GRANT v. BRISTOL-MYERS SQUIBB

97 F. Supp.2d 986 (2000) | Cited 0 times | D. Arizona | April 3, 2000

ORDER

Pending before the Court are Defendants' Motions in Limine toExclude the Testimony of Plaintiffs' Experts Dr. Gary Solomon[Doc. # 57]; Dr. David Goldsmith [Doc. # 59]; Dr. ChristopherBatich [Doc. # 61]; Dr. Pierre Blais [Doc. # 63]; Dr. SaulPuszkin [Doc. # 65]; and Dr. Douglas Shanklin [Doc. # 67]. Alsobefore the Court are Defendants' Motion for Partial SummaryJudgment re: Lack of Scientific Causation [Doc. # 51], and Motionfor Summary Judgment on Plaintiffs' Punitive Damages Claim [Doc.# 55]. The Court heard oral argument on March 15, 2000, and uponconsideration of the briefs and the record as a whole, nowconcludes as follows:

I. Background

Plaintiff Nannette Louise Grant was implanted with Surgitekbi-lumen silicone gel-filled breast implants on June 25, 1984.The first implants were removed and replaced on April 19, 1985with Surgitek bi-lumen silicone gel filled implants. Plaintiffthen had those implants removed on June 2, 1993, and they werenot replaced. Plaintiff claims that her implants cause her todevelop severe health problems, including, but not limited to,chronic fatigue syndrome, breast pain, depression, and dry mouthand eyes.

Plaintiff and her husband allege causes of action for strictliability, negligence, failure to warn, breach of express andimplied warranties, breach of warranty of fitness for aparticular purpose, breach of UCC, misrepresentation, fraud byconcealment, false advertising, negligence per se, res ipsaloquitur, negligent infliction of emotional distress, negligentsupervision, corporate negligence/vicarious and/or alter egoliability. Plaintiffs seek general and special damages, includingattorneys' fees and punitive damages.

II. Daubert Standard

Defendants' Motions In Limine seek to exclude at trial thetestimony of the Grants' proposed expert witnesses Solomon,Goldsmith, Batich, Blais, Puszkin, and Shanklin. Defendants'motions challenge the reliability and relevance of these experts'proffered testimony regarding a causal connection betweensilicone gel breast implants and systemic diseases.

The Federal Rules of Evidence govern the admission of expertscientific testimony in a federal trial. Daubert v. Merrell DowPharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d469 (1993).

Rule 702 of the Federal Rules of Evidence providesthat ". . . If scientific, technical, or other specializedknowledge will assist the trier of fact to understand theevidence or to determine a fact in issue, a witness qualified asan expert by knowledge, skill, experience, training or education,may testify thereto in the form of an opinion or otherwise."Daubert and F.R.E. 702 require the trial court act as a"gatekeeper," so that the court is satisfied that the profferedexpert scientific testimony meets certain standards ofreliability before it is admitted. Daubert, 509 U.S. at 595-97,113 S.Ct. at 2798.

The Daubert Court listed four non-exclusive factors the trialcourt is to consider in determining whether an expert's testimonyis based on reliable scientific knowledge: (1) whether the theoryor method employed by the expert has gained general acceptance inthe relevant scientific community; (2) whether the method hasbeen subject to peer-review and publication; (3) whether themethod employed can be and has been tested; and (4) whether theknown or potential rate of error and the existence andmaintenance of standards controlling the technique areacceptable. Id. at 591-95, 113 S.Ct. at 2796-97. The fourfactors enumerated are illustrative rather than exhaustive, andmay not be equally applicable in every case. The Ninth CircuitCourt of Appeals provided the following additional guidance totrial courts:

One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying. That an experts testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture. But in determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office. (Footnote omitted.) Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1317 (9th Cir. 1995). The proponents of the evidence have the burden of proving that their expert witness testimony is admissible pursuant to Rule 702 and the Daubert standards. Daubert, 43 F.3d at 1311, 1316 (9th Cir. 1995). The proponents do not have to show that testimony is scientifically correct, but just that the methodology used was reliable under Daubert's standards.

III. Discussion

Causation must be general and specific; the plaintiff mustprove that the allegedly toxic substance is capable of causing aparticular injury in the general population, and that thesubstance caused this particular individual's injury. See In reBreast Implant Litigation, 11 F. Supp.2d 1217 (D.Colo. 1998).Plaintiffs allege that both local and systemic injuries werecaused by the silicone breast implants. Whereas the local diseasemight be characterized by symptoms such as breast pain ormastitis, a systemic disease might manifest for example, ascancer, lupus, or a connective tissue disease. Some of Plaintiffsexperts opine that a new undifferentiated atypicaldisease/syndrome is associated with exposure to silicone in thesilicone gel implants. This theory sets forth various kinds ofatypical connective tissue diseases, which allegedly manifeststhrough a constellation of symptoms

and are caused by anautoimmune response to silicone in breast implants. Several areasof scientific study are implicated by these theories of systemicinjury such as immunology, toxicology, rheumatology, andepidemiology, the study of the causes of diseases in humans.

To support their motions to exclude testimony of systemicinjury under Daubert, and to support their motion for partialsummary judgment re: scientific causation, Defendants presentedthe reports of court-appointed and congressional appointedcommittees who have concluded that silicone breast implants arenot associated with systemic illness. One of the two main reportspresented and reviewed by this Court arose of out the Multidistrict Breast Implant Litigation 926. Those cases were assignedto transferee Chief Judge Sam C. Pointer, from the northerndistrict of Alabama, to handle pretrial discovery and simplifyissues for trial. Judge Pointer appointed a national committee ofexperts under Federal Rule of Evidence 706, deemed the NationalScience Panel (NSP), to consider evidence on whether siliconebreast implants cause systemic disease and to assist JudgePointer in making evidentiary rulings concerning whether therewas a causal link between breast implants and any of theindividual connective tissue diseases, all definitive connectivetissues diseases combined, or other autoimmune/rheumaticconditions.

Four experts were appointed to the NSP: an epidemiologist (Dr.Barbara Hulka), an immunologist and rheumatologist (Dr. BettyDiamond); a rheumatologist and epedimiologist (Dr. PeterTugwell), and a toxicologist (Dr. Nancy Kerkvliet). For over twoyears, the NSP considered the alleged causal relationship betweendisease and silicone breast implants with plaintiffs anddefendants each providing the top forty articles in each fieldsupporting their position. In November 1998, the Panel issued itsreport entitled "Silicone Breast Implants in Relation toConnective Tissue Diseases and Immunologic Dsyfunction." Theexecutive summary of that Panel reported their conclusion that"[n]o association was evident between breast implants and any ofthe individual connective tissue diseases, all definiteconnective tissue diseases combined, or the otherautoimmune/rheumatic conditions." [See Exhibit 35 to DF's Motionre: scientific causation; See Report at p. 6]. The Panel alsofound no association between breast implants and atypicalconnective tissue diseases or any distinctive constellation ofsymptoms observed in women with breast implants. [See id at p.7]. Panelists noted that their findings and conclusions wereunanimous, and that "a large majority of scientists in ourrespective disciplineswould find merit on our reviews and analysis."

Defendants also direct the Court's attention to a study on thesafety of silicone breast implants sponsored by the U.S.Department of Health and Human Services. In June of 1999, theInstitute of Medicine of the National Academy of Sciencesconcluded that there is insufficient evidence to supportallegations that breast implants are associated with definedconnective tissues disease, cancer, neurological diseases orundefined, atypical syndromes. [See IOM's executive summary at pp2-7; Ex. 40 to partial summary judgment motion]. In fact, the IOMCommittee asserted that "given repeated findings of no elevatedrisk, the evidence supports the conclusion that there is noassociation, and therefore no justification for the use ofresources in further epidemiological exploration of such anassociation." [IOM Report at p. 175].

To further support their contention that breast implants do notcause systemic disease, Defendants point out that more thantwenty epidemiological studies that have been published in peerreview articles have concluded that breast implants do not causeany diseases, typical or atypical. [See Reply in Support ofMotion to Exclude Testimony of Solomon, p. 3]. As evidence thatthis conclusion is accepted as fact by the scientific community,Defendants also submit as exhibits the statements of twentynational and international medical and scientific organizations,including the American Medical Association and the AmericanCancer Society, who have issued statements relating to theabsence of scientifically reliable evidence linking breastimplants to disease. [See Exs. 10-30 of Defendants' motion re:causation].

Further, many district and appellate courts have considered thesame issues that are currently before this Court and some haveheld extensive evidentiary hearings. In In Re Breast ImplantCases, 942 F. Supp. 958 (S.D.N.Y. 1996), three New York districtjudges and a magistrate held a hearing on behalf of allplaintiffs and defendants in pending and projected cases, andheard many witnesses and received in evidence documents andscientific papers, and incorporated those from breast implantcases in other district courts.

Although the southern district of New York court panelistsdeferred a ruling because the Daubert issue had not been briefedprior to the hearing, the Court stated that the evidencepresented by the parties "supports the conclusion that thesilicone implants at issue do not cause classical recognizeddiseases such as interstitial pulmonary fibrosis, systemic lupuserythematosus, rheumatoid arthritis, or Sjogren's Syndrome. Id.at 961. Experts also agreed that the breast implants did notexacerbate classic rheumatology or connective tissue diseases."Id. As for any proffered atypical disease theory, the Courtfound that "[T]he hundreds of symptoms associated with thisundifferentiated disease, the lack of any acceptable agreed upondefinition, the inadequacy of any satisfactory supportingepidemiological or animal studies, the lack of a scientificallyacceptable showing of medical plausibility, and the questionablenature of the clinical conclusions of treating doctors, all pointto a failure of proof in making a prima facie case that siliconeimplants cause any of the syndromes claimed except for localdisease." Id.

The District of Colorado in In re Breast Implant Litigation,11 F. Supp.2d 1217 (D.Colo. 1998), recently found that profferedtestimony related to systemic diseases from which breast implantrecipients allegedly suffered was not admissible under Daubert.The Order in that case explained the import of epidemiologicalstudies. Relying heavily upon the epidemiological studies as the"best evidence of causation in the mass torts context," thatcourt noted that if the available body of epidemiologydemonstrates that risk is not doubled, then causation evidence isinadmissable. Id. at 1225. The court further noted thatseventeen epidemiological studiesof breast implants had been published in peer reviewed medicaljournals, and that each controlled study demonstrated that breastimplants do not double the risk of a known disease. Id. at1226-27. The Colorado district court additionally deemed that theatypical disease was without definition and so could not be wellexamined by a controlled epidemiological study. Id. at 1227.Finding plaintiffs to be lacking in

reliable scientific evidenceof causation, the Court disallowed the plaintiff's profferedexpert testimony. Id. at 1228, 1236-44.

Plaintiffs intend to introduce the testimony of Drs. Solomon,Batich Blais; Puszkin; and Shanklin.[1] Plaintiffs argue thattheir experts are qualified and use methods that are acceptableand reliable. As such, they request that the Court find experttestimony admissible and allow a jury to ascertain the weight ofthe evidence. The proffered experts are as follows:

Dr. Puszkin holds a Ph.D. in neuroscience and has worked in thefields of pathology and immunology for more than twenty years. InPlaintiffs' Opposition to Motion to Exclude, they advised that hewould testify in this case that silicone causes pathologicalcomplications and disease, and as to immunological reactions tosilicone molecules when they migrate from a defective siliconebreast implant. [see Plaintiffs' Opposition to Motion to Excludere: Puszkin at pp 14-15]. At oral argument, Plaintiffs clarifiedthat Puskzin would not testify as to systemic disease, but wouldsolely testify as to his reading of the pathology slides underthe microscope. Puszkin's proposed testimony then is not subjectto this Daubert challenge directed at proposed systemic diseasetestimony, and the motion in limine will be denied as moot.Whether Puszkin's testimony would be helpful to trier of fact asto local disease is not before the Court at this time.

Dr. Blais holds a PhD in physical chemistry. At the hearing,Plaintiffs advised that Blais was expected to testify as tostructural integrity and biomedical sciences. In their responsebrief, they state that his testimony will include "his knowledgeand expertise with silicone gel filled breast implants" and wellas other knowledge gained while working for the implantmanufacturer.

Many other courts have excluded Blais' opinion on the allegeddefect of implants finding it unreliable and not accepted in thegeneral scientific community as to systemic injury caused bysilicone breast implants. This Court agrees that Blais is not amedical doctor and has not supported his theories with testing.Further, Blais did not develop his opinions independent oflitigation. As such, Blais may not testify as to any opinion hemay have as to defects of breast implants or any other topic thatis beyond his qualifications as a chemist.

Dr. Shanklin, a pathologist, and Dr. Solomon, a rheumatologist,both were expected to testify about a systemic siliconeassociated disease. Based on the foregoing discussion, and thefact that neither Shanklin nor Solomon have ever examinedPlaintiff, or in Shanklin's case, even reviewed her medicalrecords, the Court finds that their theories are based on theirown opinions, and are not generally accepted by scientificcommunity. Differential and clinical studies do not suffice forDaubert standards. Therefore, Solomon and Shanklin's testimonywill be excluded.

Dr. Batich, a biomaterials expert, is expected to testifyregarding his opinions on bioplausibility, specifically thatsilicone migrates outside the breast capsule and that siliconedegrades into silica in the body, thereby making the siloxicsbiologically reactive in humans. Plaintiffs have not

presentedsufficient evidence of Dr.Batich's qualifications, nor evidence that his theories aregenerally accepted in the scientific community. His testimonywill be excluded.

As a whole, the Court finds that the evidence regardingsystemic disease as proposed by Plaintiffs' experts is notscientifically valid and therefore will not assist the trier offact. As for the atypical syndrome that is suggested, whereexperts propose that breast implants cause a disease but cannotspecify the criteria for diagnosing the disease, it is incapableof epidemiological testing. This renders the experts' methodsinsufficiently reliable to help the jury.

Further, there is overwhelming evidence to the contrary. In allof the epidemiological studies, there is no associated increasingincidence of disease with increased exposure to the agent.Defendants point out that all twenty plus epidemiological studiesto date have found that the relative risk factor around 1.0, orno association, [See Defendants' Reply re: motion on causation atp. 9], and submitted several affidavits supporting thatcontention. [See, e.g., Ex. 1: Dr. Ory affidavit at ¶¶ 25-34; Ex.2: Dr. Schlesselman affidavit ¶¶ 32-40]. The Ninth Circuit notedin Daubert that studies showing a relative risk less than 2.0would not be helpful, and indeed would only serve to confuse thejury, if offered to prove rather than refute causation.43 F.3d 1311, 1320. See also Brock v. Merrell Dow, 874 F.2d 307 (5thCir. 1989) (epidemiological studies with lower end confidenceintervals less than one are not reasonably relied upon by expertsto form opinions about causation).

Plaintiffs argue that this court should focus on methodologyand not conclusions. However, the Supreme Court has noted that:

"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 testimony which is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great of an analytical gap between the data and the opinion proffered."

General Electric Company v. Joiner, 522 U.S. 136, 118 S.Ct.512, 519, 139 L.Ed.2d 508 (1997).

This Court finds that Plaintiffs' experts conclusions aboutsystemic disease have not gained acceptance in the relevantscientific community and none of the proffered expertsdemonstrated that scientific methods practiced by a recognizedminority in the field were followed. There is no explanation ofwhy these opinions should outweigh the over twentyepidemiological studies finding no valid risk of autoimmunedisease resulting from breast implants in humans. The Court willnot allow the jury to speculate based on any experts' opinionbased only on clinical experience in the absence of evidenceshowing consistent, statistically significant association betweenbreast implants and systemic disease.

Summary judgment is appropriate "in the event the trial courtconcludes that the scintilla of evidence

presented supporting aposition is insufficient to allow a reasonable juror to concludethat the position more likely than not is true." Daubert, 509U.S. at 596, 113 S.Ct. 2786. Recently in Allison v. McGhanMedical Corp., 184 F.3d 1300 (11th Cir. 1999), the EleventhCircuit, affirmed a district court's exclusion of testimonyregarding systemic disease and silicone breast implants. Theappellate court noted that "[W]hile we acknowledge that thedebate regarding systemic disease and silicone products may beongoing for years to come, we concur with the district court thatfinal summary judgment is appropriate at this time and with theseexperts."

Likewise in this case, Plaintiffs lack reliable scientificevidence to support causation between breast implants andsystemic disease. Thus, Plaintiffs cannot prove thatNannette Grant's injuries were more likely than not caused byexposure to the silicone breast implants. Accordingly,Defendants' motion for partial summary judgment will be grantedas to scientific causation on systemic disease.

Because claims related to systemic injury will be dismissed,there will be no punitive damages allowed as to those claims.Without a showing of causation, there can be no showing thatDefendant's acts were outrageous in causing harm to Plaintiffs.

Based on the foregoing,

IT IS ORDERED granting each of Defendants' Motions in Limineto Exclude the Testimony of Plaintiffs' Experts Dr. Gary Solomon[Doc. # 57]; Dr. David Goldsmith [Doc. # 59]; Dr. ChristopherBatich [Doc. # 61]; Dr. Pierre Blais [Doc. # 63]; and Dr. DouglasShanklin [Doc. # 67].

FURTHER ORDERED denying as moot Defendants' Motions in Limineto Exclude the Testimony of Plaintiffs' Expert Dr. Saul Puszkin[Doc. # 65].

FURTHER ORDERED granting Defendants' Motion for PartialSummary Judgment re: Lack of Scientific Causation [Doc. # 51].

FURTHER ORDERED granting Defendants' Motion for SummaryJudgment on Plaintiffs' Punitive Damages Claim [Doc. # 55].

1. Plaintiffs did not respond to the Motion in Limine toExclude Dr. David Goldsmith in writing or during oral argument.As such, the Court presumes there is no opposition and will grantthat motion without further discussion. [doc. # 59].