2009 WL 2750462
United States District Court, D. South Carolina, Charleston Division.

In re BAUSCH & LOMB, INC. CONTACT LENS SOLUTION PRODUCTS LIABILITY LITIGATION.
This Order Relates to: All Cases.

MDL No. 1785.
|
Civil Action No. 2:06–MN–77777–DCN.
|
Aug. 26, 2009.

West KeySummary

1 **Evidence**
Medical testimony

A contact lens solution distributor was entitled to exclude the testimony of an expert that was fundamentally flawed in a products liability proceeding brought by contact lens wearers who developed eye infections. The expert's testimony was flawed because it related to a theory that assumed, without evidence, that any increase in the lens microbial load caused infection. The expert's opinion amounted to speculation because there was no reliable evidentiary basis to connect the increase in the microbial load due to the lens solution's efficacy with the causation of infection in humans. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

9 Cases that cite this headnote

Opinion

ORDER AND OPINION

DAVID C. NORTON, Chief Judge.

***1** Before the court are defendant Bausch & Lomb Inc.'s ("Bausch & Lomb") motions to exclude the opinions of plaintiffs' expert Dr. Elisabeth Cohen related to Non–Fusarium infections,[1] and to strike the affidavit of Dr. Cohen dated May 18, 2009.[2] In conjunction with Justice Shirley Werner Kornreich of the Supreme Court of the State of New York—New York County, a joint *Frye/Daubert* hearing was held in New York City on June 3–5, 2009. For the reasons stated below, Bausch & Lomb's motion to exclude is granted.[3]

I. BACKGROUND

A. Factual History

Beginning in 2004, Bausch & Lomb manufactured and distributed ReNu with MoistureLoc ("MoistureLoc"), a multipurpose solution indicated for use in the daily cleaning and disinfection of soft contact lenses. Like all contact-lens solutions, MoistureLoc was classified as a medical device and was subject to the regulatory authority of the United States Food and Drug Administration ("FDA").[4] Pursuant to FDA rules and regulations, MoistureLoc met or exceeded all FDA requirements. The requisite data documenting MoistureLoc's safety and efficacy was submitted to the FDA in December 2003, and the FDA cleared MoistureLoc for sale and distribution in the United States on May 19, 2004.

i. MoistureLoc's Disinfectant Efficacy

MoistureLoc was a unique, patented product that was developed to enhance comfort for contact-lens wearers. Many wearers experience dry eyes, a condition that often results in consumers discontinuing their use of contact lenses. To address this problem, MoistureLoc incorporated a trio of polymers—large molecules that increase contact-lens solutions' comfort level in the eye. In clinical trials, MoistureLoc was shown to improve comfort. MoistureLoc also contained a unique disinfectant, Alexidine. Premarket testing, using FDA criteria, demonstrated that MoistureLoc with Alexidine was very effective in killing microorganisms, including Fusarium, which can cause eye infections.

The measure of a contact lens solution's disinfectant efficacy (its bactericidal and fungicidal properties) is based on a "kill rate." A kill rate is expressed, according to International Standard Organization (ISO) test protocols, as a "log reduction." A log reduction is a multiple of 10 reduction in the number of microbes: 1 log reduction means 10 times less microbes, a 2 log reduction

means 100 times less and a 3 log reduction means 1000 times less. To illustrate, if there were 1,000,000 bacteria contaminating a contact lens case and after use of a contact lens solution there was a 3 log reduction in the number of those bacteria, there would be 1,000 bacteria remaining.

To obtain FDA marketing approval, contact lens solutions must pass the ISO "stand alone" test.[5] To pass the "stand alone" test, contact lens solutions must demonstrate a greater than 3 log reduction for bacteria and a greater than 1 log reduction for fungi.[6] In its pre-marketing testing, MoistureLoc showed a reduction in the number of bacteria of 4.3–4.8 log units [i.e., more than 10,000 times reduction (10 x 10 x 10 x 10) and close to 100,000 times reduction [10 x 10 x 10 x 10 x 10], much greater than the 3.0 log units required by the ISO test.

***2** The requisite data documenting the safety and efficacy of the product was submitted to the FDA in December 2003, and the FDA cleared MoistureLoc for sale and distribution in the United States on May 19, 2004. Bausch & Lomb began distributing MoistureLoc in the United States in August 2004, and released it for sale in Asia, including Hong Kong, Singapore, and Malaysia shortly thereafter.

ii. Microbial Keratitis

A contact lens sits on the cornea—the clear layer of the eye in front of the iris, pupil, and lens. Microbial keratitis is the general term for corneal infections caused by any one of several microbial pathogens, including bacteria, fungi, viruses, and Acanthamoeba. If the specific microbe—*i.e.*, microorganism—causing the infection is known, the diagnosis of "microbial keratitis" may be further specified to identify the causative organism. For example, corneal infections caused by Fusarium, a specific type of fungus, are denominated as "Fusarium keratitis." Fungi are in a different biological classification (Kingdom) from bacteria, Acanthamoeba, and viruses. The various microbial pathogens and resulting types of microbial keratitis are very different, both scientifically and medically. These differences include what they eat, how they reproduce, how long they live, the environments in which they can survive, and how they cause disease. Medically, keratitis infections are treated with different medications, depending on which type of organism is identified as the cause.[7]

Contact-lens wearers are approximately 80 times more likely than healthy non-wearers to experience a microbial-keratitis infection.[8] The baseline—*i.e.*, background—rate of microbial-keratitis infections is estimated to be between 4 and 21 per 10,000 wearers of soft contact lenses,[9] and the majority of contact-lens-related keratitis infections are bacterial in nature.[10] Moreover, the scientific data demonstrates that the large majority—between 50% and 83%—of contact lens cases are contaminated[11] as compared to the very small minority of contact lens wearers—0.04% to 0.21% or 4–21/10,000—who get infections.[12] Prior to 2006, the specific baseline rate for contact-lens related Fusarium keratitis in the United States was not known.[13]

iii. Reports of Outbreak

In February 2006, approximately eighteen months after MoistureLoc's launch, Hong Kong and Singapore reported outbreaks of Fusarium keratitis associated with the use of MoistureLoc.[14] Bausch & Lomb launched an investigation, working in conjunction with the FDA, the United States Centers for Disease Control and Prevention ("CDC"), and health authorities around the world, as well as national and international experts in corneal infections and Fusarium. The first report of Fusarium keratitis associated with MoistureLoc use in the United States was received by Bausch & Lomb on March 2, 2006.[15] Slightly more than one month later, on April 10, 2006, the company stopped shipping MoistureLoc in the United States—withdrawing the product completely from the U.S. market on April 13, 2006.[16] Bausch & Lomb's decision to cease U .S. distribution was based on information published by the CDC on April 10, 2006, showing a high correlation between Fusarium keratitis and MoistureLoc use.[17] Over the next month, Bausch & Lomb continued its internal investigation, and continued its cooperation with the FDA and CDC. On May 15, 2006, in light of additional results from Bausch & Lomb's internal investigation as well as preliminary data from the CDC case-control study, the company recalled MoistureLoc worldwide.[18]

***3** Throughout its investigation, Bausch & Lomb never received any reports from physicians or health authorities of an outbreak of any keratitis infections other than Fusarium infections associated with MoistureLoc use.[19] Ultimately, the CDC identified 164 patients with confirmed cases of Fusarium keratitis, 94 of whom reported exclusive use of MoistureLoc as their contact-lens solution.[20] After conducting a case-control study, the results of which were published in the *Journal of the American Medical Association*, the CDC concluded that the U.S. outbreak of Fusarium keratitis was associated with the use of MoistureLoc.[21] Case-control studies published in Hong Kong and Singapore likewise concluded that there was an association between the use of MoistureLoc and Fusarium keratitis.[22] Nothing in any

of the case-control studies supports an association between MoistureLoc use and any infections other than Fusarium infections.

B. Procedural Background

Lawsuits against Bausch & Lomb commenced in the United States in 2006. In general, plaintiffs seek damages for personal injuries allegedly suffered as a direct and proximate result of allegedly negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, advertising, promoting, marketing, distribution, labeling, and/or sale of MoistureLoc. On August 14, 2006, the Judicial Panel on Multi–District Litigation consolidated federal cases relating to MoistureLoc for pretrial proceedings and assigned the Multi–District Litigation (MDL) to this court. The suits filed in New York State courts were consolidated before Justice Helen Freedman, and later Justice Kornreich of the Supreme Court of the State of New York—New York County for joint pre-trial proceedings. A joint hearing under New York State (*Frye*) and Federal (*Daubert*) law was held on June 3–5, 2009 to decide the admissibility of opinions by plaintiffs' experts on the issue of general causation; i.e, whether MoistureLoc is capable of causing infections other than Fusarium infections. Throughout the briefing and the hearing, these infections were referred to as "non-Fusarium infections."[23]

On July 15, 2009 Justice Kornreich granted Bausch & Lomb's motion in the New York proceeding to exclude the general causation opinions of plaintiffs' experts as to non-Fusarium infections.[24]

C. Plaintiff's Evidence

The MDL plaintiffs submitted the opinions of one expert witnesses, Dr. Elisabeth J. Cohen. Her expert opinions on general causation are the subject of the instant motion.[25] Plaintiffs rely solely on this expert and her opinions. Plaintiffs did not submit any peer-reviewed studies, articles or case reports concluding that there is a causal relationship between MoistureLoc and non-Fusarium infections.

i. Dr. Cohen's Qualifications and Opinions

Dr. Cohen is a Harvard College and Medical School graduate, a board certified ophthalmologist and a corneal specialist. For the past twenty years, Dr. Cohen has been a Professor of Ophthalmology at the Jefferson Medical College, Thomas Jefferson University and, for the past sixteen years also has served as Co–Director and then Director of the Cornea Service at the Wills Eye Hospital, Philadelphia, Pennsylvania. Additionally, Dr. Cohen has served as an Editor and/or has served on the Editorial Board as a peer reviewer for leading ophthalmological professional journals: Cornea, the Archives of Ophthalmology, the American Journal of Ophthalmology, Evidence–Based Eye Care and the Contact Lens Association of Ophthalmologists Journal.

***4** Dr. Cohen has written more than 200 peer-reviewed articles and more than twenty-five book chapters, almost all of which relate to her area of specialty—the cornea. She has authored several articles directly related to the issues involved in this litigation, including a Comment for the Archives of Ophthalmology entitled *Fungal Keratitis Associated with Contact Lenses,* and articles in peer-reviewed journals such as Cornea and the Archives of Ophthalmology entitled *Trends in Contact Lens–Associated Corneal Ulcers*, *An Outbreak of Fusarium Keratitis Associated with Contact Lens Use in the Northeastern United States*, *Fusarium Keratitis Associated with Soft Contact Lens Wear*, *Methods of Disinfecting Contact Lenses to Avoid Corneal Disorders*, and *Contact Lens Solutions are Part of the Problem* (in press). Dr. Cohen has never published the general causation theory she posited at the *Frye/Daubert* hearing. Nor, as an administrator at the Cornea Service at Wills, did she report any rise in bacterial or nonFusarium infections while MoistureLoc was on the market.

It is Dr. Cohen's general causation opinion that MoistureLoc is capable of being a substantial contributing factor and was a risk factor in the development of non-Fusarium corneal infections, including bacterial and other fungal and microbial infections, in users of MoistureLoc who developed such infections. Dr. Cohen holds the opinion to a reasonable degree of medical certainty that the "loss of disinfectant efficacy of [MoistureLoc] to kill a variety of organisms, such as bacteria and non-Fusarium fungi, increases the risk of corneal infection from these microbes."[26] She testified that the bases for her opinions were a number of Bausch & Lomb in-vitro studies showing that MoistureLoc lost efficacy as a disinfecting solution to kill microorganisms both in the bottle and after the bottle was opened, that such loss was related to evaporation and film formation that was unique to this product compared to other products tested, and that the loss of efficacy involved multiple organisms.

Dr. Cohen's opinions have been provided in three written installments: an original report (July 11, 2008), a

supplemental report (January 14, 2009) and a May 18, 2009 affidavit provided after expert depositions were completed, received after Bausch & Lomb filed its *Daubert* motion, and served only two weeks before the June 3–5, 2009 joint *Frye/Daubert* hearing. On May 28, 2009 plaintiffs withdrew from consideration any opinions of Dr. Cohen that were inconsistent with the opinions she reached in the May 18 affidavit.[27] Bausch & Lomb contends that Dr. Cohen's affidavit should be excluded because it is based on in-vitro testing conducted by Bausch & Lomb that Dr. Cohen either had not reviewed or relied on for her original and supplemental reports or prior to her deposition. In-vitro tests are laboratory tests done before animal or human testing. The parties agree that in-vitro testing is an important first step in the process of developing a new product for human use.

ii. Dr. Cohen's Hearing Testimony

***5** Dr. Cohen testified that a large number of contact lens care systems are contaminated. She agreed that there is more contamination in the lens cases than there is infection in the cornea of the eye, and that it is generally accepted that the purpose of disinfecting lens care products is to decrease the microbial load. In a 1996 article titled *Methods of Disinfecting Contact Lenses to Avoid Corneal Disorders* that she co-authored, Dr. Cohen noted, "no ideal disinfection system exists for contact lens care, meticulous care of contact lenses with appropriate cleaning and disinfecting can help minimize the risk of infection."

In an earlier article titled *Patterns of Lens Care Practices and Lens Product Contamination From Contact Lens Associated Microbial Keratitis* that she co-authored in 1987, Dr. Cohen wrote, "Recent reports have suggested several predisposing factors in the pathogenesis of infectious keratitis in contact lens wearers. These factors include contact lens overwear with hypoxic stress, contact lens contamination, inappropriate lens care practice and recent lens manipulations."

Dr. Cohen also referred to in-vitro studies by Bausch & Lomb on the impact of noncompliant behaviors on the efficacy of MoistureLoc. These in-vitro studies included:

> 1) Report For the Bioburden Evaluation of Opened/Used ReNu w/MoistureLoc Bottles From Various Locations, July 2006;
>
> 2) MoistureLoc Cycling Study–Residual Alexidine Concentrations, May 2006;
>
> 3) Biocidal Testing of Varying Concentrations of Alexidine in BL–400–NRCO7 Using Fusarium Solani Containing Dried Films of BL–400–NRCO7 Excipients (no Alexidine), May 2006;
>
> 4) Study on the Effect of five different Hand Soaps on the Antimicrobial Efficacy of ReNu with MoistureLoc, June 2006;
>
> 5) Biocidal Efficacy of Concentrated ReNu with MoistureLoc and ReNu MultiPlus Solutions, May 2006;
>
> 6) Study on the Effect of Testing the Biocidal Efficacy of Samples of ReNu with MoistureLoc in HDPE bottles, ReNu with MoistureLoc in PET bottles (S200*l* label adhevise) and ReNu with MoistureLoc in PET bottles (S692 label adhesive) after Storage at 40°C, 50° C, and 60° C (all at 45% RH);
>
> 7) Report for the Effect of Testing the Biocidal Efficacy of Samples of ReNu with MoistureLoc after Storage at 60° C/45% RH.

Dr. Cohen focused on Bausch & Lomb's findings that under conditions mimicking noncompliance, the solution could evaporate and polymers contained in MoistureLoc could form a polymer film that allowed at least one strain of Fusarium to survive subsequent disinfection. In this respect, MoistureLoc performed differently than other contact-lens solutions on the market. Bausch & Lomb also found that MoistureLoc loses biocidal efficacy against Staphylococcus bacteria (Staph) when half or three-fourths of the water is removed from the solution. This study was one step in the experimentation that led to the company's published polymer-film theory. The portion of the study results concerning staph was not published.

***6** Dr. Cohen also reviewed Bausch & Lomb's comprehensive report detailing thousands of tests done during its Fusarium investigation and the conclusions reached by the investigators. This report, titled *Contact Lens Related Fusarium Keratitis Investigation Summary* (the "Fusarium Investigation Report"), is nearly 1000 pages long and attaches a multitude of test reports and data considered by Bausch & Lomb in reaching its conclusions. Dr. Cohen also relied on a Bausch & Lomb document titled *Bausch and Lomb Research and Development, Why Fusarium?*, in which a Bausch & Lomb scientist hypothesized that non-Fusarium infections might not be reported by clinics as much as Fusarium infections because bacterial infections are more easily treated through the use of antibiotics. Dr. Cohen agreed that you can have a moderate increase of a common and

successfully treatable condition of bacterial infection without particularly noticing the increase.

On cross-examination, Dr. Cohen admitted that she had not done any testing of MoistureLoc, that she had not notified the CDC or the FDA of any increase in non-Fusarium infections during the time MoistureLoc was on the market, and that none of her published work had focused on the issue of non-Fusarium infections as related to MoistureLoc. She was not aware of any evidence linking MoistureLoc, as opposed to other contact lens solutions, to an outbreak of Acanthamoeba or to an increase in microbial infections at her institution which occurred in 2005 and 2006 and continued into 2007, long after MoistureLoc was withdrawn from the market. Nor was she aware of any case control study quantifying an increased risk, if any, between MoistureLoc and non-Fusarium infections.

Dr. Cohen further agreed that there was no unique presentation for a patient suffering from an infection related to MoistureLoc, and that although in-vitro testing is relevant to developing a hypothesis, more testing is necessary to prove the applicability of any resulting hypothesis to humans. She could not say if there was an increased rate, as opposed to risk, of non-Fusarium infection resulting from the use of MoistureLoc because she did not have the data. She had not reviewed four published studies regarding keratitis showing either that there had not been an increase of non-Fusarium infections when MoistureLoc was on the market or that such infections had decreased.

D. Bausch & Lomb's Evidence

Four studies looked at non-Fusarium microbial infections during the time that MoistureLoc was on the market from August 2004 through April 2006. None of these studies demonstrated any increased incidence of non-Fusarium keratitis. For example, Acanthamoeba is an organism that can cause keratitis. There was a reported increase in the incidence of Acanthamoeba keratitis. The University of Illinois at Chicago collected and analyzed data relating to the outbreak and determined that another contact-lens solution, not MoistureLoc, was associated with that outbreak.

***7** Studies from three major eye centers in the country, the Cullen Eye Institute at Baylor College of Medicine, the Bascom–Palmer Eye Institute at the University of Miami School of Medicine and the University of California at San Francisco, surveyed keratitis during the time MoistureLoc was on the market. All three institutions documented an increase in Fusarium keratitis, but none reported an increase in non-Fusarium keratitis during that time period. In fact, some of the studies showed a decrease in non-fungal infections during this period.

Bausch & Lomb presented reports by experts, studies and published articles, and established that it conducted an extensive investigation into the possible root cause of the Fusarium outbreak. The investigation focused on three main areas: 1) identifying any possible contamination or sterility problems with the manufacturing and production of MoistureLoc; 2) identifying any efficacy problems with the MoistureLoc formula as packaged; and 3) identifying any consumer-use practices that could impact the efficacy of MoistureLoc.

Because it initially appeared that many of the reported Fusarium cases stemmed from MoistureLoc manufactured at Bausch & Lomb's facility in Greenville, South Carolina, Bausch & Lomb investigated the facility. There was no evidence of Fusarium contamination at the Greenville facility. Retain (unsold solution) testing confirmed that no product from the affected lots had been contaminated in Greenville. The FDA also investigated the Greenville manufacturing facility and reached the same conclusion.

Additionally, Bausch & Lomb conducted thousands of biocidal-efficacy tests on MoistureLoc, including testing on retains, field returns and consumer returns. This testing confirmed that MoistureLoc was biocidally effective against Fusarium. Testing of unopened bottles confirmed that the solution passed FDA standards for biocidal efficacy. Opened bottles returned from consumers and from the field killed Fusarium. Testing further confirmed that MoistureLoc met chemistry specifications and was stable during its shelf life.

Bausch & Lomb then tested the impact of noncompliant behaviors on the efficacy of the product. Anecdotal reports from Singapore and Hong Kong suggested that noncompliance was a common factor among Fusarium-infected patients in those countries. The CDC case-control study also showed that re-use of the solution was a statistically significant noncompliant behavior among Fusarium patients. Bausch & Lomb found that under conditions mimicking noncompliance, the polymers contained in MoistureLoc could form a polymer film that allowed at least one strain of Fusarium to survive subsequent disinfection with the same product. No test data suggested that any organism other than Fusarium could survive in the dried-down polymer film.

These study results were peer-reviewed and published in

December 2006 in the journal Eye and Contact Lens. Bausch & Lomb's conclusion was supported by an additional peer-reviewed, published study conducted by researchers at Georgia State University. In addition to its peer-reviewed publication, Bausch & Lomb prepared the Fusarium Investigation Report, a comprehensive report detailing the thousands of tests done during the Fusarium investigation and the conclusions reached by the investigators. The Fusarium Investigation Report was submitted to the FDA.

***8** In one of the expert reports submitted by Bausch & Lomb, Dr. Stephen Spiegelberg, a chemical engineer, commented on the general causation theories offered by plaintiffs' experts. He referred to tests where MoistureLoc components were microbially-challenged as to Fusarium, as well as other microorganisms. He concluded that MoistureLoc was efficacious against multiple microorganisms when used according to the package label. As stated by Dr. Spiegelberg:

> The Plaintiffs' experts set forth multiple theories based on a set of mechanisms for the deactivation of MoistureLoc's preservative, Alexidine, resulting in too-little Alexidine for adequate Fusarium and other microorganism killing ... The various Alexidine inactivation theories proposed by the Plaintiffs' experts are all disproven by the simple experimental result that field-returned and retained bottles of MoistureLoc showed the required biocidal efficacy against all microorganisms tested.[28]

i. Hearing Testimony of Dr. Oliver B. Schein

Dr. Oliver B. Schein is both a Professor of Ophthalmology with the Wilmer Eye Institute at Johns Hopkins University and a professor of the Department of Epidemiology at Johns Hopkins Bloomberg School of Public Health. He is board certified in both internal medicine and in ophthalmology. His clinical expertise is in cornea and external disease. He spends approximately 60% of his time taking care of medical and surgical conditions, and 40% in research and administration with his focus on epidemiology and public health clinical trials. The primary focus of his research career has been the epidemiology of eye diseases, with the principle areas being infections related to contact lenses, cataracts, and dry eye. He has published extensively.

Dr. Schein has been a consultant for Bausch & Lomb for ten or eleven years. He was familiar with MoistureLoc before he was named an expert in this litigation. After reports of Fusarium infections started coming in, he advised Bausch & Lomb to undertake a case control study. However, the CDC undertook such a study first. At the request of Dr. Levy from Bausch & Lomb, Dr. Schein put together a panel of people with expertise in corneal disease and fungi.

During the course of the panel's investigation, no one reported an increased incidence of non-Fusarium infections associated with MoistureLoc. In Dr. Schein's opinion there is no evidence of an association between MoistureLoc and non-Fusarium infections in humans. Such an association is not generally accepted in the scientific community. He has not even heard of a hypothesis to that effect outside of the legal context. Dr. Schein conceded that scientists could have overlooked an outbreak of less serious and more easily treated infections, but explained there was no evidence nor even speculation among scientists, of an outbreak of non-Fusarium infections outside of the plaintiffs' hypothesis in this litigation.

Dr. Schein described the various studies and reports that support his opinion. Singapore reported an outbreak of Fusarium and Acanthamoeba, but not Staph, Strep, Serratia, Pseudomonas, Candida or Aspergillus. It also did not report a link between MoistureLoc and Acanthamoeba. In a study at the Bascom and Palmer Eye Institute, it was reported there had been a decrease in non-fungal infections during the relevant period. A study at the Cullen Eye Institute reported that only Fusarium infections had been detected. In a mathematical modeling study at the University of California at San Francisco going back twenty years at a single institution, only Fusarium and Acanthamoeba outbreaks were picked up. A study on Acanthamoeba at the University of Illinois detected an excess risk associated with the contact lens solution AMO Complete Moisture Plus, but not with Bausch & Lomb solutions. The Hong Kong Center for Health Protection reported only an excess of Fusarium cases. In another paper, it was reported that in a single hospital in Hong Kong, fungal infections had increased and bacterial infections had decreased. All of these published studies are inconsistent with plaintiffs' hypothesis that MoistureLoc caused non-Fusarium infections.

***9** With respect to Bausch & Lomb's in-vitro studies, Dr. Schein explained that extrapolating from in-vitro testing to human clinical disease is not generally accepted in the scientific community. He agreed with the concept of reducing the bioburden, but he did not agree that it is

possible to predict who will get an infection from either preclinical testing or from the fact that you have a high rate of contamination in contact lens cases.

II. LEGAL STANDARD

Federal Rule of Evidence 702 provides that:

> if 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, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed.R.Evid. 702; *Thompson v. Queen City, Inc.*, No. Civ. A. 2002359–18, 2002 WL 32345733, at *1 (D.S.C. July 9, 2002). *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, establishes the principles for the admissibility of expert testimony pursuant to Rule 702. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

In *Daubert*, the Supreme Court directed that the first step in evaluating the admissibility of expert testimony is a determination of scientific reliability. Both Dr. Cohen's opinions and her methodology must meet reliability standards. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir.2001) ("[T]he Supreme Court has recognized, 'conclusions and methodology are not entirely distinct from one another.' ") (*quoting General Electric Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)). The Supreme Court provided four non-exclusive factors for use in analyzing scientific reliability:

1. *Testing:* whether the theory can be, and has been, tested;

2. *Peer Review and Publication:* whether the theory has been subjected to peer review or publication;

3. *Rate of Error:* the known or expected rate of error of the expert's methodology; and

4. *General Acceptance:* whether the methodology has been generally accepted by the relevant scientific community as reliable for the purpose for which it is employed.

Daubert, 509 U.S. at 589;*United States v. Powers*, 59 F.3d 1460, 1471 (4th Cir.1995). In order to be considered reliable, the expert's opinions must reflect "scientific knowledge," be "derived by scientific method," and be the result of work product that amounts to "good science." *Daubert*, 509 U.S. at 590, 593. The trial court is to exclude "subjective belief or *unsupported speculation." Id.* at 590 (emphasis added).

Daubert ensures that experts are held to the same rigorous standards in the courtroom that they are held to in the scientific community. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). An expert's subjective, personal beliefs or speculation fail to satisfy the requirement of reliability. "A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Oglesby v. General Motors Corp.*, 190 F.3d 244, 250 (4th Cir.1999) ("expert" mechanical engineer's speculation about whether plastic inlet connector contained defect lacked reliability, foundation, and relevance necessary for admissibility); *see also Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1360 (6th Cir.1992) (excluding an "expert" opinion because "Personal opinion, not science, is testifying here."), *cert. denied*,506 U.S. 826, 113 S.Ct. 84, 121 L.Ed.2d 47 (1992).

***10** "[S]omething doesn't become 'scientific knowledge' just because it's uttered by a scientist." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1315–16 (9th Cir.1995) (*"Daubert II"*). As the proponent of the opinion testimony of Dr. Cohen, plaintiffs bear the burden to establish its admissibility by a preponderance of proof. Fed.R.Evid. 702 Advisory Committee note to 2000 amendment; *Higginbotham v. KCS Int'l, Inc.*, 85 Fed. Appx. 911, 915 (4th Cir.2004) (" '[T]he proponent of the expert proffer bears the burden of establishing admissibility by a preponderance of proof.' " (quoting *Daubert*, 509 U.S. at 592 n. 10)). "[A] bold statement of the experts' qualifications, conclusions, and assurances of reliability are not enough to satisfy the *Daubert* standard." *Doe 2 v. Ortho–Clinical Diag., Inc.*, 440 F.Supp.2d 465, 471 (M.D.N.C.2006) (*citing Daubert II*, 43 F.3d at 1318).

Finally, the second step of the *Daubert* analysis involves a determination whether the opinion testimony will assist the trier of fact. This is essentially a relevancy inquiry; the expert's theory and method must have a relevant

relationship with the facts at issue in the case, described by the Supreme Court as a "fit." *Daubert,* 509 U.S. at 591–93.

III. ANALYSIS

Plaintiffs seek to extrapolate from in-vitro and Fusarium studies to establish their theory of general causation. As such, the court's inquiry focuses on whether the methodologies employed by the plaintiffs' expert lead to a reliable theory or opinion.

Plaintiffs contend that the "loss of disinfectant efficacy of [MoistureLoc] to kill a variety of organisms, such as bacteria and non-Fuasrium fungi, increases the risk of corneal infection from these microbes," thus making the product "capable of contributing to ... Non–Fusraium infections."[29] Plaintiffs have not identified, or even suggested, a threshold level of microbes necessary to actually cause an onset of a non-Fusarium infection. While such a level is important in the abstract, it is critical in this litigation, since a very small minority of contact lens wearers get infections in light of the sizable majority of contact lens cases that are contaminated at any given time.[30] Plaintiffs' theory assumes, without evidence, that any increase in the microbial load causes infection. In the absence of a reliable evidentiary basis to connect any loss of efficacy/increase in the microbial load with causation in humans, plaintiffs' expert opinions amount to speculation and potentialities. As such, Dr. Cohen's theory as to general causation is built on an unsupported hypothesis, and is thus fundamentally flawed and must be excluded.

A. Application of *Daubert* factors

Plaintiff's general causation opinion would also be excluded because it fails to satisfy *Daubert's* core reliability factors: (1) testing; (2) peer review and publication; (3) potential rate of error; and (4) general acceptance in the relevant community. *Daubert,* 509 U.S. at 593–94;*Cooper,* 259 F.3d at 199. Plaintiffs' general causation theory fails to satisfy each of these factors.

i. Testing

***11** Plaintiffs' general causation theories have not been tested, despite the opportunity to do so and the availability of product for testing. Dr. Cohen relies on Bausch & Lomb internal testing; however, Bausch & Lomb testing never demonstrated that any reduced biocidal efficacy leads to an increased rate of non-Fusarium infections. That is the crux of Dr. Cohen's opinion, and it remains untested. *See Daubert,* 509 U.S. at 593 (stating that the scientific methodology "is based on generating hypotheses and testing them to see if they can be falsified"). Untested potentialities do not satisfy the *Daubert* standard.

Plaintiffs present no epidemiologic study of any kind that establishes an increased risk of non-Fusarium infections associated with MoistureLoc use. Plaintiffs simply present no testing to establish that MoistureLoc is in any way related to an increase in the number of non-Fusarium infections.

ii. Peer Review and Publication

Plaintiffs do not dispute that their expert's non-Fusarium causation opinions have never been peer-reviewed or published. Dr. Cohen has never published her opinion that use of MoistureLoc increases the risk of non-Fusarium infection. She has never published her opinion that any reduced efficacy of a contact lens solution results in an increased rate of corneal infections, or subjected it to peer review. Peer review and publication is a pertinent consideration because "submission to the scrutiny of the scientific community is a component of 'good science.' " *Id.* at 594.

Moreover, because plaintiffs' theory is novel and has not been published in the scientific and medical literature by any other scientist, it has not been vetted by peers. As a result, the theories of plaintiffs' expert in this litigation have not been subjected to the rigorous scientific critique that is part of the peer review process. The courtroom is not the forum to advance new scientific theories. *See, e.g, Rosen v. Ciba–Geigy Corp.,* 78 F.3d 316, 319 (7th Cir.1996) (noting "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it."). In the absence of any evaluation through the peer review process, the court has no assurance that Dr. Cohen's opinion is scientifically reliable.

iii. Rate of Error

For reasons addressed above, the methodology employed by plaintiffs expert cannot be analyzed for any rate of error.

iv. General Acceptance in Relevant Community

Plaintiffs' theory on general causation and methodology

fails to meet the *Daubert* general acceptance standard for reliability. This litigation is the only forum where plaintiffs' general causation theory has been espoused. Plaintiffs have cited no published, peer-reviewed or scientific literature concluding that MoistureLoc is related to an increased rate of non-Fusarium infections because there is none. No medical or scientific organization or board, epidemiological or anecdotal study has associated non-Fusarium infections with MoistureLoc use. Dr. Cohen acknowledged the dearth of scientific or medical literature connecting MoistureLoc with nonFusarium infections.[31] When asked about the general acceptance of her opinion that MoistureLoc caused non-Fusarium infections, plaintiffs' expert admitted that: "It's just not been the subject of discussion."[32] In sum, plaintiffs' theory is an educated guess.

***12** The concern over reliability in this circumstance is heightened due to Dr. Cohen's reliance on in-vitro tests. In formulating her opinion, Dr. Cohen extrapolates from in-vitro testing to real world causation. However, both Dr. Cohen and Bausch & Lomb's expert agree that in-vitro tests are only the first step, and that animal studies followed by human trials are necessary to determine applicability of an hypothesis to humans. In vitro tests generate hypotheses but lack sufficient reliability, standing alone, to demonstrate causation in humans. *See Wade–Greaux v. Whitehall Labs.*, 874 F.Supp. 1441, 1483–84 (D.Vi.1994) (noting "In-vivo and in-vitro animal test data are unreliable predictors of causation in humans."); *see also Allen v. Pa. Eng57Dg Corp.*, 102 F.3d 194, 198 (5th Cir.1996). These tests suggestion of biological plausibility is insufficient to demonstrate causation, and unreliable under *Daubert*, absent evidence establishing an association between MoistureLoc and non-Fusarium infections. *See Dunn v. Sandoz Pharms. Corp.*, 275 F.Supp.2d 672, 679 (M.D.N.C.2003). As the MDL Court in the Accutane litigation noted:

> While [the expert's] biological theory may be exactly right, at this point it is merely plausible, not proven, and biological possibility is not proof of causation.... When a theory has not been verified by testing, it obviously has not been peer-reviewed. Without verification, [the expert's] theory remains an educated guess.

In re Accutane Prods. Liab., 511 F.Supp.2d 1288, 1296 (M.D.Fla.2007).

Finally, the plaintiffs' expert's analysis of these in-vitro tests, even if accepted as reliable, raises additional concerns. In all but one of these in-vitro tests, the reduction in efficacy occurred with other contact lens solutions as well. Plaintiffs focus on the one test that indicated MoistureLoc performed differently than other products in the market—yet this test concerned efficacy against Fusarium, not non-Fusarium infections. Despite the thousands of tests performed by Bausch & Lomb, plaintiffs have produced no test data from the in-vitro experiments showing an increase in non-Fusarium infections, or showing that any microbe other than Fusarium can survive in the "polymer film." In fact, four separate studies proffered by Bausch & Lomb suggest that although the use of MoistureLoc resulted in an increase of Fusarium infections, it did not result in an increase of non-Fusarium infections.

B. Other Relevant Considerations

i. Plaintiffs' Expert Opinions Reflect a "Moving Target"

The opinions expressed by plaintiffs' expert were in flux throughout this litigation. Dr. Cohen executed an original expert report on July 11, 2008, that was eventually adopted by the MDL plaintiffs. This was followed by a supplemental report executed on January 14, 2009, containing additional opinions. In these reports, plaintiffs' expert offered numerous general causation opinions on a variety of topics such as the impact of gamma sterilization, heavy metal contamination, and alexidine instability on the biocidal efficacy of MoistureLoc. On May 18, 2009, roughly two weeks before the scheduled joint *Frye/Daubert* hearing, and after Bausch & Lomb filed its *Daubert* motion seeking to exclude plaintiffs' expert's opinions, Dr. Cohen executed an affidavit in which she abandoned a number of her prior opinions.

***13** Additionally, her affidavit contained new opinions not previously articulated in her expert reports. Plaintiffs' expert's affidavit states for the first time that "it is generally accepted in the medical community that the greater the exposure of the cornea to microorganisms such as bacteria/and or fungi, the greater the risk of corneal infection." This opinion was not only new, it was offered without citation to a single medical article or medical treatise. Indeed, Dr. Cohen's published literature demonstrates that even she recognizes that there is no general acceptance of her statement. In an article co-authored by plaintiffs' expert entitled *Methods of Disinfecting Contact Lenses to Avoid Corneal Disorders*,[33] the authors discuss contamination of lens care systems with microorganisms, noting the high rate of contamination among contact lens wearers.[34] Importantly,

the authors observe "contamination is not consistently correlated with a higher rate of microbial keratitis."[35]

Plaintiffs' expert's opinions continued to change even during the joint *Frye/Daubert* hearing. During cross examination Dr. Cohen retreated from several of her opinions when confronted with contradictory information. Specifically, she relied on a temperature test showing that MoistureLoc failed biocidal efficacy testing against certain organisms when exposed to extreme heat (60° Celsius (140° Fahrenheit)), for eight days.[36] The test data showed that, under these extreme conditions, MoistureLoc failed to meet FDA standards for Staphylococcus and Candida, but passed all standards for Fusarium, Pseudomonas, and Serratia.[37] Dr. Cohen could not reconcile the inconsistency between these test results and her opinion that if MoistureLoc lost efficacy it would be ineffective against all organisms. Instead of providing a scientific explanation, Dr. Cohen distanced herself from her prior opinion, saying "I don't think that this heat is the biggest aspect of its loss of efficacy because all of the data is that the unopened bottle was effective."[38] Similarly, she retreated from her position that all microorganisms reacted similarly to MoistureLoc, saying "I don't think it has to be identical with every stress for every organism."[39]

Dr. Cohen's changing opinions, and willingness to abandon or qualify her opinions when faced with further facts, undermines the reliability of her opinions. In *Haller v. AstraZeneca Pharms. LP*, the court rejected just this kind of "moving target" opinion under *Daubert:*

> Beyond the problems associated with the way in which Dr. Tulloch reached his opinions, the stark fact is that the grounds for his causation opinion have been a veritable moving target. And what is most troubling is that the underpinnings of his opinions have changed in direct response to AstraZeneca's motion practice.

598 F.Supp.2d 1271, 1296–97 (M.D.Fla.2009). The same concerns raised by the Court in *Haller,* are present here.

ii. Failure to Address Contradictory Data

***14** Bausch & Lomb's experts discussed four published studies regarding keratitis infections during the time MoistureLoc was on the market and explained why these studies contradicted any opinion that MoistureLoc usage was related to an increased risk of non-Fusarium infections. Dr. Cohen did not address these studies in her expert reports or affidavit,[40] and did not include them on her literature reviewed list.[41] At the *Daubert* hearing, Dr. Cohen never discussed these studies. This failure to address this contrary data renders plaintiffs' theory inherently unreliable. *See* In re *Bextra & Celebrex Prod. Liab. Litig.*, No. 762000/2006, 2008 N.Y. Misc. LEXIS 720, at *47 (Sup.Ct. N.Y. Co. Jan 7, 2008) (stating that plaintiffs must show that their experts "do not ignore contrary data").

iii. Method of Reaching Opinion Not Presented

The *Daubert* inquiry focuses on the expert's methodology and its underlying validity. *Daubert,* 509 U.S. at 592–93. Yet Dr. Cohen never articulated the method she used to arrive at her conclusions. Dr. Cohen never articulated what her hypothesis was, what evidence she considered, and why that evidence led her to either accept or reject her hypothesis. Dr. Cohen failure to clearly articulate her method is particularly concerning here, where her opinions contain numerous analytical leaps and extrapolations.

In combination, these considerations demonstrate that the general causation opinions of plaintiffs' expert and the methodology behind those opinions do not meet the *Daubert* standard for scientific reliability, and accordingly must be excluded.

IV. CONCLUSION

For the foregoing reasons, it is hereby **ORDERED** defendant Bausch & Lomb's motion to exclude the opinions of plaintiff's expert Dr. Elisabeth Cohen related to non-Fusarium infections is **GRANTED.**

The court need not reach Bausch & Lomb's motion to strike Dr. Cohen's May 18, 2009 affidavit because the inclusion of the challenged affidavit does not change the result of the court's ruling on the *Daubert* motion.

AND IT IS SO ORDERED.

All Citations

Not Reported in F.Supp.2d, 2009 WL 2750462, 80 Fed. R. Evid. Serv. 649

Footnotes

1 Docket Entry 175, MDL No. 1785, C/A No. 2:06–77777–DCN (filed May 15, 2009).

2 Docket Entry 179, MDL No. 1785, C/A No. 2:06–77777–DCN (filed May 28, 2009).

3 For the reasons stated herein, the court need not reach Bausch & Lomb's motion to strike Dr. Cohen's May 18, 2009 affidavit.

4 *See*21 C.F.R. § 886.5928.

5 ISO 14729, Sec. 4.I. at 2.

6 *Id.*

7 *See* Ex. 1 to Def.'s Mem. In Support of Motion to Exclude, MDL No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 175 (Deposition of Dr. Elisabeth Cohen at 67:12–68:9).

8 *See* Ex. 8 to Def.'s Mem. In Support of Motion to Exclude, MDL No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 175 (Douglas C. Chang et al., *Multistate Outbreak of Fusarium Keratitis Associated with Use of a Contact Lens Solution,* 296 J. AM. MED. ASS'N. 953, 953 (2006)); Cohen Dep. at 154:3–14).

9 Chang et al. at 954; Cohen Depo. at 148:21–149:10.

10 *See* Ex. 9 to Def.'s Mem. In Support of Motion to Exclude, MDL No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 175 (Brian Levy et al., *Report on Testing from an Investigation of Fusarium Keratitis in Contact Lens Wearers,* 32 EYE & CONTACT LENS 256, 256 (2006)).

11 Cohen Dep. at 413:8–415:17.

12 Testimony of Oliver Schein at 488:25–490:5 (*Daubert* Hearing (June 5, 2009)).

13 Levy et al. at 260.

14 Levy et al. at 260; Chang et al. at 954. Unlike the United States, Singapore had pre-existing data on the baseline rate of Fusarium keratitis among contact-lens wearers. *See* Levy et al. at 260.

15 *See* Ex. 10 to Def.'s Mem. In Support of Motion to Exclude, MDL No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 175 (*Contact Lens Related Fusarium Keratitis Investigation Summary* ("Fusarium Investigation Report,") at 2).

16 Levy et al. at 260; Chang et al. at 959.

17 *See* Ex. 11 to Def.'s Mem. In Support of Motion to Exclude, MDL No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 175 (United States Centers for Disease Control and Prevention, *Fusarium Keratitis—Multiple States, 2006,* 55 *MMWR,* Apr. 10, 2006, at 1–2).

18 Levy et al. at 260; Chang et al. at 959.

19 *See* Exhibits 12 and 13 to Def.'s Mem. In Support of Motion to Exclude, MDL No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 175 (Deposition of Angela Panzarella at 1066:2–16; Deposition of Brian Levy at 40:5–23, 207:19–208:11).

20 Chang et al. at 954, 956.

21 *Id.* at 961.

22 *See* Exhibits 14 and 15 to Def.'s Mem. In Support of Motion to Exclude, MDL No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 175 (Seang–Mei Saw et al., *Risk Factors for Contact Lens–Related Fusarium Keratitis: A Case–Control Study in Singapore,* 125 ARCHIVES OF OPHTHALMOLOGY 611, 611 (2007); Edmond Ma & Kellie So, *Epidemiology of Fusarium Keratitis in Hong Kong,*COMMUNICABLE DISEASES WATCH, May 28–June 10, 2006, at 45, 46 (2006)).

23 The joint *Frye/Daubert* hearing was held in recognition of the importance of coordinating related Federal and State litigation in order to reduce costs and delays. *See*Manual for Complex Litigation [Fourth] §§ 20, 20.31.

24 *See* Bausch & Lomb Contact Lens Solutions Product Liability Litigation, Index No. 766000/2007 (July 15, 2009). This court greatly benefits from Justice Kornreich's thorough and well-reasoned analysis.

25 In addition to Dr. Cohen, the New York plaintiffs submitted the opinions of two expert witnesses not offered in the MDL litigation.

26 *See* Plt's Mem. in Opp'n to Def.'s Motion to Exclude, at 8(MDL Docket No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 177), and Ex. H thereto (Cohen Aff. (May 18, 2009)).

27 *See* May 28, 2009 letter from Mitchell Breit to Eric Anielak (Ex. E to Def.'s Motion to Strike, MDL Docket No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 185).

28 *See* Ex. 22 to Def.'s Mem. In Support of Motion to Exclude, MDL No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 175 (Supplemental Expert Report of Stephen Spiegelberg at 2). Dr. Spiegelberg explained that:

> Two hundred eighty three returns were tested for Fusarium, and all showed greater than 2 log kill (BL002144896–921). Testing for C albicans (49 returns tested) and S. aureus (50 tested) showed that MoistureLoc was highly effective. Eighteen hundred retained samples were tested for Fusarium in the bottle, and all came back negative, while 1,785 of these retains were tested for Fusarium killing efficacy, and all showed greater than 2.0 log kill; 99.2% showed greater than 3 log kill (BL002144836–895). Similar results were obtained for these retained samples challenged with S. aureus, C. albicans, P. aeruginosa and S. marcescens (BL002144836–895).
> *Id.* at 2–3.

29 *See* Plt's Mem. in Opp'n to Def.'s Motion to Exclude, at 8; Cohen Aff.

30 Cohen Dep. at 413:8–415:17; 412:18–21.

31 Q. Okay, Doctor, before our break I think we established that as far as you know there is no epidemiologic study out, published epidemiologic study that shows an increased risk of non-Fusarium keratitis with MoistureLoc users; right?

> A. Not to my knowledge.
> Q. Okay, and there's also no case report published out there where a doctor suggests that non-Fusarium keratitis was associated with the use of MoistureLoc; right?
> A. Not yet.

Cohen Dep. at 274:25–275–11

32 *Id.* at 289:22–290.

33 *See* Ex. F to Plt's Mem. in Opp'n to Def.'s Motion to Exclude, at 8 (MDL Docket No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 177).

34 *Id.* at 245.

35 *Id.* at 246.

36 *See Daubert* Hr'g at 380:12–16, Exs. CC, H.

37 *See Daubert* Hr'g Exs. CC & FF.

38 *See Daubert* Hr'g 390:14–19.

39 *Id.* at 391:23–392:3.

40 *See* Ex. 6 (Expert Report of Elisabeth Cohen); Ex. 7 (Supplemental Expert Report of Elisabeth Cohen); Ex. 1 (Daubert Hearing Ex. H); to Def.'s Post–Hearing Brief (MDL Docket No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 199).

41 *See* Ex. 2 (Cohen Dep., Ex. 14), to Def.'s Post–Hearing Brief (MDL Docket No. 1785, C/A No. 2:06–77777–DCN, Docket Entry 199).

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