EXHIBIT 14

LEXSEE 2007 U.S. DIST. LEXIS 40002

MICHELL REDFOOT, individually and as guardian ad litem for ALEXANDER REDFOOT, Plaintiff, v. B.F. ASCHER & COMPANY, et al., Defendants.

No. C 05-2045 PJH

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

2007 U.S. Dist. LEXIS 40002

June 1, 2007, Decided
June 1, 2007, Filed

COUNSEL: [*1] For Alexander Redfoot, a minor by and through his Guardian Ad Litem Michell Redfoot, Michell Redfoot, Plaintiffs: C. Andrew Waters, Paul C. Cook, Waters & Kraus, LLP, El Segundo, CA.; Dana C. Fox, Julie L Celum, Dallas, TX.; Jeffrey A. Kaiser, Laurel L. Simes, Levin Simes Kaiser & Gornick LLP, San Francisco, CA.

For B.F. Ascher & Company, Defendant: Robert B. Leck, III, LEAD ATTORNEY, Leck and Associates, Santa Monica, CA.

For Kolmar Laboratories Inc., Defendant: Robert Joseph Brown, LEAD ATTORNEY, Law Offices of Dennis P. Isaac, San Francisco, CA.; Laura Sagmeister-Flynn, Mark F. Hazelwood, Low, Ball & Lynch, San Francisco, CA.; Robert B. Leck, III, Leck and Associates, Santa Monica, CA.

JUDGES: PHYLLIS J. HAMILTON, United States District Judge.

OPINION BY: PHYLLIS J. HAMILTON

OPINION

ORDER GRANTING MOTION TO EXCLUDE EVIDENCE AND ORDER GRANTING MOTION FOR SUMMARY JUDGMENT

Defendants' motion to exclude testimony of plaintiff's experts and motion for summary judgment came on for hearing before this court on April 11, 2007. Plaintiff appeared by her counsel Jonathan George, defendant B.F. Ascher & Company ("BFA") appeared by its counsel Robert Leck, and defendant Kolmar Laboratories, [*2] Inc. ("Kolmar") appeared by its counsel Laura S. Flynn and Mark F. Hazelwood. Having read the parties' papers and carefully considered their arguments, and good cause appearing, the court hereby GRANTS the motions.

INTRODUCTION

This is a products liability case. Defendant Kolmar manufactures a nasal spray called "Ayr Saline Nasal Mist," and BFA distributes it. Plaintiff Michell Redfoot administered Ayr Saline Nasal Mist to her son Alexander for nasal congestion, starting in 2000 when Alexander was two months old, and continuing until he was three or four years old. Plaintiff claims that Ayr Saline Nasal Mist was defective in design in 2000 because it was made with thimerosal, a preservative that contains ethylmercury. Plaintiff asserts that Alexander's ingestion of the thimerosal caused him to develop Pervasive Developmental Disorder or Autistic Spectrum Disorder ("autism").

In the first amended complaint ("FAC"), plaintiff alleges causes of action for strict products liability and failure to warn, against BFA and Kolmar; negligence and failure to warn, against BFA and Kolmar; intentional or reckless concealment of known defective and dangerous conditions associated with use [*3] of Ayr Saline Nasal Mist, against BFA and Kolmar; negligence per se, against BFA and Kolmar; and an undefined claim incorporating products liability, failure to warn, negligence, and misrepresentation, against Kolmar and ten "manufacturer, distributor, supplier" DOE defendants.

Plaintiff seeks compensatory damages, and also seeks punitive damages, based on defendants' alleged prior knowledge of an unacceptable risk of injury resulting from the use of the nasal spray, and defendants' alleged intentional failure to reveal the hazards of the product.

BFA and Kolmar now seek an order excluding the testimony of plaintiff's expert Dr. Mark Geier, as well as the testimony of plaintiff's "non-retained" experts, Dr. James Bradstreet, Dr. George W. Lucier, Dr. Boyd Haley, and Dr. Arthur Krigsman.

BFA and Kolmar also seek summary judgment, claiming a lack of evidence sufficient to establish either general causation or specific causation -- i.e., either that thimerosal in nasal spray causes autism, or that the thimerosal in Ayr Saline Nasal Mist caused Alexander's autism. They also assert that plaintiff has no evidence proving that defendants concealed and/or failed to disclose a known defective [*4] or dangerous condition, or that defendants made misrepresentations regarding the safety of thimerosal; and no evidence sufficient to support an award of punitive damages.

BACKGROUND

Many biological products (including vaccines and nasal saline products) contain a preservative to prevent the growth of microbial contaminants. Thimerosal has been used in biologicals since about 1930. In the body, it breaks down into ethylmercury and another compound. See generally *Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 2007 U.S. Dist. LEXIS 22998, 2007 WL 957337 at *1-2 (E.D. Pa., March 28, 2007).*

In July 1999, a review conducted by the Food and Drug Administration ("FDA") of the United States Department of Health and Human Services concluded that the use of thimerosal as a preservative in vaccines might result in the intake of mercury during the first 6 months of life that exceeded the Environmental Protection Agency's guidelines for average daily exposure to methylmercury in seafood. [1] Concurrently, the American Academy of Pediatrics ("AAP") issued a notice indicating a preference for thimerosal-free vaccines, but expressly approving vaccines containing thimerosal if that were the [*5] only alternative. Numerous lawsuits were subsequently filed under the National Childhood Vaccine Injury Compensation Act of 1986, *42 U.S.C. § 300aa-1, et seq.* ("the Vaccine Act"), asserting that exposure to thimerosal from recommended childhood vaccines had caused a novel form of mercury poisoning that manifests as autism. [2]

1 The *ethyl*mercury that is in thimerosal is different from *methyl*mercury, the mercury compound that causes the more familiar type of mercury poisoning -- e.g., from eating fish contaminated with mercury.

2 The Vaccine Act provides that vaccine-injury cases are to be brought in the United States Court of Federal Claims ("the Vaccine Court"). The Vaccine Act provides for a "no-fault" system of compensation; the petitioner need prove neither fault nor causation -- only that he received the vaccine and suffered certain symptoms within a defined period. See *42 U.S.C. §§ 300aa-13, 300aa-14*. If a plaintiff elects to proceed through the state or federal courts instead of accepting the judgment of the Vaccine Court, the types of claims he/she may bring are limited. See *Sykes, 2007 U.S. Dist. LEXIS 22998, 2007 WL 957337 at *6*.

Plaintiff here has also filed a claim in the Vaccine Court, alleging that the thimerosal in Alexander's childhood vaccines caused his autism and/or neurological problems. See Redfoot v. Secretary of Health and Human Services, Case No. 03-vv-02801-UNJ (U.S. Court of Federal Claims, filed Dec. 10, 2003). The Vaccine Court has consolidated more than 4750 autism cases into a single proceeding, in which a hearing on general causation is tentatively set for June 11-29, 2007. All the cases have been stayed pending that hearing.

[*6] The National Institutes of Health ("NIH") and

the Centers for Disease Control and Prevention ("CDC") of the United States Department of Health and Human Services requested that the Institute of Medicine of the National Academies ("IOM" -- a component of the National Academy of Sciences) review the issues raised by the vaccine litigation. The IOM's Immunization Safety Review Committee investigated the hypothesized relationship between thimerosal-containing vaccines and neurodevelopmental outcomes (specifically, autism, attention deficit/hyperactivity disorder, and speech or language delay).

In 2001, following its investigation, the IOM Committee issued a report ("the 2001 IOM Report"), [3] in which it found that

> although the hypothesis that exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders is not established and rests on indirect and incomplete information, primarily from analogies with methylmercury and levels of maximum mercury exposure from vaccines given to children, the hypothesis is biologically plausible. [4]

The Committee noted that the available case reports were "uninformative with respect to causality," that there [*7] were "no published epidemiological studies examining the potential association between thimerosal-containing vaccines and neurodevelopmental disorders," and that the unpublished and limited epidemiological studies provided "only weak and inclusive evidence regarding the hypothesis that exposure to thimerosal-containing vaccines may lead to certain neurodevelopmental disorders."

> 3 Institute of Medicine of the National Academies, National Academy of Sciences, Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders (2001).
> 4 Institute of Medicine of the National Academies, National Academy of Sciences, Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders (Executive Summary) (2001).

Because the evidence was "inadequate to accept or reject a causal relationship between exposure to thimerosal from vaccines and neurodevelopmental disorders of autism, ADHD, and speech or language delay," the Committee recommended further epidemiological, [*8] clinical, and basic science research, including "research on how children, including those diagnosed with neurodevelopmental disorders, metabolize and excrete metals -- particularly mercury."

In May 2004, following further review of the evidence on both sides, including presentations by three of the experts designated by plaintiff in this case, and the researchers on whose studies they rely, the IOM's Immunization Safety Review Committee issued another report -- the "2004 IOM Report" [5] -- in which it concluded that "the body of epidemiological evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." [6]

> 5 Institute of Medicine of the National Academies, National Academy of Sciences, Immunization Safety Review: Vaccines and Autism (2004).
> 6 Institute of Medicine of the National Academies, National Academy of Sciences, Immunization Safety Review: Vaccines and Autism (Executive Summary) (2004).

The Committee added, "In the absence of experimental or [*9] human evidence that vaccination [with thimerosal-containing vaccines] affects metabolic, developmental, immune, or other physiological or molecular mechanisms that are causally related to the development of autism, the committee concludes that the hypotheses generated to date are theoretical only." The Committee recommended that available funding for autism research should instead be "channeled to the most promising areas."

In September 2004, the AAP published an article in its journal Pediatrics concluding that

> [s]tudies do not demonstrate a link between thimerosal-containing vaccines and [Autistic Spectrum Disorder], and the pharmacokinetics of ethylmercury make such an association less likely. Epidemiologic studies that support a link demonstrated significant design flaws that invalidate their conclusions. Evidence

> does not support a change in the standard of practice with regard to the administration of themerosal-containing vaccines in the areas of the world where they are used. [7]

> 7 Parker, S.K., et al., "Thimerosal-Containing Vaccines and Autistic Spectrum Disorder: A Critical Review of Published Original Data," 114 Pediatrics 793-804 (2004).

[*10] In addition, after further research and much debate on the potential for harm from thimerosal-containing vaccines, scientific and medical organizations worldwide have rejected the hypothesis that thimerosal-containing pediatric vaccines cause or contribute to autism. In addition to the IOM and the AAP, these include the FDA, the World Health Organization ("WHO"), the CDC, the U.K. Committee on the Safety of Medicines, and the European Agency for the Evaluation of Medicinal Products. [8]

> 8 See United States Department of Health & Human Services, Food and Drug Administration, Docket No. 2004P-0349/CP1 (response to citizen petition, Sept. 26, 2006); World Health Organization, Global Advisory Committee on Vaccine Safety, Report of Committee Meeting 2-3 December 2004; United States Centers for Disease Control, National Immunization Program, "Thimerosal & Vaccines, Q&A," available at http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/facts-thimerosal.htm (last visited May 30, 2007); Committee on Safety of Medicines (U.K.) Annual Report for 2003; European Agency for the Evaluation of Medicinal Products, March 24, 2004.

[*11] **DISCUSSION**

A. Motion to Exclude Expert Testimony

1. Legal Standard

Federal Rule of Evidence 702 permits testimony by experts qualified by "knowledge, skill, expertise, training, or education," to testify "in the form of an opinion or otherwise" based on "scientific, technical, or other specialized knowledge" if that testimony will "assist the trier of fact to understand the evidence or to determine a fact in issue." *Fed. R. Evid. 702*. The expert's testimony must be based on "sufficient facts or data," it must be "the product of reliable principles and methods," and the expert must have "applied the principles and methods reliably to the facts of the case." Id.

The proponent of expert testimony bears the burden of establishing by a preponderance of the evidence that the admissibility requirements are met. See id., Advisory Committee Notes. Although there is a presumption of admissibility, *Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 588, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)*, the trial court is obliged to act as a "gatekeeper" with regard to the admission of expert scientific testimony under *Rule 702*. [*12] *Id. at 597*. "This entails a preliminary assessment of whether the reasoning or methodology is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id. at 592-93*.

Thus, the district court is required to undertake a two-part analysis. First, the court must determine whether an expert's testimony reflects "scientific knowledge," whether the findings are "derived by the scientific method," and whether the work product is "good science" -- in other words, whether the testimony is reliable and trustworthy. *Id. at 590 & n.9, 593*. Second, the court must determine whether the testimony is "relevant to the task at hand." *Id. at 597*.

Scientific evidence is reliable if it is based on an assertion that is grounded in methods of science -- the focus is on principles and methodology, not on conclusions. *Metabolife Int'l v. Wornick, 264 F.3d 832, 841 (9th Cir. 2001)*. In determining whether an expert's reasoning or methodology is scientifically valid, the district court can consider "many factors," including (1) whether the scientific theory or technique [*13] can be (or has been) tested, (2) whether the theory or technique has been subjected to peer review and publication, (3) whether a particular technique has a known potential rate of error, and (4) whether the theory or technique is generally accepted in the relevant scientific community. *Daubert, 509 U.S. at 593-94*.

The Supreme Court has indicated that

> the test of reliability is "flexible," and Daubert's list of specific factors neither necessarily nor exclusively applies to all experts or in every case. Rather, the law

> grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination.

Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141-42, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999). Thus, other factors that might be considered include whether an expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion, see *General Elec. Co. v. Joiner, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997)*; or whether an expert has adequately accounted for obvious alternative explanations, see *Claar v. Burlington Northern R. Co., 29 F.3d 499, 502 (9th Cir. 1994)*. [*14]

Rule 702's second prong concerns relevancy, or "fit." See *Daubert, 509 U.S. at 591*. The trial court "must ensure that the proposed expert testimony . . . logically advances a material aspect of the proposing party's case." *Daubert v. Merrill Dow Pharms, Inc., 43 F.3d 1311, 1315 (9th Cir. 1995)*. "[T]he standard for fit is higher than bare relevance." *In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 745 (3d Cir. 1994)*.

Finally, even under Daubert, the district court must still weigh the balancing factors of *Federal Rule of Evidence 403*. Specifically, *Rule 403* permits the exclusion of relevant evidence "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." See *Daubert, 509 U.S. at 595*.

2. Defendants' Motion

Defendants seek an order precluding the proposed opinion testimony of plaintiff's experts. They seek to preclude testimony that thimerosal in Ayr Saline Nasal Mist can contribute to the development of autism, as well as testimony that there is a genetically vulnerable sub-population of children [*15] whose ability to excrete mercury is impaired, resulting in an increased risk of autism from exposure to thimerosal-containing nasal spray.

Defendants also seek an order precluding Drs. Haley, Bradstreet, and Krigsman from offering any opinions in the areas of epidemiology, genetics, neurology, or toxicology; precluding Dr. Geier from offering any opinion in the areas of epidemiology, neurology, or toxicology; and precluding Dr. Lucier from offering any opinion in the areas of epidemiology, neurology, or genetics.

a. Dr. Geier

Dr. Geier is a medical doctor, with a Ph.D. in genetics. He specializes in obstetrical genetics, and is board-certified in medical genetics and forensic medicine. He worked as a researcher at the NIH for ten years, and was a professor at Johns Hopkins University. He is president of his own company -- Genetic Centers of America -- and has been in clinical practice for more than 25 years.

In addition, Dr. Geier has studied vaccines for more than 30 years, and has published numerous scientific/medical papers on vaccine safety, efficacy, contamination, and policy. He has been invited to make presentations to the IOM and other scientific bodies regarding adverse [*16] consequences of vaccines.

Dr. Geier is plaintiff's sole causation expert. In his report, he offers opinions regarding both general and specific causation. First, based on a review of scientific literature and on twelve of his own published studies [9] (plus four studies unpublished as of the date of his report), he asserts that the mercury in thimerosal causes neurological damage, including the development of autistic disorders in children. Second, based on his examination and testing of Alexander, he contends that Alexander suffers from a neurodevelopmental disorder -- "the apparent result of a toxic encephalopathy" -- and that Alexander presents with "clinical symptoms consistent with a DSMIV criteria autistic disorder;" that the toxic encephalopathy was "significantly contributed to by mercury exposure from the [t]himerosal-containing nasal spray he was administered;" that Alexander has biochemical and genomic markers indicating "heightened sensitivity to mercury;" and that he has laboratory test results consistent with "increased mercury."

> 9 Geier, D.A. & Geier, M.R. (2003a), "An Assessment of the Impact of Thimerosal on Childhood Neurodevelopmental Disorders," 6 Pediatr. Rehabil. 97-102 (2003); Geier, M.R. & Geier, D.A. (2003b), "Thimerosal in Childhood Vaccines, Neurodevelopmental Disorders, and Heart Disease in the United States," 8 J. Am. Phys. Surg. 6-11 (2003); Geier, M.R. & Geier D.A. (2003c), "Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief

Communication," 228 Exp. Biol. Med. (Maywood) 660-64 (2003); Geier, M.R. & Geier, D.A. (2004a), "A Review of the Vaccine Adverse Event Reporting System Database," 5 Expert Opin. Pharmacother 691-98 (2004); Geier, D.A. & Geier, M.R. (2004b), "Neurodevelopmental Disorders following Thimerosal-Containing Childhood Immunizations: A Follow-up Analysis," 23 Int. J. Toxicol. 369-76 (2004); Geier, D.A. & Geier, M.R. (2005(a), "A Two-phased Population Epidemiological Study of the Safety of Thimerosal-Containing Vaccines: A Follow-up Analysis," 11 Med. Sci. Monit. CR 160-70 (2005); Geier, M.R. & Geier, D.A. (2005b), "The Potential Importance of Steroids in the Treatment of Autistic Spectrum Disorders and Other Disorders Involving Mercury Toxicity," 64 Med. Hypotheses 946-54 (2005); Geier, D.A. & Geier, M.R. (2006a), "An Evaluation of the Effects of Thimerosal on Neurodevelopmental Disorders reported following DTP and Hib Vaccines in Comparison to DPTH Vaccine in the United States," 69 J. Toxicol. Environ. Health A. 1481-95 (2006); Geier, D.A. & Geier, M.R. (2006b), "Early Downward Trends in Neurodevelopmental Disorders Following Removal of Thimerosal-Containing Vaccines." 11 J. Am. Phys. Surg. 8-13 (2006); Geier, D.A. & Geier, M.R. (2006c), "An Assessment of Downward Trends in Neuro-developmental Disorders in the United States following the Removal of Thimerosal from Childhood Vaccines," 12 Med. Sci. Monit. CR2310-19 (2006); Geier, D.A. & Geier, M.R. (2006d), "A Prospective Assessment of Porphyrins in Autistic Disorders: A Potential Marker for Heavy Metal Exposure," 10 Neurotox. Res. 57-64 (2006); Geier, D.A. & Geier, M.R. (2006e), "A Clinical and Laboratory Evaluation of Methionine Cycle-transsulfuration and Androgen Pathway Markers in Children with Autistic Disorders," 66 Horm. Res. 182-88 (2006).

[*17] Defendants argue that an analysis of Dr. Geier's proposed testimony shows that it should be excluded under *Rule 702*. Defendants contend, first, that Dr. Geier lacks the requisite qualifications; second, that he employed unacceptable methodology; third, that the peer-reviewed literature contradicts Dr. Geier's conclusions, and that his studies are not generally accepted; fourth, that Dr. Geier's opinion testimony is not grounded in reliable epidemiological studies; and fifth, that Dr. Geier's opinions were formulated for litigation, and demonstrate evidence of bias.

Defendants first argue that Dr. Geier is not qualified to provide an opinion regarding whether the mercury in thimerosal-containing nasal sprays causes autism, or regarding whether Alexander has autism or whether the thimerosal in Ayr Saline Nasal Mist caused him to develop autism. A witness can testify on the basis of knowledge, skill, experience, training, or education. *Fed. R. Evid. 702*. Defendants contend that Dr. Geier is not qualified to testify on the subjects as to which he offers his opinions because, while he is a medical doctor with a Ph.D in genetics, he is not board-certified [*18] in pediatrics or pediatric neurology, and is not certified as an epidemiologist, a biostatistician, or a toxicologist.

Plaintiff argues, however, that Dr. Geier is qualified to provide expert testimony regarding thimerosal, mercury, and autism. Plaintiff claims that Dr. Geier has studied vaccines for more than thirty years, and has published more than 50 peer-reviewed scientific/medical papers on vaccine safety, efficacy, contamination, and policy, including more than twelve articles dedicated to the issue of thimerosal, mercury, and neurological disorders, including autism. Plaintiff also asserts that Dr. Geier has been qualified as an expert witness in numerous courts to testify regarding thimerosal in vaccines.

Defendants' second argument is that Dr. Geier did not employ acceptable methodology in arriving at his opinions. They contend that Dr. Geier's review of the scientific literature does not establish that Ayr Saline Nasal Mist causes autism, and that Dr. Geier's own studies have an unknown and indeterminate rate of error.

Defendants first note that Dr. Geier relied on a number of disparate and unconnected studies -- including some by plaintiff's "non-retained experts" Drs. [*19] Haley and Lucier -- to support his conclusion that the undetermined but small amount of thimerosal received by Alexander could cause autism.

In a case brought in the Middle District of North Carolina, *Doe v. Ortho-Clinical Diagnostics, Inc., 440 F.Supp. 2d 465 (M.D.N.C. 2006)*, the court granted the defendant's motion to exclude Dr. Geier as an expert on the question whether a thimerosal-containing RH-factor

immunoglobulin administered to the mother of a child (once before the birth of her child and once after) caused the child to develop autism. As in the present case, Dr. Geier based his opinion on a review of scientific literature, on his own studies, and on a differential diagnosis of the child.

With regard to the literature review, the court observed that Dr. Geier had "relied on a number of disparate and unconnected studies . . . to reach a piecemeal conclusion with respect to general causation," and that his methodology "consisted of attempting to connect various individual studies." *Id. at 472-73*. The court also found that Dr. Geier's analysis, "based on his collective review of a motley assortment of diverse literature," proved to be "overstated. [*20] " *Id. at 473-74*.

As did the Doe court with respect to similar literature, see *id. at 472-73 & nn. 6-13*, defendants argue Dr. Geier has attempted to cobble together a theory of causation based on disparate studies in which the researchers found, for example, that mercury exposure may destroy neurons; [10] that high levels of pre-natal methylmercury may cause developmental defects; [1111] that methylmercury can be transmitted through a mother's milk to her child; [10] that thimerosal can cross blood-brain and placental barriers at doses of 1000 micrograms of thimerosal; [11] that direct and multiple injections of 50,000 micrograms of thimerosal can kill or deform embryonic chickens; [12] that a mouse model exposed to thimerosal mimicking a childhood immunization schedule developed symptoms allegedly similar to autism; [11] that thimerosal-containing vaccines may cause a novel form of mercury poisoning in some children; [12] and that a study of hair of children with autism showed a statistically significant correlation between RhoD (RH-factor) immunoglobulin administration and autism. [13] Defendants contend that these disconnected studies do not add up to [*21] the opinion Dr. Geier is offering.

10 Baskin, D.S., et al., "Thimerosal Induces DNA Breaks, Caspase-3 Activation, Membrane Damage, and Cell Death in Cultured Human Neurons and Fibroblasts," 74 Toxicol. Sci. 361-68 (2003).

11 Grandjean, P., et al., "Cognitive Performance of Children Prenatally Exposed to 'Safe' Levels of Methylmercury," 77 Environ. Res. 165-72 (1998).

10 Amin-Zaki L., et al., "Methylmercury Poisoning in the Iraqi Suckling Infant: A Longitudinal Study over Five Years," 1 J. Appl. Toxicol. 210-24 (1981).

11 Slikker, W., "Developmental Neurotoxicology of Therapeutics: Survey of Novel Recent Findings," 21 Neurotoxicology 250 (2000).

12 Digar, A., et al., "Lethality and Teratogenicity of Organic Mercury (Thimerosal) on the Chick Embryo," 36 J. Anat. Soc. India 153-59 (1987)..

11 Hornig, M., et al., "Neurotoxic Effects of Postnatal Thimerosal are Mouse Strain Dependent," 9 Mol. Psychia. 833-45 (2004).

12 Bernard, S., et al., "Autism: A Novel Form of Mercury Poisoning," 56 Med. Hypoth. 462-71 (2001).

13 Holmes, A.S., et al., "Reduced Levels of Mercury in First Baby Haircuts of Autistic Children," 22 Int. J. Toxicol. 277-85 (2003).

[*22] As for Dr. Geier's own studies, defendants argue that Dr. Geier employed a flawed methodology. They note that the IOM, in its 2004 Report, discussed five of Dr. Geier's studies (including the three studies identified in note 9, above, as Geier 2003a, 2003b, and 2003c) and two reports presented by Dr. Geier to the IOM in 2004. Among other things, the Committee found that Dr. Geier's studies lacked a complete and transparent description of their methods and underlying data -- noting in particular that Dr. Geier had provided no information on specification of regression models, had not provided the frequency distribution of variables, and had not clearly reported calculations of statistics. As a result of these deficiencies, the Committee found the results of the studies to be "improbable," "uninterpretable," and "noncontributory with respect to causality."

In opposition, plaintiff contends that Dr. Geier's reliable and peer-reviewed epidemiological studies support general causation -- i.e., that exposure to thimerosal, generally, is a cause of autism.

In their third argument, defendants contend that Dr. Geier's studies are not generally accepted in the scientific community, and that [*23] the peer-reviewed literature flatly contradicts Dr. Geier's conclusions. Dr. Geier has published [14] a number of articles purporting to find a statistically significant link between thimerosal-containing vaccines and autism. These studies

utilize data from the Vaccine Adverse Event Reporting System ("VAERS") database and/or the Department of Education ("DOE") database. Dr. Geier has also performed an analysis of Vaccine Safety Datalink ("VSD") data. Defendants argue that these databases do not contain sufficient or appropriate data to test a hypothesized association between thimerosal-containing vaccines and autism, and that Dr. Geier's studies are therefore methodologically unsound.

14 Defendants do not contest that Dr. Geier's articles have appeared in numerous journals, but they do claim, based on the statements by one of their experts (Dr. Rodier), that some of the journals in which Dr. Geier's studies have been published are "weak" journals, not widely read in the scientific community. For example, they assert that Medical Hypotheses is not peer-reviewed for science content, but rather offers a forum for "radical ideas" that "conflict with current theory and practice" (citing from the journal's website). They also claim that it is not widely read. They contend that Journal of American Physicians and Surgeons is a political journal dealing with the rights of physicians in private practice, and is not indexed in PubMed or in Journal Citations Reports. They claim that the Medical Science Monitor is indexed by PubMed but not by Journal Citation Reports, and is an obscure journal published in Poland. They assert that Journal of the History of Medicine and Allied Science is a history journal, not widely read. They contend that no scientist, by choice, would submit his study for publication in a journal that is not widely read.

[*24] Defendants also contend that Dr. Geier's VAERS studies have met with almost universal scorn from the scientific community. For example, the 2004 IOM Report found the fact that Dr. Geier's studies relied on analyses of VAERS data to draw conclusions about causality to be "[a] major problem" (referring to Geier 2003a, 2003b, and 2003c, in note 9, above). The IOM Report described VAERS as a "passive reporting system that accepts voluntary reports from health care providers, vaccine recipients, manufacturers, and others regarding potential adverse events." Those adverse events are not formal case reports, but rather are descriptions of symptoms that are temporally associated with receipt of a vaccine or vaccines. The Report noted that "[a]ll adverse event reports are accepted into VAERS regardless of whether the vaccine plausibly caused the adverse event." The Report concluded that VAERS might be useful in "generating hypotheses," but that further validation and studies would be required before any conclusions on causality could be drawn. In other words, the VAERS data, alone, cannot support a determination of whether a vaccine was more likely than not to have caused an adverse event.

[*25] The IOM Report also stated that "the DOE dataset that [Dr. Geier] use[s] as the basis for the autism prevalence estimates has significant limitations" (referring to Geier 2003a, and to a 2004 study not cited in Dr. Geier's report in the present case). These limitations "can bias the autism prevalence estimates and make it difficult to interpret trends over time." The IOM Report concluded that Dr. Geier's studies based on the DOE data were "uninterpretable and therefore non-contributory with respect to causality."

The IOM Report found that epidemiological studies examining thimerosal-containing vaccines and autism had consistently provided evidence of no association between thimerosal-containing vaccines and autism, despite the fact that those studies utilized different methods and studied different populations in Sweden, Denmark, the United States, and the United Kingdom. The Report noted that other studies -- specifically referring to the Geier studies -- had reported finding an association, but also noted that the Geier studies had "serious methodological flaws" and "nontransparent" analytical methods, making their results uninterpretable and noncontributory toward causality. [*26] Based on this evidence, the Committee concluded that "evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism."

In May 2003, the AAP issued an official statement criticizing Dr. Geier's 2003 VAERS study, stating that it "uses data from the [VAERS] inappropriately and contains numerous conceptual and scientific flaws, omissions of fact, inaccuracies, and misstatements." The statement added that Geier "failed to acknowledge the inherent limitations of the VAERS database when drawing conclusions of adverse event associations contained in this report and . . . other publications," and that Geier was "equally unclear" as to how the data were generated, thus preventing accurate review of his methods and replication of their outcomes." [15]

15 American Academy of Pediatrics. "Study Fails to Show a Connection Between Thimerosal and Autism," available at http://www.aap.org/profed/thimaut-may03.htm (last visited May 30, 2007).

Defendants also cite to the September 2004 [*27] AAP Report, in which an in-depth analysis addressed the issue of thimerosal-containing vaccines as a possible cause of autistic spectrum disorders and neurodevelopmental disorders. The report examined many of the same studies discussed by the parties here, including four of Dr. Geier's studies (three using the VAERS database and one using the DOE database). The authors of the AAP report concluded that Dr. Geier's studies "contain critical methodological flaws that render the data and their interpretation noncontributory."

As for the articles published by Dr. Geier since the 2004 IOM Report, defendants contend that all of Dr. Geier's work since 2004 involves correlation studies based on databases from VAERS, DOE, VSD, BSS, and others, and that those newer studies are flawed for the same reason as the older ones -- reliance on passive reporting data to make causal connections. Defendants contend that correlation studies may be useful to the CDC, FDA, or others to assess the safety of vaccines and other substances -- i.e., to suggest a relationship between a substance and an injury -- but argue that they cannot be used to make causality conclusions.

Defendants argue that in view [*28] of the fact that Dr. Geier's studies are methodologically flawed and have been deemed "uninterpretable" by the relevant scientific community, those studies cannot constitute reliable epidemiological evidence prerequisite to the admission of expert opinions on general causation. They contend that plaintiff's allegation that thimerosal in nasal spray causes autism is entirely based on the earlier, and now rejected, hypothesis of a link between thimerosal in vaccines and autism.

They also contend that the peer-reviewed literature flatly contradicts Dr. Geier's conclusion that Ayr could cause autism, in that the literature -- based on multiple, well-designed, well-conducted epidemiological studies -- contradicts the hypothesis that thimerosal-containing vaccines cause autism.

In opposition, plaintiff contends that Dr. Geier's epidemiological studies are peer-reviewed, generally accepted, and reliable. Plaintiff notes that Dr. Geier has published twelve articles dealing with the subject of thimerosal and/or autism, and that defendants have cited only four of those. Plaintiff argues that the opinions of scientific organizations like the IOM, the CDC, and the AAP cannot trump the opinions [*29] of editors of scientific journals. Plaintiff also asserts Dr. Geier's articles can be found in the Hazardous Study Database of the U.S. Library of Medicine -- all tagged "peer reviewed" -- which plaintiff argues is evidence of a "super peer reviewed source."

With regard to the arguments concerning the VAERS database, plaintiff claims that VAERS, despite its limitations, has repeatedly been used by the CDC and the FDA to epidemiologically evaluate vaccine safety. Plaintiff contends that the methodology used by Dr. Geier (comparing the incidence rate of reported adverse effects following one vaccine with the incidence rate of the reported adverse events of another vaccine administered to a similarly aged population) was developed by scientists working for the CDC.

Plaintiff asserts that Dr. Geier's studies regarding the effect of thimerosal in vaccines found a statistically significant six-fold increased relative risk of autism in children who had received vaccines with thimerosal. Plaintiff contends that "the known rate of error is minimal as the results regarding autism are statistically significant and expressed with at least a 95% confidence interval and control outcomes yielded [*30] no increased risk."

Defendants' fourth argument is that Dr. Geier's opinion is not grounded in reliable epidemiological studies. Epidemiology is concerned with the incidence of disease in human populations. Thus, it is probative of general causation. *In re Silicone Gel Breast Implants Products Liab. Litig., 318 F.Supp. 2d 879, 892 (C.D. Cal. 2004)* (citing Reference Manual on Scientific Evidence (Fed. Judicial Center, 2d ed. 2000)). Defendants argue, however, that there are not only no peer-reviewed epidemiological studies suggesting a link between thimerosal in nasal sprays and autism, there are not even any reliable studies demonstrating a link between thimerosal-containing vaccines and autism.

Defendants note that several controlled, epidemiological studies that examined the link between exposure to thimerosal-containing vaccines and the development of autism have been published in peer-reviewed journals. Those studies are referred to as

the Hviid 2003 Study, the Verstraeten 2003 Study, the Andrews 2004 Study, and the Jick 2004 Study. [16] Defendants assert that those studies all reached the same conclusion -- no connection between the thimerosal-containing [*31] vaccines and autism. Defendants argue in addition that two additional published studies -- the Madsen Study and the Stehr-Green Study -- are consistent with the finding of no association between thimerosal-containing vaccines and autism. [17]

16 Hviid, A., et al., "Association between Thimerosal-Containing Vaccine and Autism," 290 JAMA 1763-1766 (2003); Verstraeten, T., et al., "Safety of Thimerosal-Containing Vaccines: A two-phased Study of Computerized Health Maintenance Organization Databases," 112 Pediatrics 1039-48 (2003); Andrews, N., et al., "Thimerosal Exposure in Infants and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association," 114 Pediatrics 584-91 (2004); Jick, H. & Kaye, J., "Autism and DPT Vaccinations in the United Kingdom," 350 Engl. J. Med. 2722-23 (2004).

17 Madsen, K., et al., "Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data," 112 Pediatrics 604-06 (2003); Stehr-Green, P., "Thimerosal and Thimerosal-Containing Vaccines, Lack of Consistent Evidence of an Association," 25 Am. J. Prev. Med. 101-06 (2003).

[*32] Defendants contend that plaintiff's witnesses ignore the weight of reliable epidemiology demonstrating no evidence of any association. They note that the IOM Committee, in its 2004 Report, considered all these studies as well as Dr. Geier's studies and concluded that the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism.

In opposition, plaintiff asserts that the studies cited by defendants are irrelevant and carry little weight. Plaintiff contends that the Stehr-Green Study had serious methodological limitations, in part because it was based on data that seriously under-reported the number of cases of autism, and that Hviid and Madsen studied the same population as Stehr-Green. Plaintiff also asserts that Andrews and Jick, which used the General Practice Research Database in the U.K. cannot be compared to the U.S. studies because the total thimerosal exposure in the U.S. was higher. Plaintiff claims that Verstraeten is the only study that looked at U.S. children, and submits that Verstraeten's conclusion was that additional study was needed, not that there was no association between thimerosal and autism.

In their fifth argument, [*33] defendants contend that Dr. Geier's opinions were formulated for litigation, and demonstrate evidence of bias. They note that Dr. Geier has published no papers and expressed no opinions on thimerosal-containing nasal spray and autism before this litigation. They also contend that he has called the CDC a "rogue organization" and an "organization out of control," which they submit reflects his potential bias.

Plaintiff denies, however, that Dr. Geier became interested in autism and thimerosal only at the time he began appearing as an expert witness on the subject. Plaintiff claims that Dr. Geier submitted his first article on thimerosal and autism for publication in August 2002, well before the complaint in Doe v. Ortho (in which he testified as an expert for the plaintiffs) was filed, and asserts that all four of the articles cited by defendants were accepted for publication before the Doe v. Ortho case was filed.

The court finds that the motion must be GRANTED, because plaintiff has not met her burden of showing that Dr. Geier's testimony is admissible. As an initial matter, the court notes that Dr. Geier is not qualified as a pediatrician, a neurologist, a toxicologist, [*34] or an epidemiologist, either by background or training. He is a medical doctor and a geneticist, but has no specialization in any of the relevant medical areas.

In particular, there is no evidence that Dr. Geier has either the training or the background to diagnose autism or to treat autism in any child. Simply having an "interest" in vaccines and the possible connection between thimerosal-containing vaccines and the development of neurodevelopmental disorders in children is not sufficient to qualify an individual as an expert in either pediatrics or neurology, or regarding the various forms of mercury and their neurotoxicity.

In addition, Dr. Geier's testimony is not reliable. While his studies have been "peer reviewed," in the sense that they have been published in scientific journals, they have been severely criticized by the IOM, the AAP, and

others. In particular, both the AAP and the IOM have pointed out the problems inherent in studies that rely on the VAERS database.

It is also true that Dr. Geier has been designated as an expert witness in about 100 cases before the Vaccine Court. However, in some of those cases, particularly the more recent ones, his opinion testimony [*35] has been excluded or accorded little or no weight beyond a determination that he was testifying beyond his expertise. See, e.g., *Doe v. Ortho, 440 F.Supp. 2d at 471-72*.

Dr. Geier's report contains his opinions regarding the capability of the mercury in thimerosal to cause neurological damage. However, many of the sources he cites (including a number of his own studies) pre-date the 2004 conclusions by the AAP, the NIH, and the CDC that ingestion of small amounts of thimerosal does not cause autism. In addition, much of the published literature focuses on the effects of exposure to methylmercury, not ethylmercury.

Dr. Geier has failed to point to a single study that has conclusively established that the amount of thimerosal contained in the Ayr Saline Nasal Mist could cause autism, and has failed to point to a single study that conclusively determined that any amount of mercury could cause the specific neurological disorder of autism. As an example, the Burbacher studies cited by plaintiff involved injecting monkeys with thimerosal in doses that would approximate the U.S. vaccination schedule -- not the minuscule amounts present in nasal spray -- and there is no evidence [*36] supporting a hypothesis that ethylmercury entering the blood system of a child would approximate ethylmercury entering the blood supply of a monkey. [18]

> 18 In general, "[e]xtrapolations of animal studies to human beings are generally not considered reliable in the absence of a scientific explanation of why such extrapolation is warranted." *Hall v. Baxter Healthcare Corp., 947 F.Supp. 1387, 1410 (D.Or. 1996)*.

In short, Dr. Geier's opinions cannot be used to establish causation because they do not address whether thimerosal in nasal sprays is capable of causing autism. While it is true that Dr. Geier has published more than 50 scientific or medical papers, none was on the subject of thimerosal in nasal spray. All Dr. Geier's studies have focused on vaccines.

Nor can his methodology support a finding that Alexander's autism was caused by ingestion of thimerosal in Ayr Saline Nasal Mist. Dr. Geier is not qualified by training or experience to provide an opinion as to the cause of Alexander's [*37] autism, and is not qualified to perform a differential diagnosis of autism. As defendants have persuasively argued, Dr. Geier's differential diagnosis is faulty because he failed to consider one specific alternative explanation -- that the cause of autism is not known today. Moreover, the differential diagnosis he did provide is incomplete, because he did not rule out the unspecified cause of dysgenesis (a brain malformation).

b. Drs. Lucier, Haley, Bradstreet, and Krigsman.

Plaintiff has also designated four "non-retained experts" -- George Lucier, Ph.D.; Boyd Haley, Ph.D.; James Bradstreet, M.D.; and Arthur Krigsman, M.D. Plaintiff describes them as "non-retained experts" based on the fact that they are not being compensated by plaintiff for their time and/or testimony and because plaintiff did not request that they prepare a report.

Plaintiff states that each of these "non-retained experts" will or may testify as to many of the subjects as to which plaintiff designated Dr. Geier to testify -- e.g., the use of thimerosal as a preservative in pediatric vaccines; the neurological effect of exposure to thimerosal; the differences between methylmercury and ethylmercury; defendants' [*38] knowledge of the alleged potential hazards of thimerosal; and the asserted conflicts of interest between "members of the vaccine industry" and the authors of published articles concerning thimerosal, the journals that have published such articles, and governmental and non-governmental agencies such as the CDC, the FDA, the NIH, and the WHO.

Defendants assert that the witnesses are not qualified by knowledge, experience, or training to give these opinions. Dr. Lucier is a retired toxicologist whose doctorate is in entomology. Defendants contend that he is not qualified to testify as to the subjects listed in the expert disclosure because he is not a geneticist, neurologist, or epidemiologist, and because he is an expert on methylmercury, not ethylmercury.

Dr. Haley is a chemistry professor. Defendants argue that he is not qualified to testify as to the subjects listed in the expert disclosure because he has no special training in toxicology, epidemiology, genetics, or neurology.

They also claim that his opinions about mercury and neurodevelopmental injuries have been rejected by at least two courts.

Dr. Bradstreet is a medical doctor who is a family practitioner. Defendants assert [*39] that he is not qualified to testify as to the subjects listed in the expert disclosure because he is not board-certified in any specialty, does not maintain hospital privileges, and has no specialized training in epidemiology, neurology, toxicology, or genetics.

Dr. Krigsman is a gastroenterologist. Defendants contend that he is not qualified to testify as to the subjects listed in the expert disclosure because he is not trained as a toxicologist. They also note that no CV was provided for Dr. Krigsman, and assert that he is apparently involved in the evaluation of gastrointestinal symptoms of autistic children.

Defendants argue in addition that Drs. Lucier and Haley cannot be considered "non-retained experts" because they never treated Alexander and have provided no expert reports.

The court finds that the motion must be GRANTED as to Drs. Lucier and Haley, because they submitted no expert reports and are not Alexander's treating physicians. The motion must be GRANTED as to Drs. Bradstreet and Krigsman because, even though they are Alexander's treating physicians, it appears that plaintiffs are seeking to have them offer true "expert" opinion, about matters as to which they are [*40] not percipient witnesses, rather than having them testify about Alexander's diagnosis, treatment, or prognosis.

Each expert who may be called upon to give opinion evidence at trial under *Rule 702, 703,* or *705* must be identified. *Fed. R. Civ. P. 26(a)(2)*. Some of these experts are required to provide a written report, containing a complete statement of all opinions to be expressed and the basis and reasons, and certain other information. See *Fed. R. Civ. P. 26(a)(2)(B)*. A report must be provided for each expert who is "retained or specially employed" to provide expert testimony at the trial; or who is employed by a party and whose duties regularly involve giving expert testimony (i.e., in-house experts). Id.

Treating physicians must be identified as expert witnesses pursuant to *Rule 26(a)(2)(A)*. However, to the extent that their testimony is based on their own diagnosis and treatment, treating physicians are not "retained or specially employed" to render opinion testimony, nor are they "regularly employed" for such a purpose. Therefore, they are not subject to the "report" requirement of *Rule* [*41] *26(a)(2)(B)*, and courts generally allow treating physicians for whom no expert witness report has been provided to testify as to their opinions on causation, diagnosis, prognosis, extent of disability, or other matters based on their treatment of a party. Schwarzer, Tashima & Wagstaffe, Federal Civil Procedure Before Trial (2006) § 11:381.

Thus, a treating physician can testify concerning the existence and cause of a diagnosed medical condition suffered by a plaintiff without first submitting the written report required under the expert disclosure rule. However, a report would be required if the plaintiff anticipated that the physician's testimony would approach an area not sufficiently related to the information disclosed during the plaintiff's care and treatment. See *First Nat'l Mortg. Co. v. Fed. Realty Inv. Trust, 2006 U.S. Dist. LEXIS 57113, 2006 WL 2228941 at *14 (N.D. Cal., Aug. 3, 2006)* ("The majority rule is that '*Rule 26(a)(2)(B)* reports are not required as a prerequisite to a treating physician expressing opinions as to causation, diagnosis, prognosis, and extent of disability, where they are based on the treatment"); see also Rangasan v. Hawaiian Tug & Barge Corp., 2000 WL 1569285 at *3 (D. Haw., Apr. 6, 2000); [*42] *Rebolledo v. Herr-Voss Corp., 101 F.Supp. 2d 1034, 1038-39 (N.D. III. 2000)*; *Brown v. Best Foods, 169 F.R.D. 385, 387-89 (N.D. Ala. 1996)*; *Bucher v. Gainey Transp. Serv. of Indiana, Inc., 167 F.R.D. 387, 390 (M.D. Pa. 1996)*.

Some courts have extended the "treating physicians" rule to other experts whose opinion testimony is based on matters personally observed or experienced by them. Since by definition they are not "retained or specially employed" to render an opinion, no expert witness report is required. Schwarzer, et al., § 11:385 (citing *Sprague v. Liberty Mut. Ins. Co., 177 F.R.D. 78, 80-81 (D.N.H. 1998))*. For example, a psychologist need not provide an expert report to give opinion testimony about his treatment of the plaintiff. Id.

Here, none of the four "non-retained experts" provided an expert report by the December 16, 2006, deadline for disclosure of expert witnesses. Two of the four are Alexander Redfoot's treating physicians. As such, they would be permitted to testify as to matters

concerning his care and treatment. However, they were not properly designated [*43] as experts to testify as to all the subjects listed in the expert disclosure, because they did not provide any expert reports.

B. Motion for Summary Judgment

1. Legal Standard

Summary judgment is appropriate when there is no genuine issue as to material facts and the moving party is entitled to judgment as a matter of law. *Fed. R. Civ. P. 56*. Material facts are those that might affect the outcome of the case. *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986)*. A dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party. Id. The court may not weigh the evidence, and is required to view the evidence in the light most favorable to the nonmoving party. Id.

A party seeking summary judgment bears the initial burden of informing the court of the basis for its motion, and of identifying those portions of the pleadings and discovery responses that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986)*. Where the moving party will have the burden of proof at [*44] trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. On an issue where the nonmoving party will bear the burden of proof at trial, the moving party can prevail merely by pointing out to the district court that there is an absence of evidence to support the nonmoving party's case. Id.

If the moving party meets its initial burden, the opposing party must then set forth specific facts showing that there is some genuine issue for trial in order to defeat the motion. See *Fed. R. Civ. P. 56(e)*; *Anderson, 477 U.S. at 250*. Regardless of whether plaintiff or defendant is the moving party, each party must "establish the existence of the elements essential to [its] case, and on which [it] will bear the burden of proof at trial." *Celotex, 477 U.S. at 322*.

2. Defendants' Motion

Defendants argue that summary judgment must be granted on the claims of products liability and negligence because plaintiff cannot establish the essential element of causation; that the federal regulation cited by plaintiff in support of the cause of action for negligence [*45] per se does not apply to Ayr Saline Nasal Mist; and that there is no evidence to support the intentional causes of action or the claim for punitive damages.

a. products liability and negligence

Defendants assert that Ayr Saline Nasal Mist contains only a trace amount (2.5 ppm, or 0.00025%) of thimerosal. They contend that all plaintiff's claims hinge upon establishing a causal link between exposure to thimerosal at this level (or at any level) and the onset of autism, and argue that summary judgment must be granted as to the products liability and negligence claims because plaintiff cannot establish causation.

Federal district courts sitting in diversity apply state law to product liability claims. *Stilwell v. Smith & Nephew, Inc., 482 F.3d 1187, 1193-94 (9th Cir. 2007)*. Under California law, causation in a personal injury action must be proven within a reasonable medical probability based on competent expert testimony. *Jones v. Ortho Pharm. Corp., 163 Cal. App. 3d 396, 402, 209 Cal. Rptr. 456 (1985)*, cited in *Kennedy v. Southern Cal. Edison Co., 268 F.3d 763, 768 (9th Cir. 2001)*. Mere possibility alone is insufficient to establish a prima facie case. [*46] *Id. at 403*.

Causation in toxic tort cases is typically discussed in terms of "generic" (or "general") and "specific" (or "individual") causation. See *In re Hanford Nuclear Reservation Litig., 292 F.3d 1124, 1133 (9th Cir. 2002)*. General causation is defined to mean "whether the substance at issue had the capacity to cause the harm alleged," while specific causation refers to "whether a particular individual suffers from a particular ailment as a result of exposure to a substance." Id. (citations omitted).

Here, the key components of plaintiff's general causation opinion are that (1) thimerosal-containing nasal spray causes autism (2) in the same manner and at the same doses as thimerosal-containing vaccines (3) in a genetically vulnerable sub-population of children whose ability to excrete mercury is impaired. Defendants contend that plaintiff has failed to produce reliable scientific evidence that establishes that thimerosal in saline nasal sprays has the capacity of causing autism in infants.

Similarly, defendants argue that neither Dr. Geier's

differential diagnosis or any other evidence can establish that the thimerosal in the Ayr Saline Nasal Mist caused [*47] Alexander's autism. Differential diagnosis [19] is an acceptable source of data on specific causation, but cannot establish general causation because differential diagnosis assumes that general causation has been proven for a list of possible causes it eliminates. See, e.g., *Hall, 947 F.Supp. at 1413*. Defendants also assert that Dr. Geier is not a pediatrician, a pediatric neurologist, or an expert on autism, and is therefore not qualified to give an opinion on the cause of Alexander's autism. Defendants argue that Dr. Geier formed his opinions based on a review of relevant literature and his own studies relating to the incidence of autism to support a conclusion of general causation.

> 19 "Differential diagnosis" is "the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings." Stedman's Medical Dictionary 474 (26th ed. 1995), quoted in *Clausen v. M/V New Carissa, 339 F.3d 1049, 1057 (9th Cir. 2003)*. Courts that have discussed differential diagnosis have come to use the term in a slightly different way than it is used in the medical community, however. "Whereas physicians use the term to describe the process of determining which of several diseases is causing the plaintiff's symptoms, . . . courts have used the term in a more general sense to describe the process by which causes of the plaintiff's condition are identified." *Clausen, 339 F.3d at 1057 n.4* (citations omitted).

[*48] Defendants argue further that plaintiff cannot establish specific causation because Dr. Geier's differential diagnosis does not rule out possible alternative causes of Alexander's autism. They contend that Dr. Geier failed to acknowledge the one conclusion that is generally accepted in the medical community with regard to the cause of autism -- that its cause is currently unknown. They assert that Dr. Geier's failure to take into account the existence of such a strong likelihood of a currently unknown cause of autism serves to negate the reliability of his differential diagnosis. In addition, they contend that Dr. Geier failed to rule out all pre-exposure illnesses and conditions. For example, they note, he failed to mention that Alexander was macrocephalic at birth, and also failed to mention that there is a family history of speech and developmental delays.

In opposition, plaintiff argues that she has presented sufficient reliable and valid evidence of both general and specific causation to raise a triable issue. Plaintiff contends that multiple peer-reviewed epidemiologic studies have demonstrated a dose-response relationship between thimerosal and autism, and that, even at low [*49] levels, exposure to thimerosal increases the risk of developing autism. Plaintiff argues further that competent, consistent peer-reviewed published clinical, biological, and genomic evidence supports the causal relationship between thimerosal and autism. Plaintiff also claims that the epidemiological studies that seem to support a refutation of the causal nexus between thimerosal and autism suffer from methodological flaws, and are, therefore, inconclusive.

With regard to specific causation, plaintiff argues that Dr. Geier's opinion that Alexander's autism was caused by exposure to the thimerosal in Ayr Saline Nasal Mist is based on proper methodology and reliable data. Plaintiff asserts that Dr. Geier reviewed Alexander's past medical history, performed a physical evaluation, had tests conducted to rule out genetic causes of autism, and reviewed biochemical and genomic markers. Plaintiff also claims that Dr. Geier was able, based on experience, to engage in "differential diagnosis" to rule out other causes of Alexander's autism.

Plaintiff contends that reliable data supports Dr. Geier's conclusion -- a brain CT scan, a Woods Lamp exam, an abdominal ultrasound, urine organic acid [*50] testing, plasma amino acid testing, DNA testing, a physical exam, and clinical observation -- and that by conducting these tests and examining Alexander, Dr. Geier eliminated all alternate causes. Plaintiff also asserts that lab testing showed "increased body burden of mercury" and that biochemical and genomic testing revealed markers indicating that Alexander had an impaired ability to detoxify the increased mercury in his body, resulting in a heightened sensitivity to the detrimental impact of the thimerosal.

The court finds, however, that the motion must be GRANTED because plaintiff has not established a genuine issue of fact as to either general or specific causation. In addition, without evidence of a causal connection between Ayr Nasal Saline Mist and Alexander's autism, plaintiff cannot maintain the failure-to-warn claim.

The only evidence provided to support causation is the report and opinion of Dr. Geier. Because the court has found, however, that Dr. Geier's testimony must be excluded because he is not qualified as a pediatrician, neurologist, toxicologist, or epidemiologist, and because the opinion is not reliable, plaintiff has no evidence of causation.

In addition, [*51] plaintiff has cited no reliable, peer-reviewed epidemiological studies showing a causal link between the administration of thimerosal-containing nasal spray and the onset of autistic disorder. As defendants assert, multiple reliable epidemiological studies have consistently found no evidence of any association between thimerosal-containing vaccines and autism. Plaintiff presents no reliable scientific evidence either that thimerosal is toxic to humans at the incremental doses delivered by nasal sprays; or that thimerosal is toxic to humans at the doses delivered by thimerosal-containing vaccines; or that there is an identified sub-population of children who are genetically vulnerable to mercury neurotoxicity; or that mercury can cause neurological damage that manifests as autism.

b. negligence per se

Defendants argue that summary judgment must be granted on the fourth cause of action for negligence per se, asserted against BFA and Kolmar.

Plaintiff alleges in the FAC that defendants' failure to warn plaintiff of the dangers associated with the use of thimerosal and/or thimerosal-containing Ayr Saline Nasal Mist violates the federal ban on thimerosal products (referring to *63 Fed. Reg. 19799* [*52] *(Apr. 22, 1998))*.

Defendants argue, however, that the referenced regulation was part of the FDA's review under the Drug Efficacy Study Implementation Program in which panels of experts reviewed data for over-the-counter drugs on the market, and that the final regulation amended *21 C.F.R. § 310.545* to require removal of thimerosal only when used as an active ingredient in first-aid antiseptic drug products. Defendants assert that the FDA did not put a "federal ban" on thimerosal, as plaintiff alleges.

In opposition, plaintiff claims to have presented sufficient evidence to raise a triable issue regarding negligence per se and negligence, and even to award punitive damages. Plaintiff suggests that it is not important whether or not the FDA banned thimerosal in 1998, because "the authorities advised of potential concerns regarding thimerosal." Plaintiff also asserts that defendants have admitted that they violated California safety regulations (referring to Proposition 65) from 1990 to 2001 by failing to warn as required. [20]

20 The California Safe Drinking Water and Toxic Enforcement Act of 1986, *Health & Safety Code § 25249, et seq.*, commonly referred to as "Proposition 65," was passed by the California voters as a ballot initiative in 1986. Proposition 65 requires the state to develop and maintain a list of chemicals "known to the state to cause cancer or reproductive toxicity," *Health & Saf. Code § 25249.8(a)*, and also requires businesses provide warnings before consumers are exposed to such chemicals, see id. *§ 25249.6*.

[*53] In support of this argument, plaintiff cites to the deposition of BFA's designated corporate representative, Christopher Ascher. Ascher testified that he learned from others at BFA of the potential hazards of mercury in 1999 or 2000; that he was aware that it was the seller's obligation to disclose to the public potentially dangerous ingredients in its products; that BFA never changed its label for Ayr to indicate that it contained mercury, despite the fact that people in the company knew that Ayr contained thimerosal and that thimerosal contained mercury; that BFA had never done any research or testing to see whether Ayr might have a toxic effect on humans or infants; that the Consumer Healthcare Products Association (an industry lobbying group) was lobbying on BFA's behalf to allow mercury-containing products to be sold; that BFA had never provided the warning required by California under Proposition 65. Plaintiff asserts that this type of conduct clearly demonstrates a conscious disregard for the safety of consumers and others.

The court finds that summary judgment must be GRANTED on the claim of negligence per se. The regulation cited by plaintiff in the FAC refers to first-aid [*54] antiseptic products only, not to nasal spray. Moreover, plaintiff did not allege any violation of California law in the FAC as the basis for the claim of negligence per se, and cannot now attempt to argue negligence per se based on an alleged failure warn in compliance with Proposition 65.

c. concealment/nondisclosure and punitive damages

Defendants argue that summary judgment must be granted on the third cause of action for intentional or reckless concealment of known defective or dangerous conditions associated with use of Ayr Saline Nasal Mist, asserted against BFA and Kolmar; on the fifth cause of action for products liability, failure to warn, negligence, and misrepresentation, asserted against Kolmar and the 10 DOE "manufacturer defendants;" and on the claim for punitive damages.

In the FAC, plaintiff alleges that defendants were aware of the mercury content of thimerosal and the dangers to human life caused by the mercury content of Ayr Nasal Saline Mist, and that they failed to warn consumers or to recall the product from the marketplace. Plaintiff also asserts that Kolmar made misrepresentations regarding the safety of thimerosal to manufacturers of thimerosal-containing [*55] products and to plaintiff. In support of the claim for punitive damages, plaintiff alleges that defendants intentionally failed to reveal their knowledge of the hazards of the product and fraudulently concealed that knowledge from those who used the product.

In California, punitive damages may be awarded only where the plaintiff establishes by clear and convincing evidence that the defendant has been guilty of "oppression, fraud, or malice." *Cal. Civ. Code § 3294(c).* Punitive damages may be awarded in a products liability action only if the plaintiff shows that the defendant placed a product on the market in conscious disregard for the safety of consumers and others. It is not sufficient for the plaintiff to show only that the defendant acted unreasonably. *Ehrhardt v. Brunswick, Inc., 186 Cal. App. 3d 734, 741-42, 231 Cal. Rptr. 60 (1986).*

Defendants argue that there is no evidence in this case of any despicable conduct by either of the defendants. They assert that there is no evidence that the thimerosal contained in the Ayr Saline Nasal Mist administered to Alexander posed any threat to human health -- and that, indeed, the FDA came to the general conclusion, [*56] after looking at all the evidence, that thimerosal in nasal products does not pose a threat to human health. Defendants also argue that there is no reliable evidence in the case that the nasal spray caused Alexander's autism, and that the reliable scientific studies have rejected any such causal connection.

Defendants contend that plaintiff cannot present any evidence of actual knowledge or recognition by any responsible employee of either defendant that Ayr Saline Nasal Mist had any dangerous propensities in terms of its effect on human life, as disclosed by reliable scientific studies.

In opposition, plaintiff argues that BFA had actual knowledge that mercury was dangerous and that thimerosal contained mercury, and that BFA was obligated to warn its customers if it was selling a product that was dangerous to human health.

The court finds that the motion for summary judgment must be GRANTED. Plaintiff cannot prevail on the products liability claim or the negligence claim because she cannot show that Alexander's autism was caused by the Ayr Saline Nasal Mist. Plaintiff presents no evidence, other than Dr. Geier's studies, showing any connection between thimerosal and autism, and [*57] no studies at all showing a connection between thimerosal in nasal sprays and autism. As indicated above, in the discussion of defendants' Daubert motion, Dr. Geier is not qualified by training or experience to express an opinion as to what caused Alexander's autism, because he is not qualified in any of the relevant disciplines. Moreover, since there is no evidence that there is any medical consensus as to what causes autism in general, Dr. Geier's opinions cannot be used to show that Alexander's autism was caused by the Ayr Saline Nasal Mist.

Plaintiff cannot prevail on the failure-to-warn or concealment/misrepresentation claims because she cannot show injury/causation -- thus, there was nothing to conceal or warn about. The evidence shows that Ascher, BFA's Executive Vice President of Marketing and Sales, was designated the person most knowledgeable regarding the issue of "sales" at BFA. There is no evidence that plaintiff took Ascher's deposition on the subject of the labeling of Ayr Saline Nasal Mist.

Moreover, general questions regarding the hazards of mercury (such as those posed to Ascher) are not relevant to the present action. The issue on which plaintiff is required [*58] to produce evidence is whether Ayr Saline Nasal Mist, containing 0.00025% thimerosal, was dangerous. Plaintiff has not produced any such evidence, and summary judgment must therefore be GRANTED on the intentional causes of action and on the claim of negligence.

In addition, plaintiff has produced no evidence

whatsoever regarding Kolmar's liability for failure to warn, negligence per se, concealment, or intentional conduct. Thus, summary judgment must also be GRANTED as to all causes of action asserted against Kolmar.

C. Defendants' Objections to Evidence

Defendants have filed objections to the evidence provided by plaintiff in support of their opposition to the Daubert motion and their opposition to the motion for summary judgment. The court does not consider these objections, as none of the evidence to which defendants object formed the basis of the court's rulings on the two motions.

CONCLUSION

In accordance with the foregoing, the court GRANTS defendants' motion to exclude expert testimony and motion for summary judgment. The trial date is VACATED. The clerk shall close the file.

IT IS SO ORDERED.

Dated: June 1, 2007

PHYLLIS J. HAMILTON

United [*59] States District Judge