period, not limited to calls in which breast implants were discussed. Both experts turned over notes and critiques, and one provided a copy of her original working outline.

Judge Pointer did not issue a general ruling on the request for documents. Rather, he ruled on specific requests for specifically identified documents. On several occasions, he examined an item in camera before

73. Plaintiffs' memorandum on discoverability, Feb. 1, 1999, at 1 (on file with authors).

ruling on its discoverability. His first ruling related to a document, "Summary of Review of Articles," that two colleagues had prepared at the expert's request. Judge Pointer ruled that it was discoverable. Based on the written submission, he ruled that generally the work of the panelists is a proper subject of inquiry and production. Judge Pointer rejected the general "decision-making privilege" claim. For the benefit of the experts, he observed that looking at notes or preliminary reports need not be a source of embarrassment and suggested to the attorneys that examining the details of such drafts may well be a waste of time.

Special counsel objected to the ruling, arguing that he had not had an opportunity to respond and that if the ruling stood "this will be probably the last time we ever see scientists as panelists."[74] Special counsel also argued that panelists believed that their notes and other communications with each other would be protected. The basis for this argument was that Judge Pointer had instructed the panel that they were free to communicate with each other. He did not, however, as his ruling made clear, say that such communications would be privileged. This legal nuance was undoubtedly lost on the experts, who had little or no legal experience.

Judge Pointer sustained an objection to a request that one of the experts identify two people whom she asked to review a draft report. He ruled that the identity of the two individuals was immaterial and insufficient to outweigh the witness's good-faith commitment not to draw these colleagues into the legal process. He permitted questions as to the content of the review.

One of the experts testified that a research assistant conducted literature searches on electronic databases such as Medline and Biosys. Plaintiffs requested that the expert search for a printout of this document, and Judge Pointer ruled that any such printout should be produced if it could be found without excess work. This expert also indicated that she probably had some notes from the hearings she attended in Birmingham and Washington, D.C., and from her own readings. Judge Pointer again ruled that these papers should be produced if they could be

74. Transcript of Rule 706 Panel Hearing (Discovery Depositions), Feb. 4, 1999, at 17 (on file with authors).

found with a reasonable effort. He directed the witness to spend no more than a couple of hours in a search for all of the above documents and to give priority to matters of substance.

Examination on contacts with party representatives

Plaintiffs and defendants examined the experts to determine what contacts they had with colleagues who served as consultants to a party. On several occasions, the experts had contacts on a professional basis with such experts, but their contacts were not related to silicone gel breast implants. For example, one expert co-authored an article with an expert witness for a defendant and another expert jointly organized a symposium with a party expert. One expert knew that faculty colleagues had consulting relationships with defendants and therefore avoided talking with them about silicone gel breast implants.

Another expert testified at some length about a contact she had with a paid consultant for a defendant. Her notes of the conversation dealt with the consultant's opinions on various studies that were central to the issues under review, the consultant's opinion on the validity of legal claims, and the consultant's recommendation of a book seen as favoring defendants' viewpoints. Not being aware of the consulting relationship, this panel member thought the consultant's interest was purely scientific and put the consultant's name on the panel for the D.C. meeting.

Rulings on disclosure of personal notes and other matters

During the deposition, Judge Pointer ruled on many objections that a particular question had not been included in the list of submitted questions. He generally treated this objection as he did many of the objections raised, saying to the witness: "If you're comfortable with it, you may answer." On another occasion, Judge Pointer tried to tone down the contentiousness of the proceedings by telling the attorneys to "hold that type of objection."

Efforts at informality sometimes had to give way to legal rules. A major dispute arose over plaintiffs' counsels' attempt to obtain copies of one expert's personal notes, references, and an annotated copy of the report that the witness brought to the conference table. Special counsel objected to production of the notes and indicated that he was prepared to

take an interlocutory appeal on the issue. He said that the notes were made on a set of documents he presented during a privileged conversation (the documents turned out to be the list of questions compiled by Judge Pointer). He argued that the notations were private thoughts and records of a conversation with another panel expert and that the panelists thought that their communications would remain confidential; that he had not had an opportunity to respond to plaintiffs' requests; and that ordering the disclosure would run the risk that no scientist would ever want to participate in such proceedings. He asked for the opportunity to file affidavits and responsive pleadings and to submit the documents to in camera review. Defendants echoed his objections.

Judge Pointer reaffirmed his earlier ruling that there is an attorney–client privilege between special counsel and the expert witnesses, that the contacts with special counsel were privileged, and that the document counsel gave them was probably privileged. Judge Pointer thought that the document had been prepared by special counsel and seemed surprised to learn later that it was the list of questions the judge himself had prepared. The conversations between the panelists, however, even if conducted at the direction of counsel were not privileged. Examination of documents with their notes of such conversations, though, could be limited by the burden of producing them or even by privacy concerns.

Special counsel persisted, arguing that he had had no opportunity to examine the requests and respond. Judge Pointer countered that he had had more than a month and all he presented was a telephone objection. Judge Pointer ordered special counsel to turn over the notes for an *in camera* review. Judge Pointer reviewed them during a short break and ruled that none of the material was protected by the attorney–client privilege. The notes consisted of circlings, underlining, question marks, and a few scribbled notes on the documents listing the questions to the parties. Judge Pointer saw the notes as analogous to Fed. R. Evid. 612 material used to refresh memory. Accordingly, he ruled that they need not be produced unless the witness referred to them during her testimony and then the item referred to would be disclosed.

One witness was asked about notes that the witness made while reviewing other studies. Judge Pointer ruled that these notes were disclos-

able unless there was some reason not to disclose. After the witness objected, asserting that these notes were the witness's intellectual property, Judge Pointer agreed to review them that evening and meet with the witness and special counsel in the morning to discuss them. After doing so, Judge Pointer indicated that he had reviewed the witness's underlinings and notations, page by page, and ruled that they are not subject to any absolute privilege.

Once again balancing the interests of the parties, Judge Pointer held that such materials are subject to review of a type that would be used in deciding whether to issue a protective order. Thus, he would weigh any burden imposed in producing the materials with the need and value of the documents to the parties. He concluded that these particular notes would have no value to anyone and that it would be a waste of time to allow the parties to inquire into the notes. The notes were made prior to the preparation of the report, and scientists need the freedom to be inquisitive and to ask questions of themselves without fear that such questions will be turned over to counsel for painstaking scrutiny. Parties have to show some reason to have them produced.

At the same time, Judge Pointer created a system for a modified review of such material. Copies of requested notes of panel members would be made and given to two attorneys on each side with instructions not to show it to the others. If those attorneys wanted to use anything, they would have to show good cause. Special counsel stated that he had no objection to the above procedure. Defendants objected on the grounds that some of them would not be able to see the materials. Judge Pointer overruled the objection, reminding the attorneys that they had objected to disclosure altogether and that if he had upheld their position, none of them would have seen the materials. At Mr. Kobayashi's request, Judge Pointer set a limit of approximately three weeks for requests to produce any of these documents.

Judge Pointer ordered the same expert to produce notes of written criteria the expert and colleagues had established for conducting a meta-analysis of existing studies. Defendants objected, but the judge overruled their objection.

One panel member testified to having an enormous pile of materials, specifically papers and analyses, forms used to gather data on studies, and

computer runs. Concerning drafts, this witness indicated that she purposely replaced each draft in anticipation of this type of inquiry. Similarly, a protocol developed to conduct a meta-analysis was folded into the final report. At this stage, plaintiffs did not press this witness to produce any materials.

Another panel member indicated that all notes taken in preparation for the hearing were on his or her computer. Perhaps because of the previous ruling, this witness was not asked to produce the notes but was asked to read them aloud when referring to them. This was done on several occasions without objection.

During one examination by defendants' counsel, Judge Pointer sua sponte objected to asking the experts questions about matters that were clearly presented in the report. This had the effect of moving the proceedings along.

All of the experts stated that they had not done any research on silicone. When one of the experts was asked whether any faculty colleagues had received grants from pharmaceutical companies or manufacturers of medical devices, the witness replied in jest that many members of a faculty of 200 would be fired if they did not have such grants.

Attorneys' reactions

With only a couple of exceptions, attorneys for both plaintiffs and defendants thought the process for discovery depositions was fair. Attorneys acknowledged that they did not get all of the procedural benefits they sought, but on balance found the process met their clients' needs and interests.

Defendants tended to think that having the questions submitted in advance was a good idea, while plaintiffs thought this process reduced their ability to ask questions effectively. One of the main reasons behind this procedure was to improve the quality of the experts' time in deposition or on cross-examination by giving the experts an opportunity to adequately prepare. One plaintiffs' attorney found the deposition process to be useless because the questions had to be submitted in advance, which inhibited plaintiffs from testing some of the pointed questions they had. On the other hand, one plaintiffs' attorney compared the procedure to the procedure used by Judge Jones in *Hall* in which the attorneys had a

half-hour to talk to the technical advisors. By comparison, he said, Judge Pointer's procedure provided a full-fledged opportunity to depose the experts. Plaintiffs also tended to find the relatively informal process for requesting and obtaining the experts' notes worked to their disadvantage.

Experts' reactions

The experts' reactions to the discovery depositions ranged from puzzlement as to the need for them to indignation and even outrage at the intrusiveness of the inquiries and the document requests. One panelist thought there was no need for depositions of any kind and that the report should stand or fall on its scientific merit, like any scientific document. This expert, giving short shrift to the needs and constraints of the legal system, asserted that "science was not served by this adversarial proceeding." Another panelist found that the discovery depositions, more than the trial depositions, focused on the science issues but she still wondered why discovery depositions were necessary at all. Another panelist was pleased with the discovery depositions and appreciated having a copy of the questions in advance. This dissipated the panelist's concern that depositions would be used to make the witness look bad.

Two panelists found the requests for documents to be overly intrusive into their private thoughts and generally inappropriate in the context of a scientific inquiry. One witness stated that as a scientist she believed raw materials and notes should be kept so others might replicate a study. At the same time, this witness argued that such notes and records are not public property but rather are the intellectual property of the scientist and should not have to be disclosed for cross-examination.

The panelists' reactions represent one measure of the gulf separating the scientific and legal spheres. One panelist, despite extensive briefing by special counsel before the discovery deposition, expressed surprise, even shock, at the degree of disclosure that might be required. Other panelists showed varying degrees of disagreement with fundamental principles of the legal system, such as access to discovery materials and rights to confront and cross-examine opposing viewpoints.

Motion to disqualify a panel member and discharge the panel

Out of the discovery depositions arose a highly controversial challenge to the status of a panel member and the panel itself, a challenge that generated national publicity.[75] The evolution and resolution of this conflict contains important lessons for instructing experts regarding limits on communications between appointed experts and the parties, and the need to set forth clear standards for identifying conflicts of interests when scientific experts are recruited for court appointment.

During and shortly after the discovery depositions, plaintiffs' attorneys followed a lead provided in a deposition to seek and find additional information about a potential conflict of interest. The attorneys found that one of the expert panel members had solicited and received funds from one of the defendants to support a professional conference that was unrelated to silicone or breast implants. As further investigation revealed, this expert had disclosed in the selection and screening process a contribution of $5,000 from one defendant, but had failed to disclose a contribution of $500 from another defendant. Plaintiffs' investigation of this payment led to further depositions of the expert and a biostatistician who worked as part of the expert's team.

In those additional discovery depositions, plaintiffs obtained information about additional contacts between the expert and the same defendant. None of the contacts related to silicone gel breast implants. Judge Pointer found later that the defendant's contacts were not intended to influence the expert's work and that they had no effect on that work, which in Judge Pointer's words was "impartial, unbiased, neutral, objective, and unaffected by any relationship or contact with the defendants."[76] The expert was paid $750 for attending a half-day conference. The biostatistician was engaged in work that was funded by a foreign subsidiary of the same defendant, but the subsidiary's name did not appear on

75. For a description of the context of that challenge, see *In re Silicone Gel Breast Implant Prods. Liab. Litig., MDL-926*, Order No. 31L, at 1, n.1 (denying plaintiffs' "Motion for Relief from Prejudicial Bias") (N.D. Ala. Apr. 25, 1999).

76. *Id.*

the conflicts list provided to the expert (and was not initially familiar to Judge Pointer when the matter first came up).[77]

After the discovery depositions and about a week before the videotaped trial depositions were to begin, plaintiffs, relying on the information sketched out above, filed a motion to vacate the expert's appointment as well as the appointments of the other panel members and to withdraw the panel's report. Defendants and special counsel for the panel members opposed the motion. Judge Pointer denied the motion orally on April 19, 1999, the day before videotaped depositions were to begin.

In a written ruling issued during the videotaped trial depositions—but before the disputed expert was scheduled to testify—Judge Pointer set forth his reasons for denying plaintiffs' motion. Judge Pointer detailed the screening process used to identify conflicts of interest. Three things about the screening process became clear from Judge Pointer's description:

- the screening form had successfully elicited information about the expert's fundraising for the conference, and the expert had properly disclosed a $5,000 payment;
- the screening form directed the experts to report any changes or additions in an expert's conflict-of-interest situation to a screening panel that was no longer functioning; and
- the question of whether the biostatistician working with the expert had any conflicts of interest had never been examined.

Plaintiffs argued that the expert should have reported the additional activity to the court. Judge Pointer ruled that this was not necessary, especially given the fact that most of the communications occurred after the report had been issued publicly. Nevertheless, the incident highlighted some of the effects of not having an explicit mechanism for addressing conflicts of interest that arise during the course of a lengthy appointment.

The question of experts communicating with defendants' representatives has been raised elsewhere in this report. Judge Pointer had restricted communications with defendants about breast implant matters, but had intentionally refrained from limiting experts' communications

77. *Id.* at 7.

with defendants regarding matters other than breast implants. In his ruling, Judge Pointer indicated that his earlier choice "was deliberate," made "in recognition that the panelists' work on the Panel would be only one of their many professional activities, [and that] they should not be unnecessarily restricted by preventing them from routine contacts with pharmaceutical companies in performing activities unrelated to issues involved in breast implant litigation."[78] Accordingly, Judge Pointer ruled that the disputed expert's belief that he was allowed to make such contacts "was both understandable and reasonable" and not a basis for disqualification.[79]

Judge Pointer's ruling also frames an issue that is a larger part of the debate about whether court-appointed experts should be used in adversarial litigation. Plaintiffs' attorneys argue that the pervasive shift of research funding from public to private sources has created subtle biases among researchers. The search for neutral, unbiased scientists, in this view, is fruitless. Judge Pointer found that accepting this view "would, in essence, have precluded consideration of a substantial proportion of academicians, who were perhaps the persons most qualified to provide valid and reliable opinions. . . ."[80] Barring communications with pharmaceutical companies might deter qualified academic scientists from accepting an appointment as an expert.

Understandably, given the national and international publicity about the allegations of conflict of interest and bias, the court-appointed expert was quite upset. Special counsel representing the expert filed a motion in limine to prohibit plaintiffs from "exploring these meritless but inflammatory allegations of bias in their examination of" the expert.[81] Judge Pointer denied the motion.

During the depositions of the other experts, the expert, who was scheduled to be the last witness, wrote a letter to the judge—which the

78. *In re* Silicone Gel Breast Implant Prods. Liab. Litig., MDL-926, Order No. 31L, at 6 (N.D. Ala. Apr. 25, 1999).

79. *Id.*

80. *Id.* at 3.

81. *In re* Silicone Gel Breast Implant Prods. Liab. Litig., MDL-926 (Special Counsel's Motion in Limine) at 18 (N.D. Ala. Apr. 18, 1999).

judge made available to the parties—asking that testimony at the videotaped deposition be limited to matters of science. In the letter, the expert reserved the "privilege to resign at the moment any questions are asked of me regarding these scurrilous and unfounded allegations of conflict of interest and bias."[82]

Prior to the scheduled appearance of the expert, special counsel made a modified motion in limine to control the order of questioning so that issues related to the report would come first and issues related to the conflict-of-interest allegations would come later. Judge Pointer denied the requests in an oral ruling. He commented that he had found that the matters alleged did not show bias or lack of objectivity, but indicated that there was at least an arguable appearance of bias and that Fed. R. Evid. 706 provides a right of cross-examination on the subject. Cross-examination, he ruled, includes the right to sequence the examination, subject always to the exercise of judicial discretion to control the order of presentation of evidence under Fed. R. Evid. 611(a). The judge reserved his right to control the order of examination if necessary. As noted above, the MDL judge had to be concerned that any restriction on cross-examination might result in a trial court ruling that the panel member's testimony would be inadmissible.

Special counsel and defendants conducted their examination of the expert without incident. Plaintiffs' counsel began his examination by exploring some of the science issues. After spending some time on those issues, plaintiffs' counsel announced that he was about to explore the bias issues. Judge Pointer gave the expert time to consult with counsel and after a request for additional time was made, adjourned the proceedings until the next morning.

After some tense moments and further consultation with counsel, the expert answered all of the questions plaintiffs posed regarding the allegations of conflict of interest and bias. Plaintiffs were able to make a detailed record of the correspondence and communications, and the expert was given a full opportunity to respond to the allegations through redi-

82. Letter from expert to Judge Pointer, Apr. 23, 1999, p. 5 (on file with authors).

rect and recross-examination by special counsel and defendants' attorneys.

This incident yielded some lessons that might guide future treatment of screening for conflict-of-interest issues. At the least, a mechanism for disclosing and considering post-appointment questions regarding possible conflicts of interest needs to be put into place. In addition, a mechanism is needed for screening and reviewing the qualifications of any colleagues working with the appointed expert. Allegations of serious conflicts of interest concerning any significant contributor to an expert's report could contaminate the entire report. Without a mechanism for prior screening, no one would know whether a member of an expert's team was even a shareholder or grantee of a defendant.

Finally, this incident revealed one facet of what Judge Pointer labeled a "cultural chasm" between scientific and legal approaches to questions of bias and conflicts of interest. Judge Pointer's observations on this subject warrant publication beyond his order:

> It appears that the approach of scientists is to critique research largely confined to the four corners of the reported research; "ad hominem" considerations directed at the individuals involved in that research generally are to be disregarded and may be viewed as inappropriate attacks on the integrity of those individuals. On the other hand, the approach of those involved in litigation, at least in this country's adversarial system, tends to be one of skepticism and distrust, ready to consider possible motivations and influences that may have affected, even subconsciously, the conduct or conclusions of a study or, indeed, even the reported observations upon which the study is based.
>
> This attitudinal difference, if the court is correct in its assessment, can produce some dysfunction when, as here, persons from the scientific community with little or no experience in litigation are coopted into the legal system via court appointment under Rule 706. This is a matter that deserves greater consideration and exploration as persons from both perspectives consider further use of Rule 706. Certainly this court, on reflection, sees that more detailed instructions as to what should or should not be permitted while a scientist

> serves as a court-appointed expert would have been desirable in bridging the gap.[83]

Judge Pointer's observations have implications for screening, instructing, and providing counsel for court-appointed experts. Because the ground rules are established by the legal system generally and Rule 706 particularly, fairness demands that experts be fully informed of the risks and demands of the system before agreeing to serve.

One of the experts we interviewed indicated, having observed the above experience, that the expert would participate again only if the rules were made very clear at the outset and special counsel were appointed earlier to frame the conditions of the appointment.

Trial depositions

Trial depositions of expert panelists were held on eight consecutive days, including the weekend, from April 20–27, 1999, in Judge Pointer's courtroom in Birmingham, Alabama. Special counsel for the expert panelists conducted the direct examination, followed by cross-examination by one attorney for the defendants then cross-examination by one attorney for the plaintiffs. Panelists were permitted to be present while other panelists were being examined.

All counsel were required to submit a list of specific topics of inquiry prior to the deposition, referring to specific pages in books and articles. Topics involving "matters in which surprise is needed for effective impeachment" need not have been submitted in advance.[84] Plaintiffs listed an average of fifty topics for each of the four panelists, covering the panelist's qualifications, biases including relationships with others who may be biased, methods of studying the issues, particular studies, and scientific issues relating to the final report. Typical topics were "the biases of the witness, including prior relationships with industry"; "the appropriateness of a panel member accepting money or other benefits from a

83. *In re* Silicone Gel Breast Implant Prods. Liab. Litig., MDL-926, Order No. 31L, at 14 (N.D. Ala. Apr. 25, 1999).

84. *Id.* Order 31K (N.D. Ala. Mar. 10, 1999).

party and/or failing to disclose a benefit received"; and "the biases or weaknesses of the studies relied upon by the witness for her opinions."

Defendants submitted a much longer list of questions and a host of new documents, which focused primarily on the report of the panel and the science questions. One panelist received 250 documents two weeks before the proceedings.

Judge Pointer explained that

> [t]he listing of topics of inquiry is intended to provide some guidance to the panelists, who were supplied by the parties with more than 2,000 documents for their consideration in preparing their report, and who therefore need some assistance in determining what is likely to be the subject of examination. The parties will not necessarily be precluded from asking questions that go beyond the topics of inquiry they have listed. However, the parties should recognize that (1) when faced with a question not within the listed topics, witnesses may respond that the subject matter was not fully considered because the question was not on the list of topics and therefore a proper answer cannot be provided, and (2) the Court may choose to comment, on the record, in a manner that recognizes the right of the witness to so respond. [85]

Trial depositions were cross-noticed to other litigants, and the topics of inquiry submitted by counsel were posted on the *MDL-926* Web site. One plaintiffs' attorney appeared in response to the cross notice and exercised his right to examine the first witness. Judge Pointer attempted to get an idea of his questions beforehand by asking the attorney to submit materials in camera before his scheduled examination; the judge was not successful in pinpointing areas of interest. Judge Pointer limited the time for this attorney, restricted questions to exclude irrelevant ones, sustained objections, and imposed modest sanctions. Despite these efforts, the attorney managed to surprise and offend the witness with extraneous questions like whether histopathology is more reliable than epidemiology and whether she took her Hippocratic oath seriously.

Unresolved in limine issues and objections to demonstrative exhibits were scheduled to be considered and resolved at a hearing one week be-

85. *Id.*

fore the depositions. Special counsel moved that many of the new exhibits proposed by the parties be excluded. Later, during the deposition, oral in limine motions were made regarding the sequencing of one witness's examination.

The depositions were transcribed stenographically by a court reporter and videotaped. Judge Pointer presided, using trial procedures. Objections and rulings on objections were handled as prescribed by the rules for taking depositions under the Federal Rules of Civil Procedure, with the understanding that trial judges would make their own rulings on evidentiary objections if the depositions were offered in trial courts.

Trial depositions lasted a total of eight days. Most of the testimony focused on the technical details of the scientific standards and the studies relied on—or not relied on in some instances—by the experts. On the whole, the testimony was complex and tended to be presented in scientific and technical terminology. The first witness spent approximately three days testifying; one witness spent about a day; and the other two witnesses spent about two days each.

Special counsel led each of the experts through his or her direct testimony. Each of the witnesses prepared slides, overheads, or blowups to outline major points. These presentations resembled lectures and were aimed at an intelligent but not necessarily scientifically sophisticated audience. Basic terms were explained, the criteria for analysis were set forth clearly, and supporting studies were described in detail. Special counsel generally posed broad questions, launching the expert into a narrative lecture. Plaintiffs objected to the form of the testimony; Judge Pointer overruled the objections subject, as he noted on several occasions, to final rulings from trial court judges who may use the videotapes.

Judge Pointer overruled numerous objections as to form, particularly as to leading questions. When a question was in fact leading he would note that for the record but overrule the objection and allow the witness to answer. On several occasions he warned counsel that different judges in other courts might rule differently on those objections. Attorneys occasionally objected that a topic or an article had not been disclosed to the witness in accordance with Judge Pointer's predeposition order, but Judge Pointer did not sustain any such objection if the witness indicated an ability to answer the question.

Attorneys' reactions

Attorneys for plaintiffs and defendants found the procedures for the trial depositions to be fair. A couple of attorneys questioned the division of labor between special counsel and attorneys for defendants. There was considerable overlap because both special counsel and defendants' attorneys elicited what was in essence direct testimony, explaining and supporting the experts' report. That overlap of roles, however, seems related to the clarity of the experts' position and its direct alignment with defendants' interests in the breast implant litigation. In other cases, it may be that an expert's report will not fully support one side or the other and that there will be a need for a lawyer for the experts to give them an opportunity to present their report before the parties challenge it. Having special counsel conduct the direct examination seems necessary given the barrier to ex parte communication that must be imposed on attorneys for the parties.

Experts' reactions

Two of the experts found that the trial depositions focused less on the science issues than the discovery deposition had. Panel members would have liked to have had written questions for the trial depositions, just as they had for the discovery depositions. Two experts also were dissatisfied with the technical aspects of the videotaping, particularly the inability to display computerized graphics on the overhead projection machine.

One expert captured a sense of the uncertainty of panel members about the usefulness of the videotapes: "I don't know about the videotapes, about how and whether they will be used. I see them sitting on a shelf. Who will use them? Who will edit them down to a useable size?"

At a later stage of this evaluation, we hope to revisit that question in examining the impact of the court-appointment process on the breast implant litigation.

VIII. Cost of the Panels of Experts

The costs associated with the use of technical advisors and court-appointed experts typically are charged to the parties.[86] Both Judge Jones and Judge Pointer sought partial payment of panel expenses from appropriations to the federal judiciary, owing to the expected benefits of the work of the panels in breast implant product liability cases throughout the nation. The Judicial Conference granted Judge Pointer's payment request and declined Judge Jones's request. This section will discuss the costs of the two programs.

Hall v. Baxter Healthcare Corp.

Judge Jones wrote to officials in the judicial branch seeking federal funding of approximately $60,000 to support the work of his panel of experts, noting that the experts' reports would be useful in resolving the numerous silicone gel breast implant product liability cases pending in federal and state courts. The work of the panel continued while these requests were pending. Judge Jones's second request was considered at the same time the Judicial Conference considered a similar request from Judge Pointer. In denying Judge Jones's second request for payment, the Judicial Conference Committee on Court Administration and Case Management expressed doubt that such benefits could be achieved in the context of local litigation and preferred that the expert panel perform its work as part of the multidistrict litigation proceedings.[87] The committee believed that funding Judge Jones's panel might encourage the development of local panels in other cases that could duplicate or contradict the work of the national panel. Following this decision, Judge Jones asked the parties to pay the outstanding amounts owed to the advisors, which they reluc-

86. As to payment of court-appointed experts, see Fed. R. Evid. 706(G). *See also* Cecil & Willging, *supra* note 28, at 59–62.

87. *See* Reports of the Proceedings of the Judicial Conference of the United States Activities of the Administrative Office of the United States Courts at 46 (Sept. 17, 1996).

tantly agreed to do. The parties together paid approximately $76,000 in fees and expenses, divided among the four panel advisors and the special master.[88]

In re Silicone Gel Breast Implants Products Liability Litigation

In his request for federal funding, Judge Pointer noted that the work of the panel would become part of the record in the 22,000 breast implant cases that had been consolidated in his court as part of the multidistrict litigation process. A single report from a national panel of experts would provide a consistent foundation for decisions regarding admissibility of evidence and contested factual issues. A single report might also save time and money that might be spent on multiple independent panels of experts in individual trials. Judge Pointer noted that funding by the federal judicial branch would show the court's commitment to resolving difficult legal–scientific questions in a manner that emphasizes truth rather than partisanship or the parties' resources.

The Judicial Conference approved the expenditure of $400,000 to support the work of the panel, and barred the use of payments by the parties to supplement this amount. Two years later, with the work of the expert panel well underway, Judge Pointer requested and was granted an additional $400,000 to support the continued work of the panel.

In his supplemental request, Judge Pointer noted unexpected difficulties encountered by the selection panel in identifying candidates suitable for appointment. Unusual circumstances arising in the breast implant litigation made recruitment of experts for the science panel especially time consuming. The six selection-panel members required extensive deliberations to reach a consensus on the best available scientists to fill the positions. Approximately half of the time was spent in screening candidates for conflicts of interest. Together, these factors increased the expense of the search beyond the expected amount.[89]

88. Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1393 (D. Or. 1996).

89. The selection-panel members were paid a total of $62,498 for the time and expense required to identify and nominate the experts. The selection-panel members were compensated at a rate of $200 per hour, the same rate of compensation paid to the mem-

Moreover, the amount of material submitted by the parties for review by the panel members greatly exceeded expectations.[90] Some of the panel members conducted their own searches of scientific literature for additional material rather than rely on the parties' submissions as being complete. The Judicial Conference approved Judge Pointer's request for additional funds with the qualification that "the costs of all post-report discovery and expert depositions be borne by the parties, to the extent feasible, authorized by law and consistent with previous representations."[91] Judge Pointer had already imposed the cost of the special counsel and a number of consulting experts on the parties.

The total cost of the national panel of experts, including fees and expenses, was $939,983.74. Of that amount, the federal judiciary provided $733,645 to cover the cost of selecting the experts and the preparation of the experts' report. The remaining $206,338.74 reflects fees and expenses of the experts that arose during their depositions and testimony, an expense that was shared equally by the parties.

The cost of two special counsels to represent the panel members, a cost paid by the parties, exceeded the total spent on the experts themselves. According to information provided by the administrator of the two court-administered funds established to support the work of the special counsels, fees and expenses related to work by the two special counsels was at least $1,157,594.67.[92] The second special counsel, Ina Leonard,

bers of the National Science Panel, and less than some of the selection-panel members have charged for other work undertaken when appointed by the court as a special master or court-appointed expert. Several panel members volunteered that they did not charge for all of the hours they spent working on panel business and one panel member declined to request payment, preferring to contribute her time to the project.

90. The parties submitted over thirty-five linear feet of materials for review by the panel members.

91. Judicial Conference of the United States Summary of the Report of the Judicial Conference Committee on Court Administration and Case Management at 29 (Sept. 1998). The Judicial Conference also directed that specific expenditure controls be adopted for the remainder of the contract, and that Judge Pointer seek reimbursement for the judiciary's expenses from any mass class-action settlement that may result.

92. Letter from Mr. Edgar C. Gentle III (an attorney–accountant appointed by Judge Pointer to administer the funds) to Mr. Thomas E. Willging (Dec. 20, 2000) (on file with authors). In his letter Mr. Gentle notes that these amounts "[do] not include any direct

was appointed to represent the experts at depositions late in the process; her fees and expenses represent 7% of the total amount.

As of December 2000, editing of the National Science Panel video depositions continues. To date, the cost related to the editing totals $164, 945.25.[93]

In our interviews, some attorneys from each side complained about the cost of the special counsel prior to the trial depositions. Specific questions were raised about the need for special counsel to review the hundreds of scientific publications submitted to the panel by the parties. The attorneys and some of the experts complained that Mr. Kobayashi was often unavailable to respond to issues in a timely manner. One defense attorney commented that "a number of attorneys felt like we were at odds with Mr. Kobayashi; the parties should not be placed in an adversarial role with special counsel. We were frustrated with the lack of information we received from him." Mr. Kobayashi declined our request for an interview, citing his concern that such a conversation may compromise his ability to represent the interests of the panel members through to the conclusion of the project. As a result we were unable to learn from Mr. Kobayashi the kinds of activities he undertook in support of the national panel. Several attorneys suggested that in the future the role of special counsel should be clarified at the outset, particularly with regard to the extent that counsel should become involved in the substance of the panel's work.

One expert panel member thought that the use of the panel in the MDL revealed ways to reduce costs: Suggestions included the use of ros-

disbursements made by the National Defendants directly to Mr. Kobayashi." Also, these costs do not reflect the fees and expenses of Mr. Kobayashi and his colleagues in preparing the videotapes and transcripts, a task that remains ongoing. Mr. Kobayashi, other attorneys, and legal assistants were compensated at their customary hourly rate up to a maximum of $200 per hour. The order appointing Mr. Kobayashi notes that this represents a reduction in Mr. Kobayashi's usual hourly rate. *See In re* Silicone Gel Breast Implant Prods. Liab. Litig., MDL-926, Order 31F(4) (N.D. Ala. Jan. 13, 1997).

93. Letter from Mr. Edgar C. Gentle III to Mr. Thomas E. Willging (Dec. 20, 2000) (on file with authors).

ters of prescreened experts, setting clearer plans and goals for the panel's work, and clarifying the role of special counsel.

IX. Preliminary Assessment of the Work of Neutral Expert Panels

The two programs examined in this report represent innovative extensions of the use of panels of appointed experts to respond to complex expert evidence. In *Hall v. Baxter Healthcare Corp.*, the panel offered advice for use in an in limine proceeding to rule on the admissibility of scientific evidence. In *In re Silicone Gel Breast Implants Products Liability Litigation,* the panel offered a report and videotaped testimony intended to become part of the record in cases that are returned to the district courts. In each instance the expert panels developed technical reports of extraordinarily high quality and presented findings that are consistent with those of recent independent science panels.[94]

Still, it is difficult to specify the effects of the two expert panels. In *Hall,* Judge Jones stayed his summary judgment order, which relied heavily on the work of the panel of experts, until he could consider the report prepared by Judge Pointer's panel. The cases before Judge Jones then settled and, consequently, Judge Jones's order was never reviewed on appeal. Judge Pointer regarded the report by his panel as an intermediate product, anticipating that the videotaped testimony of the panel members would be the primary product (editing of the videotaped testimony had not been completed as of March 2001). Extensive settlement activity has continued simultaneously with the work of the panel, making it difficult to specify the impact of the panel and leaving few cases in which the videotaped testimony can be considered. This chapter offers a preliminary assessment of the effect of the panel reports based on the impressions of the participants and citations of the reports in related litigation.

94. *See Review of the Reports of the Independent Review Group and the National Science Panel, Appendix B, in* Safety of Silicone Breast Implants, 437–43 (Stuart Bondurant et al., eds.) (Institute of Medicine, Washington, D.C. 1999).

Hall v. Baxter Healthcare Corp.

We asked the participants whether the science issues were adequately addressed by the appointed experts and whether the proceedings achieved the courts' objectives. Judge Jones expressed satisfaction with the process and indicated that it achieved its purpose. Specifically, he indicated that the advisors' assistance aided his assessment of the conflicting scientific analyses being offered by the parties. As a result of the hearing and Judge Jones's subsequent ruling dismissing plaintiffs' expert evidence on systemic injury claims, all of the cases that were subject to the hearing have settled.[95]

The technical advisors thought the process served a useful purpose by bringing science to the courtroom and helping to educate the court. They believe their reports were effective in defining the boundaries of the debate over causation. Nonetheless, they expressed some frustration at the lack of specific guidance in their task and the short amount of time they had to review the technical literature and prepare the report. Overall, however, they found their participation to be informative and beneficial.

Attorney comments varied. In general, defense attorneys, whose claims were furthered by the advisors' reports, were more pleased with the process. One defense attorney thought the process worked because it caused the court and the parties to focus on the question of scientific causation. However, another attorney suggested that a judge should not rely on inherent authority in appointing experts. Notice to the parties and specific guidelines for the experts should be provided to permit the parties to develop appropriate litigation strategies. Similarly, another attorney suggested that the court's power to appoint technical advisors be explicitly defined in the Federal Rules of Evidence, together with some procedural safeguards. Rule 706 contains clear and explicit (if incomplete) rules governing court-appointed experts; yet no similar procedural path is defined under Fed. R. Evid. 104. Plaintiffs' attorneys, who were disadvantaged by the reports, were disappointed by the process. Several

95. Judge Jones reports that virtually all of Oregon's state-court breast implant cases have settled, in part because of the joint hearing at which he presided with a state-court judge.

plaintiffs' attorneys, for example, thought Judge Jones's decision was in conflict with at least one of the advisors' findings that favored the plaintiffs.

Since Judge Jones stayed his summary judgment order pending release of the report by Judge Pointer's National Science Panel, citations to Judge Jones's holding are rare. However, the opinion has been cited for innovative use of panels of technical advisors,[96] development of authority for in limine proceedings,[97] and its definition of "differential diagnosis."[98]

In re Silicone Gel Breast Implants Products Liability Litigation

When we interviewed Judge Pointer in October 1999, he indicated that the multidistrict litigation was not at a point where he could assess whether the process had worked well, since the videotaped depositions had not yet been introduced at trial. Judge Pointer did note, however, that the report appeared to have had considerable impact on the dynamics of settlement negotiations. Although cases appear to have settled at about the same rate throughout the period of service by the panel, it seems that value of claims for systemic injuries have diminished.[99] As a result of the national panel's report, systemic injury claims are no longer part of the process, and their absence has pushed down the dollar amounts of settlements.[100] Of course, the total effect of the report and

96. Association of Mexican-Am. Educators v. California, 231 F.3d 572, 610 (9th Cir. 2000) (Tashima, J. dissenting).

97. Allison v. McGhan Med. Corp., 184 F.3d 1300, 1310 (11th Cir. 1999).

98. Glastetter v. Novartis Pharm. Corp., 107 F. Supp. 2d 1015, 1019 (E.D. Mo. 2000).

99. Michael Green, a professor at the Wake Forest University School of Law, stated that "as a consequence of the report it will be hard to find a federal judge who will permit a case to be tried or who will sustain on post-trial motions a plaintiff's claims to systemic disease." Gina Kolata, *Panel Can't Link Breast Implants to Any Diseases*, N.Y. Times, Dec. 2, 1998, at A1.

100. One author commented that "[t]he mere anticipation of the court-appointed panel's report influenced the course of breast implant litigation. Plaintiffs reached a $3.2 billion settlement with implant maker Dow Corning Corporation, driven in part by the pressure of the anticipated report." Howard M. Erichson, *Mass Tort Litigation and Inquisitorial Justice*, 87 Geo. L. J. 1983 (June 1999). Defense attorneys familiar with the litigation opined that the mere pendency of the panel's report helped to resolve breast im-

testimony by the panel may not be known until that testimony is presented at trial.

Overall, the expert panel members thought the court's objectives were met.[101] They reviewed voluminous scientific material, indicated areas of consensus, and commented on what they perceived to be outside the range of the scientific debate. One panel member expressed frustration over not knowing how and whether the panel's report will be used as evidence at trial. Another commented on the difficulty of making immediate decisions based on complex, conflicting, and sometimes incomplete data.

Most of the panel members thought the entire process could have been completed in a year if they had worked under firmer deadlines. Delays in starting the review process, getting materials to the experts, appointing special counsel, and finding an efficient means of communicating among themselves extended the time required to prepare the reports. All the experts indicated they would consider serving as a court-appointed expert in the future, though perhaps under somewhat different conditions.

The views of attorneys in the MDL process also appear to be affected by the extent to which their claims were furthered by the panel's report and testimony. Most plaintiffs' attorneys thought that the overall procedure failed to properly resolve the science issues and that such a procedure should be reserved for narrower questions. One attorney thought the court's instructions were too vague and permitted ambiguous responses. This attorney suggested that the instructions be drafted around the standards set forth in *Daubert*. Another attorney thought the panel

plant cases with systemic claims before Judges Weinstein and Baer in New York. Jane F. Thorpe et al., *Court Appointed Experts and Technical Advisors*, 26 Litig. 31, 34, no. 4 (Summer 2000).

101. *See* Barbara S. Hulka et al., *Experience of a Scientific Panel Formed to Advise the Federal Judiciary on Silicone Breast Implants*, New Eng. J. Med. 342 [1]:812–15 (Mar. 16, 2000) ("We believe that such panels should be used more frequently, because they can bring unbiased information about complex scientific and medical issues into the courtroom.").

members should have been treated as any other trial witnesses and should not have received any special protection from the court.

Most plaintiffs' attorneys see very little use in the panel's report and videotaped testimony. One commented that the process has taken so long that most of the cases have settled. Moreover, the testimony will soon be outdated as new studies appear.[102] Another noted that the "final product resulted from 'special' procedures that favored the defense. The process had no benefits for [our] clients, it was very expensive and time-consuming, but it was our only choice."

In contrast, defendants' counsel thought use of the expert panel was a step toward ensuring that unreliable evidence is not admitted. One attorney commented that the process worked because it presented a more accurate picture than had the court relied solely on party-retained experts, especially in mass tort cases where the economic stakes are high. Another attorney commented that a major benefit was greater candor by the parties' experts when they spoke before their peers on the panel at the hearing, resulting in admissions by parties' experts that would not normally be made during the discovery process.

Several defense attorneys expressed confidence that the report and testimony will be useful in resolving questions about causation of systemic disease. They believe it has heightened attention to the scientific issues and will give judges more confidence in ruling on science-based claims. One defense attorney noted that the "power of the panel's report to give nonscientist judges the courage and confidence to rule should not be underestimated." They expect the panel's report will help build a consensus on these issues and minimize the inconsistent rulings among different courts. Another defense attorney commented that the major value of the report is its corroboration of defendants' experts' positions. Yet another attorney thought the report had an impact on the Dow

102. *See, e.g.*, Louise A. Brinton et al., *Breast Cancer Following Augmentation Mammoplasty (United States)*, 11(9) Cancer Causes & Control 819–27 (2000).

Corning bankruptcy proceeding by setting the context in which those negotiations took place.[103]

The above assessment of the effect of the National Science Panel may be affected by the release of the videotaped testimony. But preliminary indications are that the report of the panel has been cited consistently in combination with other reports in excluding expert testimony linking silicone gel breast implants with systemic disease or injury.[104] Concerns that the panel's report has not been used consistently appear to have been unwarranted.[105]

103. In *In re Dow Corning*, the panel's report was cited to demonstrate that "new" research negates the case that silicone gel causes some diseases alleged by breast-implant claimants. 244 B.R. 634, 655 (E.D. Mich. 1999).

104. *See, e.g.*, Allison v. McGhan Med. Corp., 184 F.3d 1300, 1311 (11th Cir. 1999) (citing the panel's report to illustrate the thoroughness of efforts to ascertain the reliability of the scientific evidence); Grant v. Bristol-Myers Squibb, 97 F. Supp. 2d 986, 992 (D. Ariz. 2000) (citing the panel's report at length and concluding that "no association was evident between breast implants and any of the individual connective tissue diseases"); Bushore v. Dow Corning Wright Corp., 1999 U.S. Dist. Lexis 20697 (addressing the four *Daubert* factors and citing the panel's report for its discussion of causation and its conclusion that the evidence does not currently support a scientific finding of causation); Pozefsky v. Baxter Healthcare Corp., 194 F.R.D. 438, 440 (N.D.N.Y. 2000) (court stating "[i]n the absence of expert testimony concerning the causal link between the leakage of silicone from breast implants and autoimmune or corrective tissue disease, Plaintiff cannot establish a prima facie case against [the defendant]").

105. Two law professors claim the report is not having the effect intended by Judge Pointer and others. They claim that early citation to the panel's results show "signs of conflict and redundancy," which will ultimately "jeopardize the utility of the panel's findings and, even more importantly, may discourage the future appointment of similar panels." Laurens Walker & John Monahan, *Scientific Authority: The Breast Implant Litigation and Beyond*, 86 Va. L. Rev. 801, 813–17 (2000). As an illustration, they cite an unpublished case where a federal judge refused to allow the panel's findings to be heard by a jury, which subsequently returned a verdict that was in direct conflict with the panel's findings. *Id.* at 813. This jury award was subsequently overturned by the trial judge, claiming that there was no scientifically reliable basis for the jury verdict in the record. *D.C. Judge: $10 Million Breast Implant Judgment Lacks Evidence, Reversed*, vol. 5, no. 19 Mealy's Litig. Rep.: Emerging Drugs & Devices 15 (Oct. 5, 2000).

X. Suggestions for Use of Panels of Neutral Experts

The use of court-appointed experts is an extraordinary technique that is appropriate when the evidence is especially demanding and the opportunity for reasoned and principled consideration based on submissions by the parties has been exhausted or offers little promise.[106] The difficulty of accommodating the conflicting values of science and law within such a process is unlikely to satisfy those who insist on the deliberate and open-ended consideration that is characteristic of science, or those who insist on the speedy and certain resolution of issues that is valued by law.[107] In the best of circumstances, such appointments are regarded as a procedure that should be invoked only after careful thought.

Despite the high quality of the information developed by the expert panels, interviews with participants in these two programs revealed a number of difficulties that are likely to arise if such panels are developed for future litigation. In this section, we describe suggestions for judges to consider when appointing and using such panels. Most of these were explicit suggestions of the participants, or implicit in the comments of multiple participants.

Assessing the Need for Appointment

The court should fully explore the opportunity to develop the information necessary for thoughtful consideration of complex evidence without taking the extraordinary step of appointing one or more experts. Even in the best of circumstances, such appointments of expert panels are costly

106. *See* Cecil & Willging, *supra* note 28, at 88–89.

107. As one expert panel member stated, "in science, it is not a failure to say 'I don't know.' One can think about the issue a bit longer and have time to think about how to respond. One can give a thoughtful answer, not the first one that comes to mind. The law's need for an immediate decision is inconsistent with science's interest in waiting for a correct answer."

and time consuming, present difficult issues of administration, and raise concerns about the independence of judicial consideration. In *Hall* and *MDL-926,* the complexity of the evidence and the importance of establishing an accurate foundation for future litigation argued strongly for such extraordinary procedures.

It should be noted that not all litigation requiring court-appointed experts will warrant four or five expert witnesses sitting as a panel. Many MDLs, individual cases, classes, or consolidations could be aided by one witness in a key discipline.

Defining the Role and Process

Careful consideration should be given to the role that the appointed experts will play in the litigation. The anticipated role of the experts will determine the legal authority that the court invokes to undertake the appointments. At the beginning of the process, the court should generally articulate the questions it wants the technical advisors or court-appointed experts to address. Doing so will help define whether technical advisors or court-appointed experts are needed, who they ought to be, what they should be asked to do, and how they should present their conclusions.

Appointing a panel of experts as technical advisors under the inherent authority of the court may be appropriate in the rare event that the judge requires assistance in the form of direct advice from an expert panel.[108] The judge must then decide what procedural protections are necessary to ensure that the interests of the parties in an independent judicial decision are not inadvertently compromised.

More frequently, panels of experts will be appointed to serve as witnesses under the authority of Fed. R. Evid. 706 and will be subject to the procedures established therein. If the experts are naïve regarding the demands of the legal system, as were the experts examined in this report, they must be clearly informed of the nature of these obligations when they consider the possibility of accepting the appointment.

108. Reilly v. United States, 863 F.2d 149, 154 & n.4 (1st Cir. 1988) (concluding that a district court has discretion to appoint a technical advisor, but it is expected that such appointments will be "hen's teeth rare" and a "last" or "near-to-last" resort).

More specifically, experts who are appointed as witnesses must be informed that their testimony, not the preliminary written report, is the final product of their appointment. They must be informed that in addition to providing testimony they also may be required to participate in a deposition at which they will be questioned about the basis of their opinions and possible conflicts of interest.

Identifying Needed Expertise

The court, with the assistance of the parties, should decide the areas of expertise that will be needed to consider the evidentiary issues. Matching the skill of the panel members with the needs of the litigation may be a difficult task. This is especially true where the necessary skills represent narrow specialties or knowledge in a combination of areas, as is true of the breast implant litigation. In both *Hall* and *MDL-926*, it proved difficult to find appropriate candidates who were willing to serve on the expert panels. The court may choose to seek assistance from professional organizations to assist in finding qualified and neutral experts.[109] The judge must determine, as a related matter, whether to seek experts who are experienced or inexperienced in the topic of the litigation. Those who are aware of existing research in the disputed area, and perhaps have participated in such studies, will have a strong background in the disputed issues. But such persons also may have preconceived notions, or appear to have preconceived notions, that are inappropriate to the litigation.

109. Three programs are being developed to assist federal judges and others in identifying scientists, physicians, and engineers who are willing to serve as court-appointed experts. A program developed by the American Association for the Advancement of Science will receive requests for assistance by federal judges and attempt to identify specific scientists and engineers suitable for appointment in individual cases. This program will likely begin accepting requests in early 2001. *See Court Appointed Scientific Experts: A Demonstration Project of the AAAS* (visited Nov. 16, 1999) <http://www.aaas.org/spp/case/case.htm>. The Private Adjudication Center of Duke University has developed a registry of scientific and technical advisors to assist federal and state courts, agencies, arbitrators, mediators, and others who seek assistance in resolving complex scientific and technical issues. The initial focus of this program is on medical experts. *See* The Registry of Independent Scientific and Technical Advisors: A Formal Proposal (Dec. 29, 1998) (on file with the authors).

Experts who are not familiar with the disputed issues, on the other hand, will require additional time to become familiar with the issues and confident of their analyses of the subject matter.

Screening for Conflicts of Interest

A court must screen the candidates for appointment for possible conflicts of interest. In *Hall* and *MDL-926*, direct and indirect ties to the corporate defendants made it difficult to find particular types of experts, such as toxicologists. Different perceptions in science and law of what constitutes a conflict of interest result in opportunities for misunderstanding by persons of good faith. To avoid such problems, judges should consider using a screening questionnaire developed by the selection panel of special masters serving Judge Pointer (see Appendix, *infra*). The questionnaire required written certification by the expert that no conflict of interest exists as defined by the court. Parties should have an opportunity to review the credentials and background of individuals who are considered for appointment and be able to object to those whom they believe to be unqualified. Such participation should give the parties confidence in both the expertise and neutrality of the candidate and enhance the legitimacy of the appointment. The court should also establish a procedure for monitoring potential conflicts of interest that arise during the litigation, including information about communication with persons outside the panel about issues related to the litigation. If the panel members require the assistance of others not on the panel, such persons should be screened for conflicts of interest as well.

Organizing the Work

The court should establish a procedure for organizing the work of the panel. One possibility is to designate (or have the panel members select) a panel member to serve as a convenor and administrative chair. This will permit easier coordination of tasks when the panel must work together as a group. Such a person can also serve as a focus for communication with the panel when it is necessary to exchange materials with the court or parties. Adequate administrative resources must be provided to support the work of the panel.

Instructing the Experts

Shortly after appointing experts, the court should specify the duties and functions of the experts in a written order. This order should include the issues that the experts are asked to consider, the limitations and procedures for contact with persons outside the panel (including the judge), and the procedures the panel will employ in presenting its information to the court. The extent of discovery and scope of depositions should be established at the outset. A mechanism should be established that would permit the court to expand and clarify the written instructions as needed, with participation by the parties. Any substantive change in the instructions or procedures should be recorded as part of a written order and made available to the experts.

Establishing a Budget

The court should establish a budget with input from the experts and parties once the duties of the experts have been determined. Such a procedure will help ensure that a realistic budget is maintained.

Overseeing the Process

The court should maintain administrative oversight over the panel to the extent necessary to ensure that the panel proceeds in a prompt and efficient manner. Such oversight may include establishing deadlines, or at least goals, for the work of the panel, including the development of interim products. The court also may need to supervise an information-exchange process in which the parties (1) summarize their arguments and proposed findings of fact for the appointed experts, (2) prioritize or rank all written materials submitted to the panel, and (3) respond to queries from panel members regarding the parties' proffer of expert evidence.

Considering Special Counsel

A judge should consider appointing special counsel to represent inexperienced witnesses who are going to be deposed or cross-examined. The court should specify the role of special counsel in considerable detail, making clear which, if any, administrative duties will be undertaken by

special counsel. A clear definition of this role will permit special counsel to speak with authority in areas designated by the court and avoid those activities in which there is no consensus regarding the involvement of special counsel.

Appendix: Conflict and Bias Screening Questionnaire

In re:
SILICONE GEL BREAST IMPLANT
PRODUCTS LIABILITY LITIGATION
(MDL-926)

Silicone Breast Implant Science Panel
Potential Sources of Bias and Conflict of Interest Questionnaire

Instructions to Individuals Completing this Form

Before you start to complete the questionnaire please review the list of corporate defendants [omitted] and read the "General Statement Concerning Bias and Conflict of Interest" and "Instructions for Completing the Questionnaire."

Do not skip any questions. If you require clarification of any of the items on the questionnaire, contact* Professor Alan Wolf of the Selection Panel for assistance.

When you have completed the questionnaire, sign and date the form and return it to Professor Wolf by fax or express mail.

Promptly report to the Selection Panel any changes or additions to the information reported on this form while you are either being considered for service on the Science Panel or while serving on the Panel.

* Contact information for Professor Alan Wolf: [omitted].

Contact Information

Name: (Mr./Mrs./Ms./Prof./Dr.) _____
Telephone: _____
Fax: _____
Email: _____
Title: _____
Employer: _____
Address: _____

General Statement Concerning Bias and Conflict of Interest

The Silicone Breast Implant Science Panel (hereafter, the "Science Panel") will be charged with the responsibility of evaluating and critiquing pertinent scientific literature and studies bearing on issues of disease causation in the breast implant litigation. Since members of the Science Panel will be working directly for the court as neutral, independent experts, it is essential that panel members be free from any conflict of interest or significant bias as well as the appearance of such conflict or bias. This information is needed to ensure the integrity of the Science Panel. By screening potential members before they are selected, this questionnaire also safeguards panelists' professional and personal reputations by minimizing the possibility that embarrassing conflict or bias issues will arise in the courtroom.

"Bias" generally refers to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group. For purposes of service on the Science Panel, the following are *examples* of potentially problematic forms of bias:

1. A panel member being placed in the position of reviewing his or her own work (or that of a family member, close friend, or colleague) for validity or scientific merit.
2. A panel member being committed to a fixed position on a particular issue through public statements (e.g., testimony, speeches, interviews, lectures, etc.), publication (e.g., articles, books, etc.), close identification or association with the positions or perspectives of a particular group, or through other personal or professional activities.

Certain forms of bias may be more properly characterized as conflicts of interest—e.g., where the individual is a senior officer of a professional society that espouses a fixed position on the issue.

"Conflict of Interest" means any financial or other interest which conflicts with the service of an individual because it could either impair the individual's objectivity or create an unfair competitive advantage for any person or organization. A conflict is likely to be present where the efforts of the Science Panel may result in a direct or indirect economic benefit or loss to particular individuals or groups. Illustrative *examples* of direct economic benefit include:

1. A panel member (or member of his or her immediate household) has a significant financial investment or other close tie to a corporate defendant. (Highly diversified mutual funds investing in one or more corporate defendants do not constitute a significant investment.)

2. A panel member has a family member or close friend who is a party to the action, or who is otherwise involved in the litigation (e.g., a family member who is an attorney involved in the litigation).

Examples of indirect economic benefit include:

1. A panel member is a junior faculty member whose department chair (or other senior faculty) has taken a fixed position regarding the merits of this litigation.

2. For purposes of critically reviewing the relevant scientific literature, a panel member requests that another scientist furnish him or her with the raw data underlying a published work. Rather than using the data solely for the purposes of serving the court, the panel member envisions using the data for his or her own subsequent research efforts. (In such a case the panel member should contact all relevant parties for permission to use the data.)

The examples above are illustrative, but not all-inclusive. If you have any question as to the existence or appearance of bias or conflicts, please bring these matters to the attention of the Selection Panel.

Instructions for Completing the Questionnaire

Please note that the following questions refer variously to "you," "you or any members of your household," or, most broadly to "you, members of your household or members of your department."

Any reference to an "*interested party*" refers to:

- plaintiffs and defendants in the current litigation
- individuals or organizations that are otherwise substantially involved in the current litigation (e.g., law firms)
- individuals or organizations that otherwise have a stake in the outcome of the litigation (e.g., "educational" organizations funded primarily by a party or medical societies)
- potential litigants (e.g., close friends or relatives who have implants, and are therefore potential plaintiffs).

Your responses to the following questions should be typed on additional sheets of paper, rather than on this form.

Please provide all relevant details for any questions answered in the affirmative. An affirmative response to one or more questions does not automatically disqualify you from serving on the panel. Further explanations may, however, be requested.

If the answer to a question is contained in your curriculum vitae you may simply refer to and attach the appropriate pages from it.

Personal interests

1. Are you or any members of your household interested parties?

2. Do you have close friends or family members who are plaintiffs in these actions, attorneys involved in this litigation, or are employed by defendant corporations?

Financial interests

3. Have you or members of your household ever worked for any interested party to the silicone breast implant litigation? (This includes both work relating to the implant litigation and any other type of work.)

4. Have you or members of your household ever received any research funds, graduate support, or any other funds (awards, honoraria, speaking or consulting fees, etc.) from any interested party?

5. Do you or members of your household currently have significant investments in any of the defendant corporations in the form of stocks, bonds, etc.? (You need not report highly diversified mutual funds or similar investment vehicles.) Do you or members of your household currently have investments in corporations which, although not parties to the litigation, have a stake in its outcome?

6. Have you, members of your household or members of your department conducted any research in the area of disease causation due to silicone breast implants? Was this research funded? If so, by whom? Did this research result in publication? If so, give citations.

7. Have you or members of your household conducted <u>any</u> research which was funded by corporations which, although not parties to the silicone implant litigation, have a stake in its outcome (e.g., pharmaceutical corporations that use silicone in medical devices)? Have you or members of your household served as consultants to such companies on any matter?

<u>Public statement and positions</u>

8. Have you, members of your household, or members of your department made any public pronouncements (e.g., to the press, to a class, or at a professional meeting) regarding: any aspect of the silicone breast implant litigation; the conduct of the parties to the litigation; your conclusions as to the relationship between breast implants and any of the medical conditions (e.g., systemic lupus, erythematosus, rheumatoid arthritis, scleroderma, polymyalgia) that plaintiffs complain of?

9. Do you have any colleagues** at your institution or others, or a close friend at any institution, who has conducted research in the area of diseases allegedly caused by silicone breast implants? Have you ever shared a

** For purposes of this question a colleague is a person with whom you have a significant interaction in research, teaching or administration.

grant with these individuals? Have you ever co-authored any research publication with these individuals?

10. Have you or members of your household ever been contacted by anyone (e.g., parties, the press, lawyers) as regards silicone breast implants or the related litigation? What was the extent of this contact?

11. Have you ever reviewed a grant proposal or a journal article relating to diseases that might be caused by silicone breast implants?

Previous Litigation Experience

12. Have you ever served as an expert witness? If so, who were the parties to the action? For whom did you work? What was the nature of your involvement in that litigation? (e.g., did you prepare reports? testify? were you deposed?)

Additional Information

13. Please report any service (full-time or part-time) with federal, state, or local government that may be related to the silicone breast implant litigation. Also include any other consulting or advisory work with professional organizations, trade associations, public interest groups, or civic groups that may be related to the litigation.

14. Is there any other connection between you and any interested party —or any other factor—that might impair your ability to serve on the Science Panel that has not been addressed by any of the above questions? Are there factors that others might reasonably construe as creating such impairments?

I have read the "General Statement Concerning Bias and Conflict of Interest" and the "Instructions for Completing the Questionnaire" and have answered the above questions in light of those statements, completely and to the best of my ability. I know of no reason why I cannot serve the Court as a neutral, unbiased, and independent expert.

_____ _____

SIGNATURE DATE