United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 2, 2001 Decided October 26, 2001

No. 00-7241

Brenda G. Meister,
Appellant/Cross-Appellee

v.

Medical Engineering Corporation, a Wisconsin Corporation,
and
Bristol-Myers Squibb Company, a Delaware Corporation,
Appellees/Cross-Appellants

Consolidated with
No. 00-7251

Appeals from the United States District Court
for the District of Columbia
(No. 92cv02660)

Stephen L. Snyder argued the cause for appellant/cross-appellee. With him on the briefs was Sheldon N. Jacobs. Robert J. Weltchek entered an appearance.

James T. Conlon, pro hac vice, argued the cause for appellees/cross-appellants. With him on the briefs was Kimberly S. Penner. Dino S. Sangiamo and James L. Shea entered appearances.

Before: Edwards, Rogers and Tatel, Circuit Judges.

Opinion for the Court filed by Circuit Judge Rogers.

Rogers, Circuit Judge: Brenda Meister opted out of the omnibus settlement in the silicone breast implant products liability litigation and pursued her claims in federal court in the District of Columbia. She now appeals the grant of judgment as a matter of law, or a new trial, on the ground that the district court overlooked a substantial portion of her scientific evidence and otherwise mischaracterized that evidence, thereby impermissibly usurping the role of the jury. We hold that the district court properly applied Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993), in concluding that Meister failed to show causation and did not usurp the role of jury in granting judgment as a matter of law. Accordingly, we affirm.1

I.

Nearly ten years after her breast implants in 1977, Meister developed symptoms that Dr. Brian Arling, and later Dr. David Borenstein, diagnosed as late diffuse scleroderma.2 In

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1 In light of our disposition, we do not reach the issue of personal jurisdiction conditionally presented by the defendants in their cross-appeal. See Appellees' Brief at xii.

2 Scleroderma is a chronic disease that causes sclerosis of the skin and certain organs; "[t]he skin is taut, firm, and ... feels tough and leathery." Taber's Cyclopedic Medical Dictionary 1530 (Clayton L. Thomas ed., 15th ed. 1985). One of Meister's expert witnesses, Dr. Shanklin, testified that scleroderma "is the popular name given to a process by which this kind of scar tissue is laid down in the body but not seemingly in direct reaction to something at that site." Meister described her condition of scleroderma as consisting of "severe skin tightening, muscle and joint pain, reduced

1992, she filed a products liability lawsuit, alleging that she developed scleroderma as a result of exposure to silicone breast implants manufactured by Medical Engineering Corporation ("MEC"). Meister sought punitive damages from MEC and Bristol-Myers Squibb Company, which became the sole shareholder of MEC in 1982. In her complaint she pled strict liability in tort, negligence, breach of warranties, and misrepresentation, deceit or concealment. Following a remand from the consolidated breast implant litigation proceedings in the Northern District of Alabama, the district court here denied the defendants' motion to dismiss the complaint for lack of personal jurisdiction pursuant to Federal Rule Civil Procedure 12(b)(2).

The defendants thereafter moved to exclude or limit the testimony of Meister's expert witnesses on causation, pursuant to Daubert and Federal Rules of Evidence 702 and 703. The district court denied the motion after argument, ruling that Meister's witnesses should be allowed to testify. The defendants urged reconsideration of their motion a month later, in December of 1998, citing a recently published report of the Rule 706 National Academy of Sciences Panel that had found no association between breast implants and any of the individual connective tissue diseases or other autoimmune/rheumatic conditions.3 Again, following argument, the district court denied the defendants' motion, noting that the studies did not address the specific issues presented by

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pulmonary function, esophageal strictures, hair loss, vision impairment, kidney malfunction and chronic fatigue."

3 The Rule 706 National Academy of Sciences Panel, appointed by Judge Sam C. Pointer, Jr., was instructed to "review and critique the scientific literature pertaining to the possibility of a causal association between silicone breast implants and connective tissue diseases, related signs and symptoms, and immune system dysfunction." Judge Pointer was the coordinating judge for the federal breast implant multi-district litigation. The Panel published a report, dated November 17, 1998, which is entitled Silicone Breast Implants in Relation to Connective Tissue Diseases and Immunologic Dysfunction.

Meister's complaint, such as gel bleed.4

At trial, Meister presented two medical experts. The first was Dr. Borenstein, her treating physician and a specialist in rheumatology and internal medicine. He had published several peer-reviewed articles and medical textbook chapters on scleroderma and had also written a paper on silicone-related disorders. However, he disclaimed expertise in scleroderma and stated that he "didn't know too much about breast implants" before treating Meister.5 Meister's other expert was Dr. Douglas Shanklin, a pathologist tenured as a Professor at the University of Tennessee who had authored several hundred peer-reviewed medical articles, made numerous presentations to the medical community regarding the effects of silicone, and testified in several other breast implant cases. However, he had no particular training or expertise in rheumatic diseases or immunology and until 1996 had never treated a scleroderma patient. Nor had he published on scleroderma.

After Meister had finished presenting her evidence, the defendants moved for judgment as a matter of law, pursuant to Federal Rule of Civil Procedure 50(a), on the ground that Meister's case was barren of any reliable scientific evidence on causation. The district court reiterated its concern that the Panel Report had not addressed gel bleed, stated that it had yet to read the entire report, and determined that it was not comfortable granting the motion "at this time." Upon renewal of defendants' Rule 50(a) motion at the close of all the evidence, the district court denied the motion, observing that one of Meister's proposed expert witnesses "has a theory that may or may not be viable, but he has testified in other

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4 According to Dr. Thomas Fawell, who performed the surgery implanting Meister's breast implants, gel bleed is a phenomenon common to all silicone breast implants in which microscopic amounts of the silicone gel inside the implant seep through the silicone envelope to the outer surface of the implant.

5 Dr. Borenstein had not received funding to study scleroderma and had never been affiliated with any organization that devotes itself to the study of scleroderma.

cases that have no more evidence than we have here." The jury returned a verdict for Meister, awarding her $10 million in damages.

The defendants moved for judgment as a matter of law, pursuant to Federal Rule of Civil Procedure 50(b), or alternatively for a new trial, pursuant to Federal Rule of Civil Procedure 59(b), and to alter or amend the judgment, pursuant to Federal Rule of Civil Procedure 59(e). The district court granted the motion for judgment as a matter or law, or a new trial. The district court ruled that, standing alone, the testimony of Meister's experts failed to carry her burden. The court found that the reliance of one of her experts "on the case reports is demonstratively unacceptable as a valid basis for his opinion [on causation]," and that the "ipse dixit" testimony of Meister's only other expert did not fill the void. Further, the court found, "any credence that might be attributed to their testimony falls in the face of what courts have referred to as a 'solid body of epidemiological data.' "6 The district court referred to a June 1999 report of the Institute of Medicine, commissioned by the National Academy of Sciences, that concluded, after a general review of the known research on silicone breast implants, that there was insufficient evidence to support any association of the silicone breast implants with defined connective tissue disease, with any atypical connective tissue disease, or any new disease in women that is associated with implants.7 Given this record, the district court concluded that there was "no valid basis" for the jury's verdict.

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6 The district court cited Hopkins v. Dow Corning Corp., 33 F.3d 1116, 1125 (9th Cir. 1994), and the Bendectin cases of Raynor v. Merrell Pharm., Inc., 104 F.3d 1371 (D.C. Cir. 1997); Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 832 (D.C. Cir. 1988), cert. denied, 493 U.S. 882 (1989).

7 See "Safety of Silicone Breast Implants," Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine, Safety of Silicone Breast Implants, (Stuart Bondurant, Virginia Ernster & Roger Herdman eds. 1999) ("IOM Report").

II.

On appeal, Meister contends that in granting judgment as a matter of law, or a new trial, the district court impermissibly usurped the role of the jury by overlooking a substantial portion of her scientific evidence, mischaracterizing it, and ignoring the fact that her counsel poked numerous holes in the defendants' "supposed 'fortress' of epidemiological and other scientific evidence." Specifically, Meister maintains, first, that there is real doubt as to the validity of any epidemiological study because no study has ever indicated whether any of the subjects had implants containing industrial use silicone as was contained in Meister's implants.8 Second, she maintains, in urging the probativeness of her causation evidence, that her expert rheumatologist was also her primary treating physician for approximately ten years, unlike the experts in most toxic tort cases who make their living from forensic testimony and lack the benefit of experience "in the trenches." Further, Meister stresses that her treating physician used a traditional method of "differential diagnosis" hypothesis to determine the cause of her scleroderma. Moreover, she maintains, the district court, pursuant to Daubert, repeatedly denied defendants' motions to preclude her scientific evidence, each time confirming that her scientific evidence was reliable, relevant, and entitled to be heard by the jury. Finally, Meister maintains that the district court erred in relying on the June 1999 Report of the Institute of Medicine because it was not in existence at the time of trial. For these reasons, Meister contends this court should find no difficulty in reinstating the verdict. It is not to be so.

Under Daubert, the district court is required to address two questions, first whether the expert's testimony is based on "scientific knowledge," and second, whether the testimony "will assist the trier of fact to understand or determine a fact

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8 Dr. Fawell had used implants containing industrial grade silicone from General Electric, although appellees dispute whether the term "industrial" referred to its grade or merely the fact that it was being supplied to a manufacturer as opposed to a consumer. See Appellee's Brief at 30 n.31.

in issue." 509 U.S. at 592. The first inquiry forces the court to focus on "principles and methodology, not on the conclusions that they generate," id. at 595, and thus demands a grounding in the methods and procedures of science, rather than subjective belief or unsupported speculation. Id. at 590; Ambrosini v. Labarraque, 101 F.3d 129, 133 (D.C. Cir. 1996). While rejecting a requirement of scientific certainty, the Supreme Court instructed that "in order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation--i.e., 'good grounds,' based on what is known." Daubert, 509 U.S. at 590. The Court identified four factors for courts to consider in evaluating scientific validity, focusing on whether the theory or technique had been tested, whether it had been subjected to peer review and publication, the method's known or potential error rate, and the method's general acceptance in the scientific community. Id. at 593-94. Meister fails to demonstrate that her expert medical evidence passes muster under any of these factors, and thus fails to show error by the district court in applying Daubert.9

Both case reports and epidemiological studies may be used in the study of silicone breast implants, the former identifying a temporal relationship, and the latter taking the first steps toward establishing a casual relationship. See, e.g., Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 830 (D.C. Cir. 1988), cert. denied, 493 U.S. 882 (1989). However, as one of Meister's medical experts acknowledged at trial, testing the case reports through epidemiological studies--the methodology that calls for checking controlled population studies to see if they confirm the hypotheses suggested in individual case reports--is "an important scientific" approach. Federal Rule of Evidence 703 provides that "an opinion refuting ... scien-

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9 The admissibility of expert testimony and the qualification of an expert witness are preliminary questions to be determined by the district court, see Fed. R. Evid. 104(a), and Meister had the burden of establishing these matters by a "preponderance of proof." Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 592 n.10 (1993) (citing Bourjaily v. U.S., 483 U.S. 171, 175-176 (1987)).

tific consensus is inadmissible for lack of an adequate foundation, in the absence of other substantial probative evidence on which to base [the] opinion." Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159, 1162 (D.C. Cir. 1990). In the instant case, the overwhelming evidence from the epidemiological studies is that there is no causal connection between silicone breast implants and scleroderma. Meister thus faced the burden of overcoming the conclusions of the epidemiological evidence referred to by her own experts and offered by the defendants that there is insufficient evidence of a casual relationship between breast implants and scleroderma.10

Meister's first medical expert was Dr. Borenstein, who began treating Meister in 1987 as a result of color changes in her hands that indicated to him that she might have a connective tissue disease or autoimmune disease. He performed a battery of tests that led him to conclude that Meister was suffering from systemic sclerosis--the disease complex of which scleroderma is a component--in its diffuse form. Over the course of the next year, Meister developed some difficulty with her esophagus, something Dr. Borenstein thought was probably related to her scleroderma. She also was experiencing chest pains and difficulty in breathing. In addition, she was suffering from calcinosis--a condition of misplaced internal calcium deposits--as a result of her scleroderma. Lung function tests over the next three years revealed abnormal functioning capacity at roughly the fifty-five percent level. Because lung function below the forty percent level can be fatal, and because he had read in the literature that a patient under similar circumstances had improved after her breast implants were removed, Dr. Borenstein referred Meister to a plastic surgeon, who was a member of a Federal Drug Administration committee examining the possible con-

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10 To the extent that Meister contends on appeal that a judgment as a matter of law may not be based on evidentiary error, the contention is waived as she did not raise it in the district court. See Raynor v. Merrell Pharm., Inc. 104 F.3d 1371, 1373 (D.C. Cir. 1997). In any event, such a contention is meritless as that issue has been resolved by the Supreme Court. See Weisgram v. Marley, 528 U.S. 440, 457 (2000).

nection between silicone implants and systemic disease; the surgeon advised Meister that there was no connection between her scleroderma and silicone implants. After initially deciding to keep the implants, because her condition was not improving and because of the lack of any therapy for her worsening lung condition, Meister had the implants removed on May 23, 1991.

In response to the question whether he had an opinion to a reasonable degree of medical certainty as to the cause of Meister's scleroderma and accompanying symptoms, Dr. Borenstein testified that they were "related to" her silicone gel breast implants. He arrived at his conclusion, he explained, based on an extensive review of case reports and the medical literature, Meister's improved lung function following explantation,11 and his view that she had an "atypical" form of the disease, that is, "the manifestations don't match up with the disease she has."12 Although the "trigger" for classical scleroderma is unknown, Dr. Borenstein testified that since the 1960s it has been known that "there are environmental factors that have been associated with the onset and the perpetuation of [systemic sclerosis]." He explained that "at the time when [he] was investigating," the literature reflected that "there were patients who had silicone implants who were described with scleroderma." He referred to various case reports in several medical journals that suggested some connection between silica dust and scleroderma in miners, for example, and between silicone and scleroderma. For example, Dr. Borenstein cited an article by two Japanese physicians on women who received silicone injections directly into

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11 Meister's lung function improved, from a fifty-five percent level to a seventy-seven percent level during the two and a half year period following Meister's explantation. Explantation refers to the removal of tissue from the body, the opposite of implantation. See Taber's Cyclopedic Medical Dictionary 588 (Clayton L. Thomas ed., 15th ed. 1985).

12 More precisely, Meister has calcifications but does not have an anticentromere antibody, and that is unusual. There was no fibrosis and scarring, for example, in her lungs; her force vital capacity was normal.

their breasts and subsequently developed systemic sclerosis. He also reviewed literature linking various environmental exposures, such as cancer medications but not including breast implants, to scleroderma. On cross-examination, Dr. Borenstein acknowledged that there is no proof that silicone breast implants cause scleroderma, and that he did not personally know what caused classic scleroderma. Although earlier testifying that Meister's scleroderma was "atypical," he revealed that this conclusion was not reflected in his professional records, and he conceded that each of Meister's symptoms was within the constellation of symptoms making up classic scleroderma. Nevertheless, although he produced no epidemiology associating breast implants to the particular "atypical" condition he had diagnosed for Meister, Dr. Borenstein believed that her condition was related to her silicone gel breast implants.

Contrary to Meister's contention, Dr. Borenstein's testimony on causation is not as probative as scientific evidence in Daubert terms as she would have it. In discussing the case reports purporting to show a link between scleroderma and silicone implants, Dr. Borenstein recognized the limits of case reports to show causation, acknowledging, for example, that they were not controlled studies. Insofar as he relied on "differential analysis" to eliminate alternative causes, Dr. Borenstein's reliance was misplaced. That methodology rests on the assumption that whatever factors remain after other alternative causes have been eliminated is at least capable of causing the disease in question. See Raynor v. Merrell Pharm., Inc. 104 F.3d 1371, 1376 (D.C. Cir. 1997). Whether Meister's condition was atypical or not, Dr. Borenstein failed to show any nexus between her atypical symptoms and her breast implants; the mere simultaneous existence of the two clearly is not an appropriate methodology. His reliance on case reports, temporal methodology, and Meister's atypical symptoms are not sufficient to show that silicone breast implants are capable of causing scleroderma, and therefore his reliance on differential analysis does not meet Daubert standards. Regarding the literature that he reviewed, Dr. Borenstein did not testify that any of the studies had actually

concluded that scleroderma was caused by silicone breast implants. At most, his testimony revealed that the authors indicated that their observations support or "suggest" a role for silicone in the etiology of scleroderma. Additionally, Dr. Borenstein admitted that the persons with whom he conferred were unable to advise him of a causal nexus between silicone breast implants and Meister's scleroderma, and that the published epidemiology did not indicate a causal nexus.

Meister's other expert medical witness, Dr. Shanklin, accepted Dr. Borenstein's diagnosis of scleroderma (while rejecting the view that Meister's scleroderma was atypical) and testified that in his opinion, with a reasonable degree of medical probability, Meister's scleroderma "is a consequence of silicone device implantation in 1977." Dr. Shanklin based his opinion on an examination of slides of Meister's breast tissue. As he explained, after implantation silicone particles begin to come out of the shell of the implant device, causing cells in the body to respond and "try to fight off the presence of this foreign material." He went on to testify to the presence of silica13 in Meister's breast tissue, explaining that the silica resulted from "a chemical transformation back to the point of origin" of the silicone that was in Meister's system. After citing case studies in which miners and stonemasons exposed to silica develop scleroderma in a high frequency of cases, Dr. Shanklin concluded that silicone device implantation caused Meister's scleroderma.

Dr. Shanklin's testimony is problematic as well. He acknowledged that ongoing research investigating the cause of scleroderma has merely given rise to ideas about an association between certain environmental factors and scleroderma and has not yet shown a causal relationship. Instead, jump-

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13 Silicone is defined as "[a]n organic compound in which carbon has been replaced by silicon," which is a nonmetallic element found in the soil that comprises approximately 25% of the earth's crust. See Taber's Cyclopedic Medical Dictionary at 1561. Dr. Shanklin testified that silica is a less complex substance from which silicone is made.

ing from an observation of a local tissue reaction to causation of a systemic disease, Dr. Shanklin identified as the basis for his causation opinion studies linking silica with scleroderma. Still, he admitted that, although there are "some associations" between silica and scleroderma, he was not saying these environmental factors were causing Meister's scleroderma. In short, then, the substance of Dr. Shanklin's theory was, to use his words, first, "[Meister's] tissues were still trying their best to get rid of this stuff [i.e., silicone] 14 years later;" second, "after 14 years, it is possible the [immune] system is beginning to make mistakes;" and third, "Somewhere along the line she developed clinically diagnosable scleroderma." Such an approach will not do; "chemical, in vitro, and in vivo ... [s]tudies ... singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence." Raynor, 104 F.3d at 1374.

The defendants presented such contradictory evidence in the form of epidemiological studies that found insufficient evidence of an association between silicone breast implants and connective tissue disease. In addition to the testimony of three experts--Dr. Alan Shons, a plastic surgeon who was a member of the American Medical Association committee that studied the question raised by the case reports; Dr. Kenneth Kulig, a toxicologist, who reviewed 50 years of safety data on silicone; and Dr. Virginia Steen, a rheumatologist who has treated numerous patients, including those with scleroderma, for over twenty-five years--the defendants brought to the district court's attention two recent major epidemiological studies. In support of their motions to exclude or limit the testimony of Meister's experts on causation, the defendants referred to the Rule 706 Panel Report, published November 30, 1998, which reported that there was "[n]o association ... between breast implants and any of the individual connective tissue diseases, all definite connective diseases combined, or the other autoimmune/rheumatic conditions." Although the district court had expressed concern about whether the Report addressed gel bleed, the Report addressed gel bleed to the extent that all silicone breast implants bleed and silicone

breast implants were the object of study in the report. Additionally, while their post-verdict motions were pending, the defendants informed the district court of the June 1999 IOM Report, entitled "Safety of Silicone Breast Implants."14 See supra note 7. The IOM Report, commissioned by the United States Department of Health and Human Services, concluded that:

> The evidence for an atypical disease or a novel syndrome is insufficient or flawed. It consists of selected case series, few of which describe a consistent and reproducible syndrome. The controlled epidemiological studies cited provide stronger, contrary evidence. In view of the paucity, weakness, and conflicting nature of the evidence, the committee concludes that there is no rigorous, convincing scientific support for atypical connective tissue or any new disease in women that is associated with silicone breast implants. In fact, epidemiological evidence suggests there is no novel syndrome.

The IOM Report was based on "a general review of past and ongoing research on silicone breast implants." With regard to connective tissue disease, including scleroderma, the committee reviewed 17 epidemiological studies, nine of which had been reviewed by Dr. Borenstein, and at least 12 of which were discussed by defendants' experts. The committee found "no convincing evidence for atypical connective tissue or rheumatic disease or a novel constellation of signs and symptoms in women with silicone breast implants."

The district court was thus presented with a classic Daubert case. The scientific method is based on testing to determine if the questions raised by case studies can be determined to have a causative relationship. See Daubert, 508 U.S. at 593. The considerable epidemiological evidence all pointed in one direction. Moreover, the defendants

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14 There is no indication in the record that Meister objected to submission of the IOM Report. Hence, her attempt to object on appeal to the district court's consideration of the June 1999 IOM Report is not properly preserved for appeal. See Willoughby v. Potomac Elec. Power Co., 100 F.3d 999, 1002 (D.C. Cir. 1996).

brought to the district court's attention a landscape of litigation in other federal districts in which judges were unanimous in rejecting as lacking in scientific basis and contrary to the overwhelming medical literature the type of testimony offered by Drs. Borenstein and Shanklin.15 Affording Meister leeway to counter this evidence, the district court let the jury hear her expert evidence. See Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 827 n.27 (D.C. Cir. 1988).16 Dr. Borenstein had a causal hypothesis based on treating Meister and suggestions he found in the medical literature; Dr. Shanklin had merely a theory. Dr. Borenstein's conclusion is suspect for two main reasons. "Temporal methodology" may sometimes provide the basis for reliable scientific hypotheses, but not in the case of scleroderma, which typically waxes and wanes, or where the focus is on the disappearance of only one symptom following explantation as proving causation. Even more crucially, no reasonable scientist would rely on this methodology in the face of voluminous epidemiological evidence to the contrary. See Raynor, 104 F.3d at 1374. Dr.

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15 See, e.g., In re Breast Implant Litig., 11 F. Supp. 2d 1217 (D. Colo. 1998); Kelley v. American Heyer-Schulte Corp., 957 F. Supp. 873 (W.D. Tex. 1997); Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1414 (D. Or. 1996); In re Breast Implant Cases, 942 F. Supp. 958 (E. & S.D.N.Y. 1996). The defendants also cited cases from state courts in Texas and California. See Minnesota Mining and Mfg. Co. v. Atterbury, 978 S.W.2d 183 (Tex. App. 1998); Johnson v. Baxter Healthcare Corp., No. CV-92-07501 (Tr. Ct. N.M. Feb. 23, 1998); Dinerman v. McGhan Med. Corp., No. BC 065884 (Super. Ct. Calif. Aug. 12, 1997); Bailey v. Dow Corning Corp., 1996 WL 937659, at *1, (Tex. D. Ct. Sept. 6, 1996).

16 Contrary to Meister's contention at oral argument that this court should review the district court's initial rulings, they are merged when the district court grants judgment. Thus, "[i]t is of no moment that the district court granted judgment [as a matter of law] instead of taking the case from the jury earlier by directing a verdict for [the defendants]. The court has counseled that the better practice is to let the case go to the jury and, if it finds liability, to set the verdict aside." Richardson, 857 F.2d at 827 n.27 (citations omitted).

Shanklin's causation testimony was deficient perhaps most tellingly insofar as his theory relied on case reports suggesting a connection between silica and scleroderma, even though he did not purport to find support for such a connection in the epidemiological studies, thus creating an analytical gap between the data and his opinion that "is simply too great."17 General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997).18

Ultimately, it is Meister's experts' heavy reliance on case reports that is her undoing. Although case reports may suffice under some circumstances, the defendants introduced expert testimony that was supported by a uniform body of evidence including epidemiological studies failing to establish a causal link between silicone breast implants and connective tissue disease. The IOM Report was right on point. Case reports were presenting hypotheses that needed to be evaluated through the epidemiological method. The National Academy of Science evaluated the hypotheses being developed in the case studies and concluded that there was insufficient evidence to show a causal relationship between silicone breast implant and scleroderma. Hence, the district court could reasonably conclude that reasonable people could not differ as to the import of the epidemiological evidence.

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17 Meister's attempt to rely, for the first time on appeal, on the testimony of the implanting physician, Dr. Thomas Fawell, is not properly before the court. See Marymount Hosp., Inc. v. Shalala, 19 F.3d 658, 663 (D.C. Cir. 1994); Roosevelt v. E.I. Du Pont De Neumours & Co., 958 F.2d 416, 419 n.5 (D.C. Cir. 1992).

18 Meister's reliance on Carmichael v. Samyang, Tire, Inc., 131 F.3d 1433 (11th Cir. 1997), which was overruled sub nom. Kumho Tire Co, Ltd. v. Carmichael, 526 U.S. 137 (1999), is misplaced. Her reliance on Toole v. Baxter Healthcare Corp., 235 F.3d 1307 (11th Cir. 2000), is also misplaced because Dr. Shanklin did not testify on causation directly but merely described a disease process. Id. at 1312. Her reliance on Jennings v. Baxter Healthcare Corp., 14 P.3d 596 (Or. 2000), is to no avail because in that case the expert evidence addressed correlations, not causation, and the Oregon court was not confronted with overwhelming epidemiological evidence contrary to the new theory based on preliminary work that was at issue. Id. at 601-02, 608.

Accordingly, we find no abuse of discretion by the district court in excising Meister's expert medical testimony, see Raynor, 104 F.3d at 1374, and, in light of the insufficient remaining evidence to support the jury's verdict, no impermissible usurpation of the jury's function, see Weisgram v. Marley Co., 528 U.S. 440, 454 n.10 (2000); Richardson, 857 F.2d at 833, in granting judgment as a matter of law, and we affirm.