IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

LEAANN D. HALL, Plaintiff, v. BAXTER HEALTHCARE CORP.; et al., Defendants.	Civil No. 92-182-JO (LEAD) 94-892-JO 94-903-JO 94-907-JO
TAMMY JOHNSTON; ROBERT JOHNSTON; LAURA BENTLEY; RALPH BENTLEY; SUSAN EISELE; DARRELL DWAYNE EISELE; MICHELLE TYTLAR; JEFFREY TYTLAR, Plaintiffs, v. BRISTOL-MYERS SQUIBB COMPANY, et al., Defendants.	Civil No. 94-258-JO OPINION AND ORDER
DEBRA SHERVEY,	Civil No. 93

-589-JO (LEAD)

	)	94-260-JO
Plaintiff,	)	94-765-JO
	)	94-902-JO
v.	)	94-949-JO
	)	94-1280-JO
BRISTOL-MYERS SQUIBB COMPANY, et al.,	)	
	)	
Defendants.	)	

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JONES, Judge:

I. INTRODUCTION

Currently pending in this court are a number of silicone breast implant cases brought by or on behalf of the plaintiffs against various breast implant manufacturers.[1] Plaintiffs seek damages for injuries they claim to have suffered as a result of implantation with silicone gel breast implants.

Among other things, the plaintiffs assert that silicone from the implants has migrated and degraded in their bodies and has caused a systemic syndrome or illness, which they generally refer to as "atypical connective tissue disease" (ACTD). In essence, plaintiffs claim a "unique constellation of symptoms" consisting of hundreds of symptoms commonly experienced by the general population.[2]

1 The defendants involved in the present proceedings are Baxter Healthcare Company, Baxter International Inc. (collectively, "Baxter"), Bristol-Myers Squibb, and Minnesota Mining and Manufacturing (together referred to as "defendants"). An early defendant in breast implant litigation, Dow Corning Corp., sought protection under bankruptcy law in May 1995. The bankruptcy proceedings are ongoing.

2 The defense refers to these symptoms as "diseases of ordinary life," e.g., headache, fatigue, joint pain, confusion,

This opinion addresses the defendants' motions in limine to exclude testimony by plaintiffs' experts concerning any causal link between silicone breast implants and the alleged systemic disease or syndrome.[3] To resolve these motions, the court, in its role as "gatekeeper" (see Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) (hereinafter Daubert I), initiated proceedings under Federal Rule of Evidence 104. The process through which the court has endeavored to resolve the pending motions, a process the court believes to be unique in federal practice to date, is described below.

II. FACTS AND PROCEDURAL BACKGROUND

The breast implant cases at issue here were either filed initially in this court or removed from state court. The cases were then transferred to the Judicial Panel for Multidistrict Litigation, In re Silicone Gel Breast Implant Products Liability Litigation, MDL No. 926, where they have been managed expeditiously under the watchful eye of the transferee judge, Chief Judge Sam C. Pointer, Jr. In 1995 and 1996, Judge Pointer remanded a number of cases to Oregon for trial.

All breast implant cases remanded to Oregon federal

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etc.

3 Many of the plaintiffs also allege "local injuries" from the implants, such as rupture, contracture, and chest wall pain. This opinion does not address the admissibility of plaintiffs' witnesses' testimony concerning any local injuries. The scope of what constitutes a "local" injury is discussed infra.

district court have been assigned to this judge. After a series of status conferences involving all interested parties and counsel, I determined that, at least initially, similar cases should grouped for trial. I designated the following three trial groups:

	Plaintiffs	Defendant(s)
Group 1[4]	Hall Pope Stern Preskey	Baxter
Group 2[5]	Andrews Johnston Eisele Bentley Tytlar	Bristol-Myers Squib
Group 3[6]	Shervey Zingarelli Adamson D. Hall Young Mitchel	Bristol-Myers and Medical Engineering Corp.

After initial trial dates were set, the court instructed counsel for Groups 1 and 2 to provide a list of all lay and expert witnesses to be called at trial, together with a

4 Group 1 consists of Case Nos. 92-182 (LEAD), 94-892, 94-903, and 94-907.

5 Group 2 consists of Case No. 94-258.

6 Group 3 consists of Case Nos. 93-589 (LEAD), 94-260, 94-765, 94-902, 94-949, and 94-1280. Although they were invited to participate and attended all four days of the Rule 104 hearing, counsel for the Group 3 plaintiffs repeatedly requested, and the court agreed, that this decision does not apply to them.

narrative statement of each witness' proposed testimony. The court also instructed counsel to summarize each expert witness' 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.

Once the witness materials were duly filed, in July 1996, defendants jointly filed a series of motions in limine to exclude plaintiffs' experts' testimony concerning causation.[7] To address these motions, I scheduled an integrated hearing under Rule 104(a) on the admissibility of the scientific evidence. All interested parties and counsel were invited to attend the hearing, which I set for August 1996.

In view of the complicated scientific and medical issues involved and in an effort to effectively discharge my role as "gatekeeper" under Daubert I, I invoked my inherent authority as a federal district court judge to appoint independent advisors to the court.[8] See, e.g., Goetz v. Crosson, 967 F.2d 29, 37 (2d

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7 The motions in limine were filed in Group 2 (dkt. Nos. 69, 70, 72, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, and 95). Some of the motions address plaintiffs' experts' testimony on issues other than a general causal link between silicone and systemic disease. Those portions of the above-listed motions are moot, with leave to refile as necessary in further pretrial proceedings.

8 To keep the advisors independent of any ongoing proceedings, I appointed them under FRE 104, not FRE 706, which requires court-appointed experts, in effect, to act as additional witnesses subject to depositions and testifying at trial. Although certain plaintiffs (in Group 3) moved to invoke Rule 706 procedures (in No. 93-589, dkt. Nos. 31 and 36), I

Cir. 1992)(VanGraafeiland, J., concurring and dissenting)(citing Scott v. Spanjer Bros., Inc., 298 F.2d 928 (2d Cir. 1962)); see also 1972 Advisory Committee Notes to FRE 702. Pursuant to that inherent authority, I began a search to find technical advisors with the necessary expertise in the fields of epidemiology, immunology/toxicology, rheumatology, and chemistry to assist in evaluating the reliability and relevance of the scientific evidence.[9] Dr. Richard Jones, M.D., Ph.D.,[10] assisted the court by screening dozens of potential appointees and ultimately selecting four totally unbiased and uncommitted experts in the necessary fields, which the court approved and appointed. The technical advisors and their fields of expertise are: Merwyn R. Greenlick, Ph.D. (epidemiology); Robert F. Wilkens, M.D. (rheumatology); Mary Stenzel-Poore, Ph.D. (immunology/toxicology); and Ronald McClard, Ph.D. (polymer

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denied those motions.

9 Although I requested federal funding for the Rule 104 experts' fees, my request was denied. The fees, approximately $76,000, have been paid by the parties. Because I did not appoint the experts under Rule 706, their fees are not "costs" that may be awarded to the prevailing party under Fed. R. Civ. P. 54(d) and 28 U.S.C. § 1920(6). See, e.g., In re Philadelphia Mortg. Trust, 930 F.2d 306, 308-09 (3d Cir. 1991); State of Kansas v. Deffenbaugh Indus., Inc., 154 F.R.D. 269, 270 (D. Kan. 1994) ("The legislative history of § 1920(6) expressly refers to court-appointed expert witnesses 'as permitted by rule 706 of the Federal Rules of Evidence'").

10 Dr. Jones is the former acting president of Oregon Health Sciences University and is the longtime chair of the University's biochemistry department.

chemistry).

With the exception of Dr. McClard, whom I appointed shortly after the initial Rule 104 hearing terminated, the technical advisors reviewed the parties' voluminous materials in preparation for the hearing and observed most of the testimony in court. After his appointment, Dr. McClard reviewed all of the relevant materials and the videotaped arguments of counsel, and participated in all subsequent proceedings.

I structured the Rule 104 hearing according to subject matter, with plaintiffs presenting their experts in a particular field, followed by defendants' witnesses in the same field. All participating parties stipulated to the experts' qualifications under Rule 702. Because in proceedings pursuant to Rule 104(a) the court is not bound by rules of evidence, except those that pertain to privileges I ruled that no evidentiary objections would be permitted.[11]

At the hearing, which spanned four intense days (August 5-8, 1996),[12] experts on both sides were questioned by counsel,

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11 This ruling was remarkably effective, both in permitting the parties to focus on presenting their evidence and in expediting the proceeding. In four days of hearings, only rare objections were made, yet counsel and the witnesses confined the testimony to what, for the most part, would be admissible under the rules of evidence.

12 This court and state court Judge Nely Johnson jointly presided at the hearing. Judge Johnson has been assigned all of the Oregon state court breast implant cases pending in Multnomah County Circuit Court. Judge Johnson participated extensively in the Rule 104 hearings, and her contributions are greatly

the court, and the technical advisors. The parties then submitted videotaped summations, which the court and all technical advisors reviewed.[13] The court also asked the parties to submit proposed questions to guide the technical advisors in evaluating the testimony and preparing their reports. After considering the parties' proposed questions, the court prepared and submitted the following questions to the advisors:

1. Is the expert's opinion supported by scientific reasoning and methodology that is generally accepted in the expert's particular scientific community or otherwise qualified as stated in Daubert II, as quoted above?[14]

2. Is the expert's opinion based upon scientifically reliable data?

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appreciated. Judge Johnson has yet to rule on the admissibility of the scientific evidence in the state court proceedings.

13 The video presentations by plaintiffs' counsel Mike Williams and defense counsel Mary Wells, Nathan Schachtman, and Jane Thorpe demonstrated the highest professional skills I have had the pleasure to observe in 33 years on first the state and then the federal bench. The level of professionalism and competency shown by all counsel throughout these proceedings is appreciated and commended.

14 This reference is to the following language from Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1319 n.11 (9th Cir. 1995):

> [t]he focus * * * is on the reliability of the methodology and in addressing that question the court and the parties are not limited to what is generally accepted; methods accepted by a minority in the scientific community may well be sufficient. However, the party proffering the evidence must explain the expert's methodology and demonstrate in some objectively verifiable way that the expert has both chosen a reliable scientific method and followed it faithfully.

3. 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?

4. Do the methodology and data support the expert's conclusions?

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

The court also submitted almost all of the parties' proposed questions[15] to the technical advisors for their consideration, with this instruction:

> We are also enclosing suggested questions and references provided by counsel. Do not feel obligated to answer all of counsel's questions, but respond to those that you feel are relevant and that you feel will be helpful to the court in discharging our "gatekeeping" role. For instance, the defense contends that the record of the hearing does not reflect the plaintiffs' reconstruction of their witness' testimony. We leave that issue to you.[16]

The technical advisors submitted their reports to the court in September 1996,[17] and on September 13, 1996, the court gave

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15 Only certain questions posed by one plaintiff (LeaAnn Hall) concerning specific causation were withheld.

16 Counsels' questions that the court submitted to the advisors are appended to this opinion as APPENDIX A.

17 The advisors' reports, which were marked as court exhibits, are appended to this opinion as APPENDICES B, C, D, and E (the appended copies do not include any exhibits that were attached

counsel on both sides an opportunity to question them. Following this hearing, the court expressed preliminary concerns that plaintiffs' position could not be sustained and asked defense counsel to submit proposed findings of fact and conclusions of law. Plaintiffs then filed objections and proposed alternative findings, and the defendants filed a further response.

Having fully reviewed the entire record and the reports of the advisors, I am now prepared to rule on the pending rULE 104 hearing motions in limine. For the reasons explained below, the defendants' motions in limine to exclude plaintiffs' expert testimony concerning causation of any systemic disease or syndrome are GRANTED.

I note, however, that while this court was in the midst of the Rule 104 proceedings, Judge Pointer appointed a national panel of experts pursuant to FRE 706 to assist in a similar evaluation of the scientific evidence in the MDL. As recognized by Senior Judge Jack B. Weinstein and Judge Harold Baer, Jr., in their recent joint opinion in breast implant cases pending in the Southern and Eastern Districts of New York (see In re Breast Implant Cases (Amended Preliminary Memorandum Oct. 23, 1996)), it will probably be some time before the national panel completes its important work.[18]

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to the original reports).

18 Because the national Rule 706 panel has not completed its work, Judges Weinstein and Baer determined that the defendants' motions for summary judgment on the systemic claims were not yet

In view of the ongoing national proceedings and the potential for further scientific developments during their pendency, the court will defer the effective date of this opinion until the findings of the national Rule 706 panel are available.[19] Depending on the court's evaluation of those findings, plaintiffs in these cases may seek reconsideration, if appropriate, of this decision. Plaintiffs' motion to add the national Rule 706 panel members to the witness lists in Groups 2 and 3[20] is also deferred pending completion of the panel's work.

III. ADMISSIBILITY STANDARDS

A. Rule 702 and Rule 104(a)

The Federal Rules of Evidence govern in diversity cases, except in the rare circumstance where a state rule of evidence is "'intimately bound up' with the rights and obligations being asserted * * *." Wray v. Gregory, 61 F.3d 1414, 1417 (9th Cir. 1995)(quoting Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938)). With respect to the issues presently before the court, no state evidence rule supplants the federal rules.[21]

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ripe for adjudication.

19 My decision will only be changed in the unlikely event that new scientfic research would require such modification. The views of the Rule 706 panel will be carefully considered, but this opinion is not dependent upon the testimony or conclusions of the Rule 706 experts.

20 Docket No. 175 in No. 94-258. Plaintiff Laura Bentley settled her case; accordingly, her separate motion (# 177 in No. 94-258) is moot.

21 In any event, Oregon law concerning scientific evidence, as

Rule 702 is the starting point for any evaluation of the admissibility of expert testimony. Daubert I, 509 U.S. at 589 (Rule 702 is the "primary locus" of the expert screening "obligation"). Rule 702 provides:

> If the scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

The assessment of whether proferred expert testimony is admissible under Rule 702 is a preliminary question for the court under Rule 104(a). Daubert I, 509 U.S. at 592. Rule 104(a), which provided the framework for the hearing in this case, states:

> Preliminary questions concerning the qualification of a person to be a witness, the

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first articulated in State v. Brown, 297 Or. 404, 687 P.2d 751 (1984) and explicated in State v. O'Key, 321 Or. 285, 899 P.2d 663 (1995), does not significantly differ from federal law as outlined in Daubert I and II. As the author of State v. Brown, a unanimous decision that predates Daubert I by 10 years, I wish to assure Judge Nely Johnson, who will be facing these issues in the state cases, that the Brown court was the first court in the nation to adopt the Weinstein/Berger thesis, which Justice Blackmun utilized in writing Daubert I. In United States v. Downing, 753 F.2d 1224 (3d Cir. 1985), Judge Becker utilized the same procedures as set forth in Brown for federal litigators. Judge Becker has since amplified Downing and Daubert I in In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717 (3rd Cir. 1994) (hereinafter Paoli II). By like token, Justice Richard L. Unis, writing for the Oregon Supreme Court in O'Key, amplified Brown without any fundamental changes. I do not interpret Justice Van Hoomissen's recent opinion for the Oregon Supreme Court in State v. Lyons, 324 Or. 256, 924 P.2d 802 (1996), as altering the message of Brown, O'Key, or Daubert.

> existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.[22]

The Ninth Circuit recently emphasized that the proponent of the expert testimony bears the burden of proving admissibility under Rule 104. Lust v. Merrell Dow Pharmaceuticals, Inc., 89 F.3d 594, 598 (9th Cir. 1996)("[i]t is the proponent of the expert who has the burden of proving admissibility"); see also Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (hereinafter Daubert II)("the party presenting the expert must show that the expert's findings are based on sound science"). In this case, the plaintiffs, as proponents of the evidence, have the burden of establishing admissibility by a preponderance of the evidence. Daubert I, 509 U.S. at 592 n.10.

In determining whether the plaintiffs have met their burden of establishing the admissibility of their expert evidence, the court is guided by Rule 702 and the recent Supreme Court and Ninth Circuit decisions interpreting it, particularly Daubert I and Daubert II. In Daubert I, the Supreme Court clarified that adoption of Rule 702 displaced the traditional Frye[23] test, which made "general acceptance" in the relevant scientific community

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22 See also FRE 1101 ("The rules (other than with respect to privileges) do not apply * * * [to] [t]he determination of questions of fact preliminary to admissibility of evidence when the issue is to be determined by the court under rule 104").

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

the prerequisite to admissibility. Daubert I, 509 U.S. at 589. Instead, under Daubert I, which focused closely on the language of Rule 702, expert scientific opinion is admissible if it qualifies as "scientific knowledge" and is therefore sufficiently "reliable." Daubert I, 509 U.S. at 589-90; see also Lust, 89 F.3d at 597.

According to Daubert I, "the adjective 'scientific' implies a grounding in the methods and procedures of science," and "the word 'knowledge' connotes more than subjective belief or unsupported speculation." 509 U.S. at 590. The Court explained 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.

Id. The requirement that an expert's testimony pertain to "scientific knowledge" "establishes a standard of evidentiary reliability," i.e., trustworthiness. 509 U.S. at 590 and n.9.

The Supreme Court charged district courts with the duty to act as "gatekeepers," to ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable. Daubert I, 509 U.S. at 597-98. Thus, the court must determine at the outset, pursuant to Rule 104(a), "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." Id. at 592-93. This determination "entails a

preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id.

The task before this court, then, is two-pronged. First, the court must determine whether plaintiffs' experts' testimony reflects "scientific knowledge," constitutes "good science," and was "derived by the scientific method." Daubert II, 43 F.3d at 1316. Second, the court must ensure that the proposed testimony "fits," that is, that the testimony is "'relevant to the task at hand'" in that it "logically advances a material aspect of the proposing party's case." Id. at 1315 (quoting Daubert I, 509 U.S. at 597).

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Reliability.

Daubert I and Daubert II list several factors to guide federal courts in deciding the first prong, whether the expert testimony is scientifically valid and therefore reliable. These factors, which may or may not apply in a particular case, include:

> 1.Whether the theory or technique employed by the expert is generally accepted in the scientific community;
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> 2.Whether the theory has been subjected to peer review and publication;
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> 3.Whether the theory can be and has been tested;
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> 4.Whether the known or potential rate of error is acceptable; and
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> 5.Whether the experts are proposing to testify about matters growing naturally or directly out of research, or whether they have developed their opinions expressly for purposes of testifying.[24]

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24 Bias is more important at trial than at the Rule 104 level, where the focus is on the expert's methodology. Even if an expert is a highly paid trial expert or the expert's research is litigation-driven, the expert's testimony may nonetheless reflect valid methodology and sound science. Because of this, I did not allow the parties to raise bias in their questioning. Interestingly, only the plaintiffs objected to this ruling -- a curious fact given that the motions in limine were directed solely to plaintiffs' experts, some of whom are paid extraordinary sums for their testimony. I assume that both plaintiffs' and defendants' experts were fully compensated for their present and past services. I have not relied, however, on

Daubert I, 509 U.S. at 593-94 (first four factors); Daubert II, 43 F.3d at 1316-17 (adding fifth factor). The list is illustrative, not exhaustive. Daubert II, 43 F.3d at 1317.

As mentioned earlier, with respect to the first listed factor, whether the expert's theory or method is generally accepted, the Ninth Circuit explained in Daubert II that in certain circumstances it may be sufficient if a minority in the scientific community accepts the methods employed, but only if the proponent demonstrates in "some objectively verifiable way that the expert has both chosen a reliable scientific method and followed it faithfully." Daubert II, 43 F.3d at 1319 n.11.

2.Fit.

Even if the proponents meet their burden of establishing that an expert's testimony qualifies is scientific knowledge, the court must still exclude the evidence if it does not "fit" the matters at issue in the case. Daubert I, 509 U.S. at 591. As the Ninth Circuit in Daubert II, explained, to "fit," testimony must "logically advance a material aspect of the proposing party's case." Daubert II, 43 F.3d at 1315; see also In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 743 (3d Cir. 1994)(hereinafter Paoli II[25]). In Paoli II, Judge Becker

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any of the defense experts in deciding the Rule 104 issues, but have restricted my evaluation solely to the validity of the plaintiffs' experts' presentations.

25 The Paoli litigation involved two trips to the Third Circuit. In In re Paoli R.R. Yard PCB Litigation, 916 F.2d 829 (3d Cir. 1990), commonly referred to as Paoli I, the Third

described the "fit" requirement as follows:

> For example, animal studies may be methodologically acceptable to show that chemical X increases the risk of cancer in animals, but they may not be methodologically acceptable to show that chemical X increases the risk of cancer in humans. Daubert explains that, "'[f]it' is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." * * * Thus, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge for purposes of the case. "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." * * * For example, in order for animal studies to be admissible to prove causation in humans, there must be good grounds to extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves. Thus, the requirement of reliability, or "good grounds," extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case.

Paoli II, 35 F.3d at 743 (citations omitted; emphasis in original).

As the defendants correctly point out in their proposed findings and conclusions, the issue before the court, as in the Bendectin litigation considered in Daubert II, is causation. In Daubert II, the Ninth Circuit concluded that the plaintiffs in

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Circuit, under pre-Daubert analysis, reversed the district court's exclusion of certain expert witnesses pursuant to FRE 702 and 703 because the district court's analysis was no sufficiently detailed. Paoli I, 916 F.2d at 853-54. After remand, the Third Circuit again reviewed the district court's exclusion in Paoli II, this time pursuant to the standards elucidated in Daubert I.

that case failed to make any objective showing of admissibility under the first prong of Rule 702. Because the plaintiffs had submitted their expert materials while Frye was the law of the circuit, however, rather than remand the case to permit the plaintiffs to augment the record, the court proceeded to reach the second prong, or "fit" requirement, of the Daubert I analysis. Daubert II, 43 F.3d at 1320. In doing so, the court explained that in assessing whether proferred expert testimony "will assist the trier of fact" in resolving the causation issue, the court must look to the substantive standard -- in that case, California tort law. The court commented:

> California tort law requires plaintiffs to show not merely that Bendectin increased the likelihood of injury, but that it more likely than not caused their injuries. * * * In terms of statistical proof, this means that plaintiffs must establish not just that their mothers' ingestion of Bendectin increased somewhat the likelihood of birth defects, but that it more than doubled it--only then can it be said that Bendectin is more likely than not the source of their injury. Because the background rate of limb reduction defects is one per thousand births, plaintiffs must show that among children of mothers who took Bendectin the incidence of such defects was more than two per thousand.

Id. at 1320 (citation omitted).[26]

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26 The court did note that, in certain circumstances, "[a] statistical study showing a relative risk of less than two could be combined with other evidence to show it is more likely than not that the accused cause is responsible for a particular plaintiff's injury." Daubert II, 43 F.3d at 1321 n.16. At the very least, however, plaintiffs making use of this exception must demonstrate that they differ in some significant way from the subjects of the statistical study, so as to eliminate

The substantive standard under Oregon tort law is quite similar to the California standard. Under Oregon law, the plaintiffs in this litigation must prove not merely the possibility of a causal connection between breast implants and the alleged systemic disease, but the medical probability of a causal connection. See Harris v Kissling, 80 Or. App. 5, 9, 721 P.2d 838 (1986); see also Griffin v. K.E. McKay's Market of Coos Bay, Inc., 125 Or. App. 448, 451-52, 865 P.2d 1320 (1993), in which the court stated:

> [The plaintiff] must introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a substantial factor in the result. A mere possibility of such causation is not enough * * *. (Citation omitted.)[27]

Under this substantive standard, if an expert cannot state the causal connection in terms of probability or certainty, the expert's testimony must be excluded under the second prong of Rule 702. In Daubert II, for example, the Ninth Circuit affirmed the district court's exclusion of certain of plaintiffs' experts' opinions, reasoning that:

> As the district court properly found below, "the strongest inference to be drawn for plaintiffs based on the epidemiological evidence is that Bendectin could *possibly* have caused plaintiffs' injuries."

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another, higher relative risk cause. Id.

27 Plaintiffs argue that all they need to prove at the Rule 104 hearing level is "possibility" and that the "probability" test is to be reserved for trial. As will be demonstrated, infra, the probability test is relevant in deciding the causation issue at the Rule 104 stage of the proceedings.

> * * * The same is true of the other testimony derived from animal studies and chemical structure analyses--these experts "testify to a possibility rather than a probability." * * * Unlike these experts' explanation of their methodology, this is not a shortcoming that could be corrected on remand; plaintiffs' experts could augment their affidavits with independent proof that their methods were sound, but to augment the substantive testimony as to causation would require the experts to change their conclusions altogether. Any such tailoring of the experts' conclusions would, at this stage of the proceedings, fatally undermine any attempt to show that these findings were 'derived by the scientific method.' Plaintiffs' experts must, therefore, stand by the conclusions they originally proffered, rendering their testimony inadmissible under the second prong of Fed.R.Evid. 702.

Daubert II, 43 F.3d at 1322 (citation omitted; emphasis added).[28]

3. Methodology v. Conclusions.

The plaintiffs insist that this court must focus solely on the expert's methodology and may not consider the experts'

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28 The question of whether expert testimony is admissible under Rule 702 is separate from the question of whether the testimony is sufficient to submit the case to the jury. The "admissibility" and "sufficiency" of scientific evidence "necessitate different inquiries and involve different stakes." In re Joint Eastern & Southern Dist. Asbestos Lit., 52 F.3d 1124, 1132 (2nd Cir. 1995)("Admissibility entails a *threshold* inquiry over whether a certain piece of evidence ought to be admitted at trial. * * * A sufficiency inquiry, which asks whether the collective weight of a litigant's evidence is adequate to present a jury question, lies further down the litigational road"). Although Daubert II's discussion of the "more likely than not" standard at first glance could be interpreted as a discussion of sufficiency, the emphasized portion of the quoted language makes it quite clear that the Ninth Circuit was analyzing the expert evidence against substantive law under the second prong, or "helpfulness" requirement, of Rule 702.

conclusions in any respect. Certain language in Daubert I can be read, superficially, to support plaintiffs' position. The Daubert I Court wrote:

> The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. Its overarching subject is the scientific validity--and thus the evidentiary relevance and reliability--of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.

Daubert I, 509 U.S. at 595 (emphasis added).

Since Daubert I was decided, however, courts and commentators have wrestled with the methodology/conclusion distinction, concluding that the distinction is of limited practical import. In Paoli II, for example, Judge Becker offered the following cogent analysis:

> Plaintiffs are correct, of course, that Daubert requires the judge's admissibility decision to focus not on the expert's conclusions but on his or her principles and methodology. * * * But we think that this distinction has only limited practical import. When a judge disagrees with the conclusions of an expert, it will generally be because he or she thinks that there is a mistake at some step in the investigative or reasoning process of that expert. If the judge thinks that the conclusions of some other expert are correct, it will likely be because the judge thinks that the methodology and reasoning process of the other expert are superior to those of the first expert. This is especially true given that the expert's view that a particular conclusion "fits" a particular case must itself constitute scientific knowledge--a challenge to "fit" is very close to a challenge to the expert's ultimate conclusion about the particular case, and yet it is part of the judge's admissibility calculus under Daubert.

35 F.3d at 746 (emphasis added). In a footnote, Judge Becker added that:

> The methodology/conclusion distinction remains of some import, however, to the extent that there will be cases in which a party argues that an expert's testimony is unreliable because the conclusions of an expert's study are different from those of other experts. In such cases, there is no basis for holding the expert's testimony inadmissible.

35 F.3d at 746 n.15 (citations omitted).

In Claar v. Burlington Northern R. Co., 29 F.3d 499 (9th Cir. 1994), the Ninth Circuit emphasized that a district court is "both authorized and obligated to scrutinize carefully the reasoning and methodology" underlying the expert's proffered testimony. 29 F.3d at 502 (emphasis added). According to the court in Claar:

> This requirement means that the court had to determine that [the experts] arrived at their conclusions using scientific methods and procedures, and that those conclusions were not mere subjective beliefs or unsupported speculation.

29 F.3d at 502 (emphasis added).[29]

More recently, in Lust v. Merrell Dow Pharmaceuticals, Inc., supra, the Ninth Circuit acknowledged that a district

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29 One of plaintiffs' counsel, Linda Eyerman, insists that Claar prohibits the court from scrutinizing the experts' conclusions in any respect, but Claar does not permit that reading. Claar itself makes clear that the court must scrutinize the validity of the reasoning leading to the experts' conclusions, if not the conclusions themselves. 29 F.3d at 502. Ambrosini v. Labarraque et al, No. 95-7270 (D.C. Cir. 1996), recently cited by Ms. Eyerman, is consistent with this court's analysis under relevant Ninth Circuit law.

court need not ignore an expert's anomalous conclusions in determining admissibility under Rule 702. In Lust, plaintiff's expert, Dr. Done, proposed to testify that ingestion of the drug Clomid causes a substantial increase in the probability of all birth defects on the ground that human epidemiological studies and animal studies show an association between the drug and a wide variety of problems. Uncontradicted testimony from defendant's expert, however, indicated that Done's chief premise -- that if there is evidence of a positive association between an agent and a wide variety of birth defects in human epidemiological and animal studies, then the agent substantially increases the probability of all types of birth defects -- was not espoused by a relevant minority of teratologists. Lust, 89 F.3d at 596.

The Ninth Circuit held that the district court properly excluded Done's testimony. Responding to Done's contention that the district court "violated Daubert's command that "'[t]he focus . . . must be solely on principles and methodology, not on the conclusions that they generate,'" the court stated:

> Done's conclusions did arouse the district court's suspicion, but that is to be expected. When a scientist claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist, the district court should be wary that the method has not been faithfully applied. It is the proponent of the expert who has the burden of proving admissibility. To enforce this burden, the district court can exclude the opinion if the expert fails to identify and defend the reasons that his conclusions are anomalous.

Lust, 89 F.3d at 598 (emphasis added; citation omitted).

In a recent law review article evaluating the admissibility of scientific evidence after Daubert, the author suggests the following approach to the methodology/conclusion debate:

> Rule 702 seeks to ensure that there is a valid scientific connection to the pertinent inquiry, and scientific validity for one purpose is not necessarily scientific validity for other purposes. * * * In a case where a plaintiff alleges personal injury from exposure to a substance, the issue at hand is not whether the agent can potentially cause that injury. Rather, the issue is whether the agent caused the particular plaintiff's injury.
>
> To return to the animal study hypothetical, the court should not simply ask whether the type of animal study relied on by the expert can be validly used to determine whether Bendectin is a teratogen, but should also ask whether scientists reasonably rely on that type of animal study to prove that Bendectin is a teratogen in humans. If the answer is yes, the court should ask whether the animal study provides sufficient information to allow a scientist to reasonably rely on it to prove that Bendectin caused a birth defect in a particular individual.
>
> Finally, assuming those questions are answered to the court's satisfaction, the court must determine whether the expert's principles and methodology are sound. In other words, has the expert properly extrapolated from the animal study at issue, or is her reasoning flawed? Some have argued that Daubert forbids courts to ask this question. * * *
>
> This reasoning is wrong-headed. When Daubert forbids courts to examine an expert's conclusions, it is obviously alluding to the Frye rule. Some courts used Frye to exclude novel expert testimony if it conflicted with the established view in the scientific community, regardless of the soundness of the expert's

> methodology and reasoning. That is no longer permissible after Daubert.
>
> But Daubert does demand that courts assess the scientific validity of the expert's testimony. Daubert demands that in reviewing the expert's principles and methodology, a court should determine whether "the principle supports what is purports to show." * * * Daubert therefore not only allows, but requires, courts to determine whether an expert's extrapolations from underlying studies or data are proper, or whether the expert has committed scientific or mathematical errors.

David E. Bernstein, The Admissibility of Scientific Evidence After Daubert v. Merrell Dow Pharmaceuticals, Inc., 15 CARDOZO L. REV. 2139, 2165-66 (1994)(emphasis added; footnotes omitted).

> In Paoli II, 35 F.3d at 745, Judge Becker noted that Daubert's requirement that the expert testify to scientific knowledge--conclusions supported by good grounds for each step in the analysis--means that any step that renders the analysis unreliable under the Daubert factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology. (Emphasis in original; footnote omitted.)

There 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 body of knowledge." 509 U.S. at 590 (citation omitted). This court need not and should not ignore any step in that 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," or, in the words of Dr. Stenzel-Poore, a "leap of faith." The Ninth Circuit requires no less. See Claar, 29 F.3d at 502; see also Lust, 89 F.3d at 598.

Accordingly, in resolving the pending issues before me, this court will examine the evidence to ensure, as Judge Becker noted in Paoli II, that every step in the expert's reasoning process, including the expert's formulation of conclusions, are grounded in good science.

IV. FINDINGS AND CONCLUSIONS

Physicians have used silicone[30] "Silanols" are silicone

30 The terminology surrounding silicone can be confusing.

molecules containing a silanol group. In silanols, a silicon atom in the chain bonds to an -OH, or hydroxyl, group instead of to a carbon atom and its attached hydrogens, collectively referred to as a -CH3, or methyl group. Hydroxyl groups, which are the defining group for alcohols, are generally more reactive than methyl groups. products in the human body for various purposes since the 1950s. Medical devices made from hard silicone include shunts, finger joints, hip joints, and heart valves. In addition, the United States and Japan experimented with injecting liquid silicone directly into the human body in the 1950s and 1960s. However, the FDA eventually classified silicone liquid directly injected as a drug and has approved it only for experimental investigations. The silicone gel breast implants involved in this litigation consist of 80 to 90 percent liquid silicone combined with 10 to 20 percent silicone gel, contained in a silicone rubber shell.

> Plaintiffs' theory of causation -- or, as they refer to it, bioplausibility -- begins with the premise that silicone from breast implants is released into a woman's body, either through implant rupture or through "gel bleed," the slow but continuous release of very small

"Silicon" is an element, chemically very similar to carbon. "Silica" is any combination of elemental silicon with elemental oxygen. Silicas occur in nature and either have a more ordered structure, referred to as "crystalline silica," or a less ordered structure, referred to as "amorphous silica." Both crystalline and amorphous silicas are solids, but they differ in structure much as a diamond (crystalline carbon) differs from graphite (amorphous carbon).

"Silicone," by contrast, is a human invention, the combination of elemental silicon with elemental carbon. Silicone molecules are chains of carbon and silicon atoms, with hydrogens attached to the sides, and can be made to almost any length. The chains can also be cross-linked to form sponge-like networks. Shorter chains are fluid, forming liquid silicone; longer, cross-linked chains form silicone gels. Different configurations can also form silicone rubber or a hard silicone "plastic."

droplets (“microdroplets”) of silicone gel through the silicone rubber implant cover. Once released into the body, plaintiffs assert, silicone migrates throughout the body, either by diffusing through cell membranes or by being carried by macrophages, the cells in a person’s body that devour and eliminate invading foreign bodies and wastes. In the process, the silicone degrades, or is chemically converted, into more reactive molecules such as silanols. The released silicone and the reactive products of silicone degradation purportedly elicit an autoimmune response from the woman’s immune system, essentially turning her immune system against her. The result, plaintiffs conclude, is general, systemic disease and particular signs and symptoms such as muscle and joint pain, headaches, rashes, and an inability to concentrate.

Plaintiffs’ theory of causation thus brings four general areas of science into play: epidemiology; rheumatology; immunology/ toxicology; and polymer chemistry. As has been described, the Rule 104 hearings and many of the parties’ arguments have been generally structured around these scientific fields. Thus, while I am mindful that the motions in limine actually address the exclusion of particular expert witnesses, my findings and conclusions will track the various disciplines at issue.

A. Atypical Connective Tissue Disease

Plaintiffs premise many of their claims on the existence of a variously-titled atypical connective tissue disease (ACTD).[31] This "disease" allegedly manifests itself through a constellation of various symptoms[32] and is allegedly caused by an autoimmune response to silicone from breast implants. Plaintiffs have offered Dr. Eric Gershwin and Dr. Kip Kemple as experts in rheumatology to testify that silicone exposure is the probable cause of plaintiffs' atypical constellation of symptoms.

By definition, ACTD is not one of the classical autoimmune diseases, such as lupus, scleroderma, or rheumatoid arthritis. In addition, plaintiffs' expert Dr. Goldsmith testified that ACTD does not exist even as a hypothesis yet. "Epidemiologically, the question that you have asked me twice is where we are with these atypical

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31 The parties have referred to the atypical, silicone-caused disease or disorder variously as "systemic silicone related disorder," "systemic silicone-related disease," "silicone-related disorder," "silicone-induced disorder," and "siliconosis." For purposes of this opinion, "ACTD" refers to any postulated, non-classical, autoimmune disease that exposure to silicone can allegedly cause.

32 According to plaintiffs, this constellation of symptoms allegedly always includes fatigue, myalgias (muscle pain), arthralgias (joint pain), and a sicca complex of dry eyes and dry mouth. Cognitive dysfunction, such as memory loss or concentration problems, is almost always present. Other symptoms and signs can, but do not always, include hair loss, skin changes, headaches, elevated levels of antinuclear antibodies (ANAs), elevated SED rates, chronic inflammation, and "other signs of immune system disturbance."

diseases. And I am telling you we are back at the beginning of formulating studiable hypotheses to test. We are really at the beginning of that." TRANS. OF PRETRIAL HEARINGS BEFORE THE HONORABLE ROBERT E. JONES (hereinafter PORTLAND TRANS.), Aug. 6, 1996, at 164:23 to 165:2. A silicone research group has proposed criteria for this alleged disease, but these criteria have not yet been tested, nor does the rheumatology community generally accept the existence of ACTD. Dr. Gershwin has acknowledged that he would not rely on these criteria as authoritative for his medical opinion. PORTLAND TRANS., Aug. 5, 1996, at 78:25 to 79:23. He also admitted that there is no specific diagnostic test for this alleged disorder. PORTLAND TRANS., Aug. 5, 1996, at 88:1-4, 15-19. Finally, women who allegedly have ACTD do not uniformly exhibit the same signs and symptoms, and there is no "signature" disorder to suggest either that the cause is silicone exposure or that the cause is the same for all women showing this constellation of symptoms.[33] Instead, the asserted constellation of symptoms comprising ACTD overlaps significantly with those comprising chronic fatigue syndrome and fibromyalgia.[34]

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33 A signature disease is one so associated with a particular cause that the presence of the disease presumes that cause. For example, malignant mesothelioma is a signature disease for asbestos causation. In re Joint Eastern & Southern Asbestos Litigation, 52 F.3d at 1130.

34 Fibromyalgia is a condition of pain in the connective

Because ACTD is at best an untested hypothesis, there is no scientific basis for any expert testimony as to its causes and presence in plaintiffs. Therefore, defendants' motions are GRANTED as regards any expert testimony relating to the existence and causation of any atypical, silicone-caused, autoimmune disorder.

With the possible exception of plaintiff LeaAnn Hall, moreover, plaintiffs have not been diagnosed as having classical autoimmune disorders. Therefore, the rest of this opinion will address expert testimony in regards to plaintiffs' individual signs and symptoms.

B. Epidemiology

Plaintiffs offer Dr. David Goldsmith as an expert to testify that there is epidemiological and other scientific data showing that women with silicone breast implants have significantly elevated probability of suffering from classical diseases when compared to women without breast implants.[35] In contrast, plaintiffs offer Dr. Shanna Swan,

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tissue and muscles near joints. The plaintiffs' proposed constellation of symptoms overlaps significantly even with the notoriously subjective "sick building syndrome."

35 Plaintiffs also offer Dr. Goldsmith to testify that there is epidemiological and other scientific data showing that women with silicone breast implants have a significantly elevated probability of suffering from ACTD than women without such implants. However, as was discussed above, no expert testimony regarding ACTD will be allowed because, given the pre-hypothetical state of ACTD, there is no scientific basis for such testimony. Therefore, this proffered testimony is excluded

through transcripts of her previous testimony in other cases, to testify that no valid epidemiological studies regarding the relationship of silicone breast implants and disease have been completed as of August 1996.

Epidemiology is the medical science devoted to determining the causes of disease in human beings. Epidemiologists compare control groups of unexposed individuals to groups of individuals exposed to a hypothetical cause of the disease being studied to determine whether exposed individuals have a greater risk of manifesting that disease. In epidemiological terms, any difference in risk of getting the disease between the two groups is the exposed individuals' relative risk. The existence or nonexistence of relevant epidemiology can be a significant factor in proving general causation in toxic tort cases. Daubert II, 43 F.3d at 1320-21; Brock v. Merrill-Dow Pharmaceuticals, Inc., 874 F.2d 303, 311-13 (5th Cir. 1989).

To support admissible expert opinions, epidemiological evidence must fit the legal as well as the substantive issues of the case. Because this is a diversity action, Oregon substantive standards of law must apply. Erie Railroad Co. v. Tompkins, 58 S. Ct. 817 (1938).[36] As

on that basis.

36 As is discussed elsewhere, however, the federal standards of evidence under Daubert is applicable to this litigation

discussed above, under Oregon law, a plaintiff seeking to prove causation must "'introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a substantial factor in the result.'" Griffin v. K.E. McKay's Mkt., 125 Or.App. at 451-52 (quoting Eitel v. Times, Inc., 221 Or. 585, 594, 352 P.2d 485 (1960)). This burden requires plaintiffs to demonstrate that exposure to breast implants more than doubled the risk of their alleged injuries. Daubert II, 43 F.3d at 1320.

In epidemiological terms, Oregon's standard of proof means that plaintiffs must be able to show a relative risk of greater than 2.0:

> The threshold for concluding that an agent was more likely the cause of a disease than not is relative risk greater than 2.0. Recall that a relative risk of 1.0 means that that agent has no effect on the incidence of disease. When the relative risk reaches 2.0, the agent is responsible for an equal number of cases of disease as all other background causes. Thus, a relative risk of 2.0 implies a 50% likelihood that an exposed individual's disease was caused by the agent.

Bailey, et al., Reference Guide on Epidemiology, Reference Manual on Scientific Evidence at 168. The Ninth Circuit has reached a similar conclusion under California's standard of proof, which is very similar to Oregon's, holding that "[f]or an epidemiological

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because screening of evidence under FRE 104 is a procedural, not a substantive, matter. In contrast, the standard of proof in a toxic tort case is a substantive issue and Oregon law applies.

study to show causation under a preponderance standard, 'the relative risk of [the condition at issue] arising from the epidemiological data . . . will, at minimum, have to exceed "2".'" Daubert II, 43 F.3d at 1321 (quoting DeLuca v. Merrell Dow Pharmaceuticals, 911 F.2d 941, 958 (3d Cir. 1990)). Although, as discussed above, epidemiological studies showing a relative risk of less than 2.0 might be relevant under some circumstances, here, as in Daubert II, "plaintiffs' experts did not seek to differentiate these plaintiffs from the subjects of the statistical studies. The studies must therefore stand or fall on their own." Id. at 1321 n.16.

Plaintiffs' experts base their proffered expert opinions on the sixteen epidemiological studies[37] assessing the relationship

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37 These studies are:

Dugowson, C.R., et al. Silicone Breast Implants and Risk for Rheumatoid Arthritis. Arthritis Rheum. 35[9] (Supp.) Abstract 192:566 (Sept. 1992).

Englert, H.J., et al. Scleroderma and Augmentation Mammoplasty -- A Causal Relationship? Aust. NZ J. Med. 24:74-79 (1994).

Gabriel, S.E., et al. Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation. MPJM 330[24]:1697-1702 (June 1994) ("Mayo Clinic Study").

Giltay, Eric J., et al. Silicone Breast Prostheses and Rheumatic Symptoms: A Retrospective Follow-Up Study. Annals of Rheumatic Diseases 53:194-196 (1994).

Goldman, J.A., et al. Breast Implants, Rheumatoid Arthritis, and Connective Tissue Diseases in a

of silicone breast implants to classical connective tissue disease. In addition, plaintiffs have called this court's attention to the 1996 Liang-Schottenfeld abstract recently presented at a meeting of the American College of Rheumatology that reports a relative risk of 2.27 for Undifferentiated

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Clinical Practice. J. Clin. Epidemiol. 48[4]:571-582 (1995).

Hennekens, Charles H., et al. Self-Reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals. JAMA 273:8 616-621 (February 28, 1996).

Hochberg, B., et al. Association of Augmentation on Mammoplasty with Systemic Sclerosis Preliminary Results from a Case-Control Study. Amer. College of Rheum., Abstract 1249 (October 26, 1994).

McLaughlin, et al. Correspondence Re: Breast Implants, Cancer, and Systemic Sclerosis. J. Of the Nat. Cancer Inst. 87[18] (Sept. 20, 1995).

Sanches-Guerrero, J., et al. Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms. NEJM 332[25]:1666-1670 (June 1995) ("Harvard Nurses Study").

Schollenfield, D., et al. The Design of a Population-Based Case-Control Study of Systemic Sclerosis (Scleroderma). Commentary on the University of Michigan Study. J. Clin. Epidemiol. 48[4]:583-596 (1995).

Schusterman, Mark A., et al. Incidence of Autoimmune Disease in Patients After Breast Reconstruction with Silicone Gel Implants Versus Autogenous Tissue: A Preliminary Report. Ann. Plastic Surg. 31[1]:1-6 (1993).

Strom, P.L., et al. Breast Silicone Implants and Risk of Systemic Lupus Erythematosus. J. Clin. Epidemiol. 47[10]:1211-1214 (1994).

Connective Tissue Diseases (UCTD).[38]

Dr. Goldsmith testified in the proceedings before this court that he was not willing to testify, based on the 16 then-available studies, that silicone more likely than not could cause disease in women. That testimony was as follows:

> DR. GREENLICK: You were asked a question if you had an opinion on causality based on whatever other evidence was left, case studies, other animal evidence. I think there is a sense that when you talked about there was a suggestion from some of the things that would mean you had a very low certainty of causality and that causality could go from saying, "We don't know if there's any link at all," all the way to saying, "We are really quite certain, short of randomly implanting women, we are very certain."
>
> Given the fact that there is no epidemiological data on this, where would you say your sense of certainty of your causality is? How close to zero as

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Weisman, Michael H., et al. Connective Tissue Disease Following Breast Augmentation: A Preliminary Test of the Human Adjuvant Disease Hypothesis. Plastic & Reconstructive Surgery82[4]:626-630 (1988).

Wells, Karen E., et al. The Health Status of Women Following Cosmetic Surgery. Plastic Reconstr. Surgery 93[5]: 907-912 (1994).

Willliams, James, et al. Silicone Based Implants in Patients with Undifferentiated Connective Tissue Disease. Amer. College of Rheum., Abstract 1562.

Wolfe, P. Silicone Breast Implants and the Risk of Fibromyalgia and Rheumatoid Arthritis. Arthritis Ctr. & Univ. Of Kansas, Wichita, KS USA 87214.

38 The court notes that Dr. Goldsmith has admitted that UCTD is not the same disease as the ACTD plaintiffs claim they have. Trans. Of Hearing before the Honorable Jack B. Weinstein, Nyitray v. Baxter Healthcare Corp., No. 93-159 (E.D.N.Y.) (hereinafter New York Trans.), at 130:16-20, 133:19-24 (Oct. 7, 1996).

opposed to 100 percent are you? Are you in certainty with your opinion that there is a causal relationship with breast implants and atypical connective tissue disease?

DR. GOLDSMITH: Let me also make sure that I give you an answer that I think is reflective of the -- of the question in front of us. I don't believe it should go from zero to -- to fully sure. I think it's also possible that breast implants could, in fact, be negatively related to those atypical syndromes as well.

DR. GREENLICK: Right. I was just starting from a zero, yes, could you have gone all the way from they are highly protective through no relationship, all the way to certain causality.

But let's just -- I assume you don't -- you are not suggesting that the current data would tell you they are protective against atypical disease. So let's start from zero at "I have no certainty whatever there's a relationship," all the way to "I am absolutely certain there's a relationship from the existing data given no epidemiological data." I was wondering where you would --

DR. GOLDSMITH: <u>At the moment, I must suggest to you that the evidence looks to me as if it's just that, that it's a possibility, and I would have to characterize it as less than 50 percent.</u> That would be where I am at the moment.

But where the new evidence is going to show that there is or is not an association, I think we have to wait for the science to tell us. We have to wait for the epidemiology.

PORTLAND TRANS., Aug. 6, 1996, at 241:14 to 243:4 (emphasis added).

With the release of the Liang-Schottenfeld abstract, Dr. Goldsmith now indicates a willingness to testify that such causation is "more likely than not."[39] This court cannot accept

39 Indeed, he did so testify in the proceedings before Judge Weinstein in the District Court of New York, on the basis of the

his proffered change in testimony because it finds the methodology supporting this changed testimony unreliable under Daubert I and Daubert II. First, none of the 16 epidemiological studies found that women with silicone breast implants faced a relative risk of classical diseases or disease signs and symptoms of anywhere near 2.0. Indeed, only one study -- the Hennekens study -- found any statistical relationship between the presence of silicone breast implants and disease, and there the relative risk was only 1.24. Therefore, these studies cannot support expert testimony that silicone "more likely than not" causes disease or signs and symptoms of disease in women.

Second, the Liang-Schottenfeld abstract cannot in itself support Dr. Goldsmith's change in testimony. The abstract is not yet published, nor is a full write-up of the study, including the supporting data, yet available. Indeed, Dr. Goldsmith admitted in his New York testimony that his only knowledge of the details of the study came from a telephone inquiry. NEW YORK TRANS., at 71:17-24. According to the abstract, moreover, the study included only three women with breast implants, calling its epidemiological significance severely into question. In addition, the abstract explicitly concludes that

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new Liang-Schottenfeld abstract. NEW YORK TRANS., at 75:8-22, 122:22 to 123:3. I find this change in so-called "scientific opinion" not only suspect, but shocking, with no scientific basis to support it. This is exactly the type of "junk science" that the Supreme Court in Daubert I commanded courts to exclude. However, this is not to say that at some future date new studies may justify what is now unjustifiable.

"silicone breast implants were not significantly associated with UCTD," suggesting that silicone gel breast implants are not associated with disease. In contrast, the abstract concludes overall that, "[a]mong all types of implanted devices, including breast implants, both those containing silicone * * * and those that did not contain silicone * * * were significantly associated with UCTD." This apparent internal contradiction within the abstract's conclusions calls the value of this study further into question. In light of these shortcomings[40] and in the face of the other 16 studies, which Dr. Goldsmith has already admitted do not support expert testimony that silicone "more likely than not" causes disease in women, this court GRANTS defendant's motion to exclude Dr. Goldsmith's epidemiological testimony.[41]

As for defendants' motion to exclude Dr. Swan's proffered testimony, the motion must be GRANTED because Dr. Swan's testimony is unreliable and no longer "fits" plaintiffs' theory of the case. I first note that several courts have rejected Dr.

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40 I concur in Judge Weinstein's assessment that the Liang-Schottenfeld abstract is not "in the form that scientists would want" and that Dr. Goldsmith "can't get information like this over the phone that is critical." Like Judge Weinstein, moreover, "I'm very unimpressed by this." NEW YORK TRANS., at 80:2-6.

41 During the course of these proceedings, plaintiffs accused defendants of improperly concealing the Liang-Schottenfeld abstract, to the plaintiffs' prejudice. I find these accusations to be unfounded.

Swan's testimony and her "reanalysis" approach as unreliable.[42] Dr. Swan's reanalysis of the silicone epidemiology has never been subjected to peer review. MERLIN HEARING TRANS., at 73-76. Moreover, her theory has not been espoused by any other scientist whose work has been subjected to the peer review process. MERLIN HEARING TRANS., at 73-74. Peer review and publication weigh heavily in the calculus of the reliability of expert testimony because such peer review "increases the likelihood that substantive flaws in methodology will be detected." Daubert I, 509 U.S. at 594. Thus, the lack of peer review for Dr. Swan's theories weighs heavily against the admissibility of Dr. Swan's testimony.

In addition, Dr. Swan's testimony involves only her opinions and criticisms of others' work; as such, it is not based on any technique that can be scientifically tested.

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42 See Lynch v. Merrell-National Laboratories, 646 F. Supp. 856 (D. Mass. 1986) (noting that "this Court still could not accept result-based reanalysis of epidemiological studies and criticisms of others' methodology, such as that performed here by Dr. Swan, as reliable data upon which to base an opinion on causation"); Lynch v. Merrell-National Laboratories, 830 F.2d 1190, 1195 (1st Cir. 1987) ("Swan's study has never been refereed or published in a scientific journal or elsewhere * * * . On the basis of what we have, it could not form the foundation for an expert opinion challenging the scientific consensus * * * ."); Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159, 1162 (D.C. Cir. 1990) ("the plaintiff's epidemiology expert, Dr. Shanna Swan, tried to refute the validity of the published epidemiological data through her own unpublished reanalysis"); Lee v. Richardson-Merrell, Inc., 772 F. Supp. 1027, 1030 (W.D. Tenn. 1991); Turpin v. Merrell Dow Pharmaceuticals, Inc., 736 F. Supp. 737, 743 (E.D. Ky. 1990).

Moreover, her criticisms of the existing epidemiology for silicone gel breast implants have not been generally accepted. In fact, they have not been accepted at all. MERLIN HEARING TRANS., at 92-93. In contrast, Dr. Swan admits that no studies have established a causal link of any scientific significance between silicone breast implants and disease, MERLIN HEARING TRANS., at 82, and this is the recognized consensus of the relevant scientific community. As the Supreme Court stated, "widespread acceptance can be an important factor in ruling particular evidence admissible, and a known technique that has been able to attract only minimal support within the community may properly be viewed with skepticism." Daubert I, 509 U.S. at 594. Many courts have recognized that an unexplained conflict with the generally accepted methodology or theories in a given scientific field can be a basis for excluding proffered expert testimony. See Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349, 1360 (6th Cir.), cert. denied, 113 S. Ct. 84 (1992) (finding no scientific basis for testimony of a causation expert who did "not testify on the basis of the collective view of his scientific discipline, nor [did] he take issue with his peers and explain the grounds for his difference"); O'Connor v. Commonwealth Edison Co., 807 F. Supp. 1376, 1398 (D. Ill. 1992), aff'd 13 F.3d 1090 (7th Cir.), cert. denied 114 S. Ct. 2711 (1994) (holding that "an expert opinion that *actually contradicts directly* the scientific consensus in inadmissible");

Conde v. Velsicol Chem. Corp., 804 F. Supp. 972, 1024 (S.D. Ohio 1992), aff'd 24 F.3d 809 (holding that "when an expert expresses an opinion which is not generally accepted within the medical and scientific communities, he has an obligation to provide a reasoned explanation of why his methodology and opinions differ"). In addition to not being peer-reviewed and to being untestable, Dr. Swan's proffered testimony inexplicably conflicts with the general consensus of the epidemiological community. Thus, it is unreliable and hence inadmissible.

In addition, Dr. Swan's testimony has no "fit." As discussed above, even if the proponents of expert testimony establish that that testimony is reliable scientific knowledge, the court must still exclude the evidence if it does not fit the issues to be decided in the case. Daubert I, 509 U.S. at 591. In the Ninth Circuit, testimony only "fits" a case if it logically advances a material aspect of the proponent party's case. Daubert II, 43 F.3d at 1315. Here, Dr. Swan seeks to testify that current epidemiology regarding the relationship of silicone breast implants and classical disease is invalid. However, this court has already determined that the proffered testimony based on that epidemiology is inadmissible, and it will determine, see discussion below, that plaintiffs cannot base their entire case on differential diagnosis. In addition, to the extent that plaintiffs intended to use Dr. Swan's testimony to support their argument that silicone breast

implants can cause ACTD, I have already ruled that no testimony regarding ACTD will be permitted. Therefore, Dr. Swan's testimony is now a stepping stone that leads nowhere; it no longer "fits" plaintiffs' case.

There is no doubt but that Dr. Swan has impressive credentials, as Justice Blackmun himself recognized in Daubert I. 509 U.S. at 583 n.10 (noting that Dr. Swan has "a master's degree in biostatics from Columbia University and a doctorate in statistics from the University of California at Berkeley, is chief of the section of the California Department of Health and Sciences that determines causes of birth defects, and has served as a consultant to the World Health Organization, the Food and Drug Administration, and the National Institutes of Health.") However, as Judge Weinstein noted in the Agent Orange litigation, the jury should "not be permitted to be misled by the glitter of an expert's accomplishments outside the courtroom" if the expert opinion is based on "untrustworthy" data or is otherwise not reliable.[43] In re "Agent Orange" Product

43 Judge Weinstein was relying on FRE 403 as he made this assessment. In re "Agent Orange Products Liability Litigation, 611 F. Supp. at 1245. Nevertheless, his comments are appplicable here because Rule 403 remains in play during a Daubert hearing. Daubert I, 509 U.S. at 595. See also United States v. Powers, 59 F.3d 1460, 1471 (4th Cir. 1995) ("In determining whether the evidence will be helpful to the trier of fact, the Supreme Court warned that throughout an admissibility determination, a judge must be mindful of other evidentiary rules, such as FRE 403, which permits the exclusion of relevant evidence 'if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or

Liability Litigation, MDL No. 381, 611 F. Supp. 1223, 1245 (E.D.N.Y. 1985) (citations omitted). As in that case, "'the speculation and unfounded assumptions underlying [the] testimony [of Dr. Swan] decrease its probative value, perhaps to the level of the gossamer.'" Id. at 1256 (quoting American Bearing Co. v. Litton Indus., Inc., 729 F.2d 943, 950 n.14 (3d Cir. 1984)). In this litigation, Dr. Swan's well-traveled opinions are no more than educated guesses dressed up in evening clothes. Therefore, for all of the above reasons, I GRANT defendants' motions to exclude Dr. Swan's testimony.

C. Immunology and Toxicology

Plaintiffs have offered Dr. Eric Gershwin as an expert in immunology to testify that silicone is capable of causing plaintiffs' constellation of symptoms because (1) silicone in contact with human tissue results in chronic inflammation through immune activation and cellular reactions; (2) silicone is an immune adjuvant and thus can produce enhanced immune

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misleading the jury." (quoting FRE 403 and citing Daubert, 509 U.S. at 595)); Robinson v. Missouri Pacific Railroad Co., 16 F. 3d 1083, 1088 (10th Cir. 1994) (observing that, under Rule 403, "trial judges should carefully and meticulously examine proposed animation evidence for proper foundation, relevancy, and the potential for undue prejudice."). Therefore, the relevance and probative value of Dr. Swan's testimony, as well as its scientific reliability, is an issue currently before this court. Dr. Swan's testimony would be excludable pursuant to FRE 401, 402, and 403 because it is now, in light of my other rulings, irrelevant and potentially prejudicial. However, because I find Dr. Swan's testimony to be scientifically unreliable and to lack "fit," I do not base its exclusion on these grounds.

responses when in the presence of a triggering condition and exacerbate existing immune-mediated conditions; and (3) the surface of silicone changes or degrades in vivo into silanol groups and/or silica. He relies on the epidemiological studies discussed above, his own clinical experience, biomarker, immune activation, and toxicological studies,[44] and the work of the

44 These studies include:

Abeles, M. An Evaluation of Silicone Breast Implants for Silicone Associated Disease. ACR 38[9], Supp. (Sept. 1995).

Baker, M. Treatment of Silicone Implant Associated Symptoms. Abstract presented at the American College of Rheumatology Annual Meeting (1996).

Baldwin, C. Silicone-Induced Human Adjuvant Disease. Annals of Plastic Surg. 10[4]:172-175 (April 1983).

Bar-Meir, E., et al. Multiple Antibodies in Patients with Silicone Breast Implants. J. Of Autoimmunity 8:267-277 (1995).

Bernstein, M. A Multiple Sclerosis Like Syndrome Associated with Silicone Breast Implants. Abstract presented at the American College of Rheumatology Annual Meeting (1996).

Borenstein, D. Siliconosis: A Spectrum of Illness. Seminars in Arthritis and Rheumatism 24:1, Supp. 1 (Aug. 1994).

Bridges, A.J., et al. Autoantibodies in Patients with Silicone Implants. Potter, M., and Rose, N., Current Topics in Microbiology and Immunology -- Immunology of Silicones 210:277-290 (1996).

Bridges, A.J., et al. Clinical and Immunological Evaluation of Women with Silicone Breast Implants and Symptoms of Rheumatic Disease. Supp. Arthritis and Rheumatism 35(90):S46:184 (Sept. 1992).

Harvard NMR Center on the degradation of silicone as the bases of his proffered opinion.

Plaintiffs also offer Dr. Kip Kemple to testify that silicone can produce an immunological response in women. Dr. Kemple relies on immunological studies showing that

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Bridges, A. A Clinical and Immunological Evaluation of Women with Silicone Breast Implants and Symptoms of Rheumatic Disease. Annals of Internal Med.118[12] (June 15, 1993).

Brozena, S. Human Adjuvant Disease Following Augmentation Mammoplasty. Arch Dermatology 124:1383-1386 (Sept. 1988).

Claman, H.N., Robertson, A.D., Antinuclear Antibodies in Apparently Healthy Women with Breast Implants. Potter, M., and Rose, N., eds., Current Topics in Microbiology and Immunology -- Immunology of Silicones 210:265-268 (1996).

Cuellar, M. Clinical Outcome of Silicone Breast Implant Women Following Implant Removal. Amer. Coll. Rheumatology 38[9], Supp. (Sept. 1995).

Davis, J. Clinical Characteristics of 343 Patients with Breast Implants. ACR 38[9], Supp. (Sept. 1995).

Gutierrez, F. Progressive Systemic Sclerosis Complicated by Severe Hypertension: Reversal After Silicone Implant Removal. Amer. J. Med. 89:390-392 (Sept. 1990).

Kaiser, W. Human Adjuvant Disease: Remission of Silicone Induced Autoimmune Disease After Explantation of Breast Augmentation. Annals of Rheumatic Diseases 49:937-938 (Nov. 1990).

Kemple, K., and Pestronk, A. Antiglycolipid Antibodies in Symptomatic Women with Silicone Breast Implants. Abstract presented at the American College of Rheumatology Annual Meeting (Sept. 1995).

autoantibodies are elevated in women with breast implants[45] and his own study of antiganglioside antibodies in women with breast implants.

The court submitted immunological/toxicological issues to

Lugowski, S., et al. Silicon Levels in Blood, Breast Milk, and Breast Capsules of Patients with Silicone Breast Implants and Controls. Fifth World Biomaterials Congress, Toronto, Canada (1996)

Mease, P. Clinical Symptoms/Signs and Laboratory Features in Symptomatic Patients with Silicone Breast Implants. ACR 38[9], Supp. (Sept. 1995).

Peters, W., et al. Silicon and Silicone Levels in Patients with Silicone Implants. Potter, M., and Rose, N., Current Topics in Microbiology and Immunology -- Immunology of Silicone 210:39-48 (1996).

Peters, W., et al. Do Patients with Silicone Gel Breast Implants Have Elevated Levels of Blood Silicon Compared with Control Patients? Annals of Plastic Surg. 34[4]:343-347 (April 1995).

Romano, T.J. Clinical Characteristics of Silicone Breast Implant Patients. Amer. J. Of Pain Management 6[1]: 13-16 (Jan. 1996).

Rowle, M.J., et al. Antibodies to Collagen: Comparison Epitope Mapping in Women with Silicone Breast Implants, Systemic Lupus, Erythematosus and Rheumatoid Arthritis. J. Of Autoimmunity 7:775-789 (1994).

Sahn, E. Scleroderma Following Augmentation Mammoplasty. Arch. Dermatology 126:1988-1202 (Sept. 1990).

Sanchez-Roman, J., et al. Multiple Clinical and Biological Autoimmune Manifestations in 50 Workers After Occupational Exposure to Silica. Annals of the Rheumatic Diseases 52:534-538 (1993).

its expert, Dr. Mary Stenzel-Poore,[46] who specifically looked at the adjuvant potential of silicone gel implants, the potential for immune stimulation of T cells by silicone gel implants, altered natural killer cell activity, and immune system cancer formation in rodents. She opined that the studies relied upon

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Seleznick, M. Is Silicone Associated with Connective Tissue Disease? 78[2]:85-87 (Feb. 1991).

Shons, A. Silicone Breast Implants and Immune Disease. Annals of Plastic Surg. 28[5]:491-501 (May 1992).

Silver, R. Demonstration of Silicon in Sites of Connective-Tissue Disease in Patients with Silicone-Gel Breast Implants. Arch. Dermatology 129[1]:63-68 (Jan. 1993).

Solomon, G. Clinical and Serologic Features of 639 Symptomatic Women with Silicone Gel Implants: Evidence for a Novel Disease Siliconosis. Amer. Coll. Rhematology (1994).

Solomon, G. A Clinical and Laboratory Profile of Symptomatic Women with Silicone Breast Implants. Seminars in Arthritis and Rheumatism 24[1], Supp. 1 (Aug. 1994).

Solomon, G. Clinical Features of a Subset of Symptomatic Women with Silicone Breast Implants and Extreme Elevations of Serum IGM. Abstract presented at the Amer. Coll. Rheum. Annual Meeting (1996).

Spiera, H., and Kerr, L.D. Scleroderma Following Silicone Implantation: A Cumulative Experience of 12 Cases. Rheumatology 20:958-961 (1993).

Spiera, H. Immunological Reactions to Silicone Implants. Clin. Immunology 1[6] (1994).

Steenland, K., and Goldsmith, D., Silica Exposure and Autoimmune Diseases. Amer. J. Of Indus. Med. 28:603-608

by plaintiffs' experts justified the following conclusions regarding silicone gel adjuvant potential:

1a. Silicone gel *emulsified with antigen* may act as an adjuvant in humoral and cell-mediated immune responses in rodents.

1b. Silicone oils that are both linear and low molecular weight, *emulsified with antigen* do not act

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(1995).

Sun, L., et al. Silicone in the Blood and Capsule of Women with Breast Implants. Fifth World Biomaterials Congress, Toronto, Canada (1996).

Teuber, S.S., et al. Serum Silicon Levels Are Elevated in Women with Silicone Gel Implants. Potter, M., and Rose, N., eds., Immunology of Silicones 210:59-65 (1996).

Teuber, S.S., et al. Anti-Collagen Autoantibodies Are Found in Women with Silicone Breast Implants. J. Of Autoimmunity 6[3]:367-377 (June 1993).

Teuber, S. Remission of Sarcoidosis Following Removal of Silicone Gel Breast Implants. Intl. Arch. Allergy Immunology 105:404-407 (1994).

Uretsky, B. Augmentation Mammoplasty Associated with Severe Systemic Illness. Annals of Plastic Surg. 3[3]: 445-447 (Nov. 1977).

Vasey, F. Observations on Women with Breast Implants. J. Fla. Med. Assn. 82:5 (May 1995).

Vasey, F. Clinical Findings in Symptomatic Women with Silicone Breast Implants. Seminars in Arthritis and Rheumatism 24[1], Supp. 1 (Aug. 1994).

Vasey F. Prospective Clinical Status Comparison Between Women Retaining Gel Breast Implants vs. Women Removing Breast Implants. Abstract presented at the American College of Rheumatology Annual Meeting (1996).

as adjuvants in rodents.

1c. Silicone oils that are low molecular weight and cyclic (D4) *emulsified with antigen* may act as adjuvants.

APPENDIX D, at 2. However, "[d]irect attempts to demonstrate that immunization with these agents emulsified with 'auto-antigens' or given in the absence of antigens failed to show evidence of autoimmune disease despite obvious disease induction by Freund's adjuvant," except in a genetic strain of rat developed to have a high susceptibility of developing arthritis. Id. Thus, in rodents only, "enhanced immune responses are not found if the antigen is not emulsified with the silicone agents * * * ." Id. at 2-3 (citations omitted).

Dr. Stenzel-Poore further stated that "[f]orming the conclusion that elicitation of autoimmune and/or inflammatory disease occurs in women with SBI based on the evidence that silicone gel acts as an adjuvant *when emulsified with antigen* is **unsupported by the data** since peer-reviewed studies failed to show evidence of any autoimmune-mediated disease." APPENDIX D, at 3. Although "[t]he scientific methodology used in the aforementioned studies is generally sound,"

Young, V.L., et al. HLA Typing in Women with Breast Implants. PLASTIC & RECONSTR. SURG. 96[7]:1497-1520 (Dec. 1995).

45 The studies Dr. Kemple relies on are essentially the same as those Dr. Gershwin relies upon.

46 See generally Dr. Stenzel-Poore's Report at APPENDIX D.

> Dr. Gershwin's opinion regarding the adjuvant properties of silicone gel requires a substantial leap of faith since it is undetermined from these studies whether silicone gel breast implants would lead to adjuvant actions, much less autoimmune responses or systemic inflammation; indeed, studies designed to test this hypothesis argue against such an outcome. Thus, the position of Dr. Gershwin is not well-supported by the data available in the published scientific literature nor is it derived from valid conclusions of the studies cited above.

Id. (emphasis added).

With regard to T-cell stimulation, Dr. Stenzel-Poore opined that "[t]he view that SBIs stimulate antigen-specific T cell mediated responses in vivo is not well substantiated by the experimental studies reported in the literature." APPENDIX D, at 4. Moreover, although "[s]everal studies have been performed attempting to establish a link between silicone breast implantation in women and silicone-specific T-cell responses," "these studies have a number of methodological shortcomings and thus should not form the basis of an opinion." Id. at 5. As a result,

> those opinions of Dr. Gershwin regarding the role of silicone gel breast implants in stimulating specific T cell immunity and thereby providing a plausible mechanism of autoimmune induction are not upheld by the literature discussed above. The position of Dr. Gershwin is simply not well-supported by studies available in the published scientific literature nor is it derived from appropriate conclusions regarding the studies cited above.

Id. at 8.

Dr. Stenzel-Poore also examined the literature regarding changes in natural killer cell function. She noted that "[c]hanges in natural killer (NK) cell function have been reported to be associated with silicone gel exposure in rodents and humans." APPENDIX D, at 9. Such an association could be significant because "changes in NK cells have also been associated with increased susceptibility to pathogens and tumor formation." Id. However, "[g]iven the concerns raised by the degree of irreproducibility and fluctuations in time and dose-dependency [in the silicone gel/NK cell studies], conclusions made regarding the suppressive effect of silicone gel on NK function based on these studies are premature." Id. Moreover, "although the data indicate that 50% of symptomatic women with implants had lower NK activity prior to removal of the implant, it is misleading since the degree of variation is not shown in the implanted women, or in women without implants. It is invalid to conclude that silicone-gel breast implants in women lead to a depressed NK cell activity that is reversible with explanation." Id. at 10.

Finally, in evaluating the studies evaluating the development of immune system cancer in response to silicone, Dr. Stenzel-Poore stated that "Dr. Gershwin's opinions regarding the development of immune system cancers in women with silicone breast implants is unwarranted" from the current studies, which are all animal studies. APPENDIX D, at 11. "There is no

conclusive evidence to date that this model of tumor formation in mice has any human correlate." Id.

I agree with and accept Dr. Stenzel-Poore's assessments of Dr. Gershwin's scientific methodology in light of legal standards for Daubert hearings. As a preliminary matter, I note that most if not all of the studies that Dr. Gershwin and Dr. Kemple rely upon are animal studies (generally involving rodents), case reports or collections of case reports, and/or studies involving crystalline silica. Extrapolations of animal studies to human beings are generally not considered reliable in the absence of a scientific explanation of why such extrapolation is warranted. See Viterbo v. Dow Chemical Co., 826 F.2d 420 (5th Cir. 1987) (excluding the evidence where there was only a single animal study of picloram and it showed a link to a disease completely different than plaintiff's diseases); Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 830 (D.C. Cir. 1988) (excluding animal studies of Bendectin because of the overwhelming body of contrary epidemiological evidence and the admissions of the expert that animal studies merely raise a suspicion of causation in humans); Lynch v. Merrell-National Laboratories, 830 F.2d at 1194 (excluding animal studies of Bendectin where they stood in the face of significant contrary epidemiological data); Turpin v. Merrell Dow Pharmaceuticals., Inc., 959 F.2d at 1360 (excluding testimony where the record failed to make clear how the animal studies were sufficient to

show that Bendectin causes birth defects more probably than not). Plaintiffs offer no explanation of why extrapolations from the rodent studies their experts rely upon to humans are warranted here.

Similarly, case reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls. Casey v. Ohio Medical Products, 877 F. Supp. 1380 (N.D. Cal. 1995); Muzzey v. Kerr-McGee Chemical Corp., 921 F. Supp 511, 519-20 (N.D. Ill. 1996); In re Three Mile Island Litigation Cases Consolidate II, 911 F. Supp. 775, 795-96 (M.D. Penn. 1996); Grimes v. Hoffman-LaRoche, Inc., 907 F. Supp. 33, 35 n.2 (D.N.H. 1995). Therefore, these cannot be the basis of an opinion based on scientific knowledge under Daubert.

Third, as will be discussed below, studies based on crystalline silica cannot support the testimony of plaintiffs' experts because plaintiffs make no showing that silicone breast implants are associated with the presence of crystalline silica in women. In other words, the purported disease-causing agent in the silica studies has not been show to be scientifically relevant regarding the purported disease-causing agent -- namely, silicone gel -- in these cases.

Finally, Daubert's establishment of the court as gatekeeper requires that proffered scientific expert opinions that make too great a leap of faith from the scientific knowledge currently

available be excluded. As discussed above, an evaluation of whether scientific methodology is valid for Daubert purposes should include an examination of how the proffered conclusions relate to the bases upon which the expert relies. The court's neutral technical advisor has advised that Dr. Gershwin -- and, by implication, Dr. Kemple, who relies on most if not all of the same studies as Dr. Gershwin -- has made too great a leap from the underlying data to his conclusions. In other words, those conclusions are themselves not the result of the faithful application of valid scientific methodology. Therefore, defendants' motions to exclude Dr. Gershwin's and Dr. Kemple's testimony on these issues is GRANTED.

D. Chemistry

Plaintiffs offer Dr. Christopher Batich as an expert in chemistry to testify that: (1) silicone migrates out of breast implant capsules; (2) there is an increase in surface area of silicone from gel breast implants to which the body reacts over time; (3) silicone changes in the body and forms bioreactive silanol groups on its surface; (4) silicone degrades into silica in the body; and (5) there is similar surface chemistry in all siloxics (silicones, silicates, and silicas) that make the siloxics reactive in humans. In addition, plaintiffs offer Dr. Harold Alexander, a biomaterials engineer, to testify that: (1) silicone microdroplets and/or particles are released from breast implants through gel bleed or rupture and have a high

potential to cause inflammatory reactions in body tissues, and (2) the small size of silicone microdroplets and/or particles allows them to migrate through the body via microphages and other migrating cells, and their low molecular weight allows them to diffuse through tissue.

The court's technical advisor for polymer chemistry, Dr. Ronald McClard, carefully reviewed the question of whether the scientific evidence supports Dr. Batich's and Dr. Alexander's proffered testimony that silicone degrades to silica in vivo.[47] In reviewing the plaintiffs' main scientific support for silica-induced biological reactions, a paper published by B. Razzaboni and P. Bolsaitis in Environmental Health Perspectives,[48] Dr. McClard stated that:

> The Razzaboni article * * * clearly attempts to offer a biochemical explanation for the silica-caused hemolytic process. This article seems scientifically sound. If silicones are converted to silica then this article seems relevant to the issue at hand. I am unaware that any of the papers that I reviewed clearly demonstrated the conversion of silicone to silica (most likely amorphous forms thereof), though the process seems possible given the known chemistry of silicon. The link between silicones and the Razzaboni article is a prospective one.
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> APPENDIX E, at 11 (emphasis added). In other words, the opinions plaintiffs' experts proffer regarding the in vivo degradation of silicone to silica are currently unsupported by the scientific literature. As with the immunological/ toxicological conclusions discussed

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47 See generally Dr. McClard's report at APPENDIX E.

48 Razzaboni, B., and Bolsaitis, P. Evidence of an Oxidative Mechanism for the Hemolytic Activity of Silica Particles. ENVTL. HEALTH PERSPECTIVES 87:337-341 (1990).

above, plaintiffs' experts again make too great a leap of faith in their proffered testimony that silicone gel from breast implants degrades to silica. This is especially true for any testimony that silicone gel degrades in vivo to crystalline, as opposed to amorphous, silica. Therefore, I hereby GRANT defendants' motions as pertains to such testimony.

In addition, because there is no scientifically valid evidence to support the conclusion that silicone gel degrades to silica in the human body, any other immunological or toxicological studies involving the inhalation, ingestion, or absorption of crystalline silica cannot "fit" the issue of whether silicone breast implants can cause signs or symptoms of disease in women. Therefore, as discussed above, I must also exclude testimony based on this evidence under the "fit" prong of Daubert I and Daubert II.

Dr. McClard also had several strong reservations about the other chemical studies upon which Dr. Batich and Dr. Alexander rely. Nevertheless, Dr. McClard consistently reported that these studies are supported by valid scientific reasoning and methodology. Moreover, while plaintiffs' experts' opinions are, in his view, "controversial," he concluded that those opinions are generally scientifically valid in that they properly may be derived from the chemical studies: It's a bit like two doctors looking at a chest X-ray (having both agreed that a chest X-ray was the correct diagnostic procedure to use) and disagreeing, sometimes heatedly, over the interpretation of a shadow on the film and perhaps how long the exposure should have been. I have no doubt that all of the chemical studies examined in these hearings are based on appropriate methods, whether or not there are serious questions about fine points of technique or far-reaching conclusions. Indeed some of the work is inadequately documented and of clearly debatable value, but that is really not for me to decide, to be sure.

APPENDIX E, at 12.

I find Dr. McClard's exposition of the numerous

methodological flaws in the other chemical studies troubling. Nevertheless, I need not decide whether this evidence is admissible on the basis of valid scientific methodology because the evidence now does not "fit" plaintiffs' case, as Daubert I, 509 U.S. at 594, and Daubert II, 43 F.3d at 1315, require. Testimony as to how silicone behaves chemically inside the human body cannot, in itself, establish that silicone gel breast implants cause signs and symptoms of disease in women in the absence of any epidemiological, rheumatological, or immunological/toxicological evidence linking those breast implants to disease. Thus, such testimony no longer logically advances a material aspect of the proponent party's case. Daubert II, 43 F.3d at 1315. Therefore, I hereby GRANT defendants' motions to exclude the testimony of Dr. Batich and Dr. Alexander.

E. Differential Diagnosis

Plaintiffs have offered Dr. Robert Bennett, M.D., both to testify that silicone gel breast implants can cause disease in women and to testify as a case-specific expert in LeaAnn Hall v. Baxter Healthcare.[49] Case No. 92-182-JO. Dr. Bennett is plaintiff Hall's treating physician and is prepared to testify, on the basis of differential diagnosis, that plaintiff Hall suffers from systemic sclerosis sine scleroderma, manifested by her pulmonary fibrosis, as a result of having silicone gel breast implants.

As has been noted, the issue before me in this Daubert hearing is silicone gel's ability to cause disease in women with breast implants. Courts, however, have recognized two levels of

49 LeaAnn D. Hall v. Baxter Healthcare Corp.,

causation: general causation (*i.e.*, whether silicone gel can cause disease in anyone) and specific causation (*i.e.*, whether silicone gel breast implants caused disease in this plaintiff). In Re: Silicone Gel Breast Implants Products Liability Litigation, 887 F. Supp. 1469, 1477 (N.D. Ala. 1995); Jones v. United States, 933 F. Supp. 894, 900 (N.D. Cal. 1990); DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d at 958; Rutigliano v. Valley Business Forms, 929 F. Supp. 779, 783 (D.N.J. 1996).

Differential diagnosis is a patient-specific process of elimination that medical practitioners use to identify the "most likely" cause of a set of signs and symptoms from a list of possible causes. However, differential diagnosis does not by itself prove the cause, even for the particular patient. Nor can the technique speak to the issue of general causation. Indeed, differential diagnosis assumes that general causation has been proven for the list of possible causes it eliminates:

> The process of differential diagnosis is undoubtedly important to the question of "specific causation." If other possible causes of an injury cannot be ruled out, or at least the possibility of their contribution to causation minimized, then the "more likely than not" threshold for proving causation may not be met. But, it is also important to recognize that a fundamental assumption underlying this method is that the final, suspected "cause" remaining after this process of elimination must actually be capable of causing the injury. That is, the expert must "rule in" the suspected cause as well as "rule out" other possible causes. And, of course, expert opinion on this issue of "general causation" must be derived from scientifically valid methodology.

Cavallo v. Star Enterprise, 892 F. Supp. 756, 771 (E.D. Va. 1995) (emphasis added), aff'd on this ground, rev'd on other grounds --- F.3d ---, 1996 WL 670142 (4th Cir. 1996).

Testimony regarding specific causation in a given patient is irrelevant unless general causation is established. DeLuca, 911 F.2d at 958; Jones, 933 F. Supp. at 900; Rutigliano, 929 F. Supp. at 783; Grimes, 907 F. Supp. at 38. Hopkins v. Dow Corning Corp., 33 F.3d 1116 (9th Cir. 1994), does not require a different conclusion for differential diagnosis. First, nothing in Hopkins indicates that any witness used differential diagnosis to establish any level of causation, let alone both general and specific causation.[50] Second, even if the expert's medical examination of the plaintiff in Hopkins were a differential diagnosis (and that is far from clear), it was not, as would be the case here, the only evidence of causation proffered. Although the court concluded "that Hopkins' experts based their opinions on the types of scientific data and

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50 Indeed, it is difficult to discern from the Hopkins opinion how exactly the causal connection was made. In March 1979, one of Hopkins's treating physicians, Dr. Stephen Gospe, "diagnosed plaintiff with mixed connective tissue disease (MCTD)." Hopkins, 33 F.3d at 118. However, neither Dr. Gospe nor plaintiff's physician, Dr. Pelfini, could provide information to her regarding a causal connection between silicone breast implants and her disease. Id. at 1119. Indeed, "[n]one of plaintiff's physicians informed her that the ruptured implant could be responsible for the connective tissue disease from which she suffered." Id. Apparently, plaintiff initially made the causal connection herself after she "learned from her mother that a possible connection between the ruptured implants and the immune disorder might exist." Id. at 1119, 1121.

utilized the types of scientific techniques relied upon by medical experts in making determinations regarding toxic causation where there is no solid body of epidemiological data to review," id. at 1124, this data was collective and included: toxicological experience; reviews of medical records; reviews of Dow's studies; "general scientific knowledge of silicone's ability to cause immune disorders as established by animal studies and biophysical data"; published scientific studies; personal research; "participation in a preliminary epidemiological study involving over 200 women"; animal studies; clinical experience; "preliminary results of an epidemiological study"; medical literature; and an examination of the plaintiff. Id. at 1125. Most of this information, as this Daubert hearing has demonstrated, would have been offered to establish general causation -- that is, the issue of whether silicone gel breast implants can cause disease in anyone.

Finally, the Hopkins court, because of the timing of the case, was reviewing a pre-Daubert district court decision to admit the expert testimony. As a result, the district court had reached that decision on a record not shaped by Daubert's elucidation of the court's gatekeeping function, nor did the Ninth Circuit delve into the methodology underlying the scientific data upon which Hopkins' experts relied. Because I have done so and have excluded all proffered testimony regarding general causation, Dr. Bennett's testimony now stands in

isolation -- an evidentiary predicament substantially different from that in Hopkins.

Plaintiffs have consistently claimed that this court has jumped the gun in stating that plaintiffs cannot make out a prima facie case. Plaintiffs assert that they have more evidence to present at trial in the nature of differential diagnosis as well as pursuing their theory of "bioplausibility." The fact of the matter is that plaintiffs cannot resort to these purported additional arrows in their legal quiver because neither differential diagnosis nor their bioplausibility theory can make out a prima facie case to prove specific causation of a systemic disorder or particular signs and symptoms absent proof of general causation. Moreover, plaintiffs cannot use Dr. Bennett's testimony, by itself, as part of their proof of general causation because a single differential diagnosis is a scientifically invalid methodology for such a purpose. Therefore, I must exclude Dr. Bennett's testimony for all cases to the extent that plaintiffs proffer it to prove general causation.

Nor is Dr. Bennett's testimony admissible to prove specific causation in LeaAnn Hall's case, and for two reasons. General causation issues aside, an expert must rule out other potential causes of the patient's condition in order for differential diagnosis testimony to be admissible. Hines v. Consolidated Rail Corp., 24 F.3d 809, 814 (3d. Cir. 1991); Paoli II, 35 F.3d

at 759. Here, Dr. Bennett has not testified as to how he eliminated other potential causes of Ms. Hall's disease. Moreover, his conclusion is inconsistent with the epidemiology for classical diseases. Therefore, his testimony is unreliable and exclusion of it is warranted on that basis. See Conde v. Velsicol Chemical Corp., 24 F.3d at 814 (upholding the district court in excluding doctors' opinions purporting to link plaintiff's health problems to chlordane exposure when they failed to exclude other potential causes for the symptoms and their theories were inconsistent with the scientific literature).

In addition, in the absence of proof of general causation, Dr. Bennett's testimony regarding his differential diagnosis does not "fit" LeaAnn Hall's case because there will be no evidence that silicone gel breast implants are a legitimate possible cause of Ms. Hall's disease.[51] Therefore, for all of the above reasons, I hereby GRANT defendants' motions to exclude the testimony of Dr. Bennett.

V.CONCLUSION

For the reasons stated above, those portions of defendants' motions in limine (## 69, 70, 72, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, and 95 (filed in Group 2)) that seek exclusion of any expert testimony concerning a general causal link between silicone gel breast

51 This conclusion would hold for any proffer of differential diagnosis plaintiffs may offer in the future without supporting proof of general causation.

implants and ACTD or any systemic illness or syndrome are GRANTED. The remaining portions of the above-listed motions are MOOT, with leave to refile as necessary in further pretrial proceedings.

In light of these rulings, the court will sever plaintiffs' local injury claims[52] from their claims for ACTD or any systemic illness or injury. The cases that do proceed to trial will do so on a much more restricted basis than Judges Weinstein and Baer may even contemplate in the New York litigation.[53] Specifically, I will exclude as irrelevant any testimony or evidence of the following: ACTD; any systemic illness or syndrome or autoimmune disorder of any kind; any emotional distress claims arising out of any alleged fear of developing any systemic disease or injury or fear of cancer.[54]

Finally, as stated earlier, I will defer the effective date of this decision pending the reports of the national Rule 706 panel, and likewise will defer plaintiffs' motion to incorporate the panel members as witnesses. Nonetheless, I wish to make it abundantly clear that while I will evaluate the Rule 706 panel reports before finalizing my decision, I am unlikely to amend

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52 In addition to what is explicitly excluded here, see also discussion supra note 3.

53 See discussion above.

54 This list is not exhaustive. To the extent any plaintiff claims injuries that are not plainly local in nature, the court will rule on the admissibility of evidence of those claimed injuries as the need arises.

these findings and conclusions absent substantial and compelling developments in the scientific arena.

I am mindful that this opinion goes farther in evaluating and in eliminating plaintiffs' claims than any other opinion in breast implant litigation pending in this country. However, litigation over the ability of silicone gel breast implants to cause disease in women has been chaotic in its results, in part because, as Hopkins demonstrates, the interjection of the Daubert standards into the screening process for proposed scientific evidence has substantially heightened the scrutiny through which such evidence must pass. In my opinion, Daubert I and Daubert II and their progeny command this disposition.

DATED this 18th day of December, 1996.

/s/ Robert E. Jones
ROBERT E. JONES
U.S. District Judge