IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

JOHN AND JANE DOE 2, INDIVIDUALLY, and as GUARDIANS AD LITEM, OF MINOR CHILD DOE 2,	)	
Plaintiffs,	)	
v.	)	1:03CV00669
ORTHO-CLINICAL DIAGNOSTICS, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION

BEATY, District Judge.

Plaintiffs John and Jane Doe 2 ("Plaintiffs") have initiated this lawsuit based upon their contention that the thimerosal in Defendant Ortho-Clinical Diagnostics, Inc.'s ("Ortho-Clinical" or "Defendant") biologic product RhoGAM caused their child's autism. This matter is presently before the Court on three motions: Defendant's Motion to Exclude All Testimony that Thimerosal-Containing RhoGAM Causes Autism [Document #63], Defendant's Motion to Exclude Plaintiffs' Expert Suzanne Parisian, M.D. [Document #65], and relatedly, Defendant's Motion for Summary Judgment [Document #94]. The Court heard testimony concerning Defendant's motions to exclude witnesses for three days at the end of May 2006. Based upon the testimony at that hearing, the Court will grant Defendant's Motion to Exclude All Testimony that Thimerosal-Containing RhoGAM Causes Autism. More specifically, the focus of the

Court's present Memorandum Opinion is the testimony of Plaintiffs' expert witness, Dr. Mark Geier. Dr. Geier was the only expert offered in this case by Plaintiffs who is designated to testify as to both general *and* specific causation. For the reasons given by the Court herein, Dr. Geier's testimony is specifically being excluded pursuant to Defendant's Motion to Exclude. As such, without Dr. Geier's testimony, Plaintiffs are unable to meet their burden to demonstrate that the thimerosal in Defendant's RhoGAM product caused Plaintiff Minor Child Doe 2's autism, a result that leads directly to the failure of all of Plaintiffs' claims. Accordingly, for the reasons detailed below, the Court will also grant Defendant's Motion for Summary Judgment.

I. FACTUAL BACKGROUND[1]

Plaintiffs allege that Minor Child Doe 2 ("Minor Child Doe") has suffered severe neurodevelopmental disorders and permanent injuries from exposure to toxic levels of mercury. Plaintiffs claim that this mercury exposure resulted from one single shot of RhoGAM that Jane Doe received while 28-weeks pregnant and another shot of RhoGAM that Jane Doe received shortly after Minor Child Doe's birth.[2] Plaintiffs argue that this limited amount of thimerosal,

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[1] The Court in this Memorandum Opinion will refer to some scholarly works and other documents that were attached to Defendant's Brief in Support of the Motion to Exclude All Testimony that Thimerosal-Containing RhoGAM Causes Autism. For ease in citing to these articles, the Court will refer to the Appendix filed by Defendants and located in the record as Documents ##67-70. The format for such references will be "Def. Apx. Tab #, name of article, p.#." In other instances, the Court will refer to articles discussed by either Plaintiffs' or Defendant's experts during the hearing, and will cite those articles as appropriate.

[2] RhoGAM is used to suppress the immune response of Rh negative women to Rh positive red blood cells. This treatment is used whenever it is suspected that fetal red blood cells have entered the circulation of an Rh negative mother, unless either the fetus or the father is

which contains a mercury derivative, in both of those shots given to his mother caused Minor Child Doe to develop autism approximately sixteen months after his birth. Based upon these allegations, Plaintiffs' several claims against Defendant consist of the following: (1) negligence; (2) negligent failure to warn; (3) breach of express warranty; (4) breach of implied warranty; (5) negligent misrepresentation; (6) intentional misrepresentation and fraud; (7) unfair and deceptive trade practices; (8) inadequate design; (9) negligent infliction of emotional distress; (10) gross negligence; (11) loss of consortium; and (12) punitive damages. It is significant to the Court's ultimate disposition of this matter that the viability of all of the listed claims hinge on Plaintiffs' ability to prove that the thimerosal in RhoGAM caused Minor Child Doe's autism.

In order to prove their claims, Plaintiffs designated three experts on the question of whether thimerosal could cause autism: Dr. Mark Geier ("Geier"), Boyd Haley, Ph.D. ("Haley") and George Lucier, Ph.D. ("Lucier"). As a separate matter, Plaintiffs have designated a fourth expert, Dr. Suzanne Parisian, to testify about the FDA regulatory process as it relates to claims regarding negligent failure to warn and inadequate design. The Court conducted a Daubert hearing in this matter that included the testimony of Dr. Geier, as well as testimony from several of Defendant's experts who asserted that Dr. Geier's methodology that supports his proffered opinion on the causal connection, both general and specific causation, as it relates to the autism

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shown to be Rh negative. Without such treatment, the immune response of the mother could cause Hemolytic Disease of the Newborn, which in turn may lead to perinatal injury or death.

of Minor Child Doe, was flawed, as well as his conclusions in that regard.[3]

II. THE DAUBERT STANDARD

The nature and necessity of a Daubert hearing is derived from the case of Daubert v. Merrell Dow Pharms., 509 U.S. 579, 113 S. Ct. 2786 (1993). Under Daubert, this Court must rule on the admissibility of expert scientific testimony. See id. at 598, 113 S. Ct. at 2799. Daubert requires a two-part analysis: first, this Court must determine whether an expert's testimony reflects "scientific knowledge," whether the findings are "derived by the scientific

[3] At the hearing, Plaintiffs also made available expert reports from their other two experts, Dr. Haley and Dr. Lucier, as to the general causation question. The Court has appropriately taken this information into account, but nevertheless finds that Dr. Haley's report does not state an expert opinion that thimerosal causes autism, rather just that he has a *theory*, (see Def. Apx. Tab 18, Dep. of Boyd Haley, at 190), about how such a thing could happen. At best, he expressed "strong belief" that the cause of "neurodevelopmental disorders in infants" is exposure to an organic-mercury compound such as thimerosal. (See Def. Apx. Tab. 14, Haley Expert Report, p. 5.) Additionally, Plaintiffs proffered the report of Dr. Lucier, who is an expert in *methyl*mercury and not *ethyl*mercury, which is the substance in RhoGAM. Dr. Lucier does not offer an opinion that methylmercury causes autism, but rather that it may cause "developmental disorders." Significantly, the Court notes that neither Dr. Haley nor Dr. Lucier asserts that he is an expert on autism nor are they offered as such. In any event, the Court finds that neither of the proffered reports of Dr. Haley nor Dr. Lucier are sufficiently reliable under Daubert on the general causation issue because neither is relevant to the "task at hand." It would be an unacceptable scientific leap to suggest that they serve as proof, by a preponderance of the evidence, of Plaintiff's claim that the thimerosal in RhoGAM can cause autism. See Dunn v. Sandoz Pharms. Corp., 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003) ("While hypothesis is essential in the scientific community because it leads to advances in science, speculation in the courtroom cannot aid the fact finder in making a determination of whether liability exists. Ultimately, speculation is unreliable evidence and is inadmissible."). Accordingly, the majority of the Court's opinion is focused only on the testimony of Dr. Geier, Plaintiffs' primary general causation expert and single specific causation expert. Nevertheless, it is the Court's finding that the discussion and analysis herein regarding the relevant scientific literature applies equally to the proffered reports of Drs. Haley and Lucier, which also purport to survey the relevant literature in coming to their respective conclusions.

method," and whether the work product is "good science." Id. at 590 & 593, 113 S. Ct. at 2795 & 2797. Second, this Court must determine whether the expert's testimony is "relevant to the task at hand." Id. at 597, 113 S. Ct. at 2799. This gatekeeping function is important because, "due to the difficulty of evaluating their testimony, expert witnesses have the potential to be both powerful and quite misleading." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999) (quoting Daubert, 509 U.S. at 595, 113 S. Ct. 2786) (internal quotation marks omitted).

In Daubert and related cases, the U.S. Supreme Court has elucidated a number of factors for District Courts to consider when determining whether to admit expert testimony under Federal Rule of Evidence 702.[4] For example, the U.S. Supreme Court stated in Daubert that courts may consider whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it has been subjected to peer review and publication; whether it can be and has been tested; whether the known or potential rate of error is acceptable; and the existence and maintenance of standards and controls. Id. at 593-95, 113 S. Ct. at 2796-98. These factors are not exclusive nor dispositive. Since Daubert, the U.S. Supreme Court and lower courts have also identified additional factors that may be considered, such as whether an expert has unjustifiably extrapolated from an accepted premise to an unfounded

[4] Rule 702 of the Federal Rules of Evidence 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."

conclusion, see GE v. Joiner, 522 U.S. 136, 146, 118 S. Ct. 512, 519 (1997), whether an expert has adequately accounted for obvious alternative explanations, see Claar v. Burlington N. R.R., 29 F.3d 499, 502 (9th Cir. 1994), or whether an expert is proposing to testify about matters "growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." Daubert v. Merrell Dow Pharms., 43 F.3d 1311, 1317 (9th Cir. 1995) (hereinafter, Daubert II).

In this case, much, but not all, of Dr. Geier's proposed testimony is not based upon his own research, but instead upon a review of the relevant literature. Where proffered expert testimony is not based on independent research, but instead on such a literature review, the party proffering such testimony must "come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.' One means of showing this is by proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication." Daubert II, 43 F.3d at 1318. Thus, the research Dr. Geier relied upon must itself be able to meet the Daubert test. The fact that a journal is peer-reviewed is a significant consideration. Id.

While Daubert itself focused on an expert's methodology, the Court notes that later decisions have gone beyond methodology in certain instances. While in Daubert the U.S. Supreme Court stated that a Daubert analysis must "focus . . . solely on principles and methodology, not on the conclusions that they generate," the Court later recognized that "conclusions and methodology are not entirely distinct from one another." GE, 522 U.S. at 146,

118 S. Ct. at 519. Put another way – "Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." Id. Finally, a bold statement of the experts' qualifications, conclusions, and assurances of reliability are not enough to satisfy the Daubert standard. See Daubert II, 43 F.3d at 1319.

In addition to a consideration of the Daubert analysis, the Court notes that it must also distinguish in this case between Dr. Geier's proffered testimony as to both "general causation" and "specific causation." See, e.g., Dunn v. Sandoz Pharms. Corp., 275 F. Supp. 2d 672, 676 (M.D.N.C. 2003) (citing Reference Manual on Scientific Evidence 444 (2d ed. 2000)). On the one hand, "[g]eneral causation 'is established by demonstrating . . . that exposure to a substance can cause a particular disease.'" Id. "Specific, 'or individual causation, however[,] is established by demonstrating that a given exposure is the cause' of a particular individual's disease." Id. Where a "plaintiff is not able to establish general causation, it is unnecessary to consider whether the plaintiff can establish specific causation." Id.; see also Raynor v. Merrell Pharms., 104 F.3d 1371, 1376 (D.C. Cir. 1997).

With these legal standards in mind, it was the Court's undertaking to determine whether Plaintiffs' evidence satisfied their burden of proof to show that their experts used proper scientific methodology in reaching their ultimate conclusion that Minor Child Doe's autism was

caused by the thimerosal in Defendant's product RhoGAM. At the close of Plaintiffs' presentation at the Daubert hearing, Plaintiffs argued that their evidence would support such a conclusion. In response to Plaintiffs' position, Defendant challenged Plaintiffs' proffer by way of a cross examination of Plaintiffs' expert Dr. Geier and by offering its own experts to demonstrate that Plaintiffs' experts used unsound methodology or otherwise failed to follow sound protocol. Having closely considered the evidence and arguments both by Plaintiffs and Defendant, the Court has made a number of findings with respect to the testimony by Plaintiffs' primary expert Dr. Geier. These findings form the basis of the Court's ultimate conclusion that Plaintiffs have not met their burden under the Daubert analysis.

III. ANALYSIS OF DAUBERT AS APPLIED TO DR. MARK GEIER

As initial background information with respect to the qualifications of Dr. Geier, the Court notes that he is the president of his own company, The Genetic Centers of America. He is a medical doctor who specializes in obstetrical genetics with a Ph.D. as well in genetics. He is board certified in medical genetics and forensic medicine. However, it is significant to the Court that he is not board certified in pediatrics or in pediatric neurology, nor is he certified as an epidemiologist or biostatistician. Dr. Geier did serve as a researcher at the National Institutes of Health for 10 years and worked as a professor at John Hopkins University. While he has published more than 50 peer-reviewed medical papers, none of these prior publications were on the specific issue at hand, that is, whether RhoGAM with thimerosal causes autism. The Court has taken into account, as well, the fact that Dr. Geier has testified as an expert witness in about

one hundred cases before the National Vaccine Injury Compensation Program of the United States Court of Federal Claims. It is noteworthy that in more than ten of these cases, particularly in some of the more recent cases, Dr. Geier's opinion testimony has either been excluded or accorded little or no weight based upon a determination that he was testifying beyond his expertise.[5] In this case, subject to the Court's Daubert analysis, Dr. Geier's testimony is being offered by Plaintiffs for presentation at trial to support Dr. Geier's ultimate conclusion that the

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[5] See, e.g., Piscopo v. Sec'y of HHS, 66 Fed. Cl. 49, 55 (May 26, 2005) (approving Dr. Geier's exclusion under Daubert because his training is in genetics and obstetrics, which is "largely irrelevant to the expertise needed to establish a causal relationship between the Hepatitis B vaccine and the petitioner's autoimmune disorder"); Weiss v. Sec'y of HHS, No. 03-190V, 2003 WL 22853059 (Fed. Cl. Oct. 9, 2003) (finding Dr. Geier is a "professional witness in areas for which he has no training, expertise, and experience"); Thompson v. Sec'y of HHS, No. 99-436V, 2003 WL 21439672 (Fed. Cl. May 23, 2003) (finding Dr. Geier was not qualified because his causation theory was filled with "speculation that is directly contrary to the conclusions reached in well-respected and numerous epidemiologic and medical studies ranging over two decades"); Bruesewitz v. Sec'y of HHS, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Dec. 20, 2002) (finding Dr. Geier unqualified to diagnose neurological diseases); Raj v. Sec'y of HHS, No. 96-294V, 2001 WL 963984 (Fed. Cl. July 31, 2001) (finding Dr. Geier "wholly unqualified to testify concerning the two major issues in this case [encephalopathy and infantile spasms] . . . because he is neither board certified nor has formal training in pediatrics and pediatric neurology"); Haim v. Sec'y of HHS, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Aug. 27, 1993) (finding that Dr. Geier's testimony did not reach "the level of evidentiary reliability that Daubert requires because it is not based upon scientific validity, valid methodology, peer review or testing, and more than minimal support within the scientific community"); Marascalco v. Sec'y of HHS, No. 90-1571V, 1993 WL 277095 (Fed. Cl. July 9, 1993) (finding Dr. Geier's testimony "intellectually dishonest" and that his affidavit was "nothing more than an egregious example of blatant, result-oriented testimony").

Plaintiffs point to a number of cases in which Dr. Geier was apparently able to give his opinion as to causation in vaccine cases. However, the Court finds that the majority of cases cited in Plaintiffs' Response concern testimony by Dr. Geier on vaccine issues prior to 1995. Plaintiffs, however, do not assert that any of these cases or any previous testimony by Dr. Geier concern or even address the issue of whether thimerosal in RhoGAM causes autism.

thimerosal in RhoGAM caused Minor Child Doe's autism. However, appropriately under Daubert, the Court's focus, principally, is on the acceptability of the methodology by which Dr. Geier reached his ultimate conclusion. The specific methodology at issue here is Dr. Geier's method of using (1) a review of the relevant literature and his own studies as related to the incidence of autism, so as to support a general causation theory, and furthermore, (2) his use of a differential diagnosis of Minor Child Doe, so as to establish specific causation with respect to Minor Child Doe's own condition. The Court will address each of these areas in turn.

A. Dr. Geier's Review of Literature Concerning Whether RhoGAM Causes Autism

In examining Dr. Geier's methodology, the Court notes that, in fact, a literature review can be an appropriate part of a method of determining general causation. See, e.g. Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1384 (4th Cir. 1995) (allowing an expert opinion based upon patient history, examination, lab and pathology data, and a study of the peer-reviewed literature). However, a literature review must still be performed appropriately. As revealed by his testimony at the Daubert hearing, Dr. Geier, however, relied upon a number of disparate and unconnected studies, including the findings of Dr. Haley and Dr. Lucier, to reach a piecemeal conclusion with respect to general causation that the small amount of thimerosal received in this case by the mother of Minor Child Doe during the course of her pregnancy and shortly after the child's birth, could cause autism. Dr. Geier's methodology consisted of attempting to connect various individual studies that had developed the existence of certain findings such as the

following: (1) mercury exposure could destroy neurons[6]; (2) high levels of methylmercury exposure may cause developmental defects in children (Faroe Islanders study[7] and Iraq study[8]); (3) mercury can be transmitted through a mother's milk to her suckling child (Iraq study); (4) thimerosal can cross the blood-brain and placental barriers[9] (this study considered doses of 1,000 micrograms of thimerosal, whereas the product RhoGAM has only about 10 micrograms of thimerosal); (5) direct and multiple (6x) injections of 50 milligrams of thimerosal can kill or deform embryonic chickens[10]; (6) topical use of thimerosal as an antimicrobial by pregnant women may have caused birth defects[11]; (7) a mouse model exposed to thimerosal in a way mimicking a childhood immunization schedule developed physical, psychological, and

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[6] Leong CWC, Syed NI, Lorscheider FL. "Retrograde degeneration of neurite membrane structural integrity of nerve growth cones following in vitro exposure to mercury." NeuroReport 2001; 12: 733-737.

[7] Grandjean P, Weihe P, White RF, Debes F. "Cognitive deficit in 7-year-old children with prenatal exposure to methylmercury." Neurotoxicol. Teratol. 1997; 19:417-28; *and* Grandjean P, Weihe P, White RF, Debes F. "Cognitive performance of children prenatally exposed to 'safe' levels of methylmercury." Environ. Res. 1998; 77:165-72. These studies and the Iraqi study both looked at children whose mothers had ingested high levels of methylmercury in their diets while pregnant and found some neurodevelopmental effects such as delayed onset of speech, tunnel vision, increased reflexes, delayed motor development, and small head size.

[8] Amin-Zaki, L, S. Elhassani, et al. (1974). "Intra-uterine methylmercury poisoning in Iraq." Pediatrics 54(5): 587-95.

[9] Slikker W. "Developmental neurotoxicology of therapeutics: survey of novel recent findings." Neurotoxicology 2000; 21:250.

[10] Digar A, Sensharma GC, Samal SN. "Lethality and teratogenecity of organic mercury (thimerosal) on the chick embryo." J. Anat. Soc. India 1987; 36:153-9.

[11] Heinonen, Olli P. et. al., Birth Defects and Drugs in Pregnancy 302 (1977).

pathological symptoms similar to autism[12]; and (8) a hair study of children with autism showed a statistically significant correlation between Rho D immunoglobulin administration and autism (Holmes study).[13] Thus, on its face, all these study results, when pieced together, would seem to support Plaintiffs' general causation theory, as offered by Dr. Geier, that RhoGAM could cause autism.

However, upon being subjected to extensive cross examination, much of Dr. Geier's analysis, based upon his collective review of a motley assortment of diverse literature, proved, in the Court's view, to be overstated. For example, in examining Dr. Geier's methodology, the Court notes that Dr. Geier could not point to a single study, including anything that he had published, that conclusively determined that the amount of thimerosal in RhoGAM when given not to the fetus but to the mother, as in this case, could cause autism. It is also significant in the review of his methodology that Dr. Geier could not point to a single study that conclusively

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[12] Hornig M, Chian D, Lipkin Wi. "Neurotoxic Effects of Postnatal Thimerosal are Mouse Strain Dependent." Mol. Psychiatry 2004;9:833-45. However, it is significant that this particular study also noted that it is based upon the *assumption* that autism is caused by an autoimmune reaction, there is a lack of evidence to show that an autoimmune disease caused damage in the brains of patients with autism, and the relevance of mouse models is difficult to assess because "rodent clinical pinpoints may not reflect human ones" and because "there is limited understanding of the etiology of autism."

[13] Holmes A.S., Blaxill M.F., et al. (2003). "Reduced Levels of Mercury in First Baby Haircuts of Autistic Children." Int. J. Toxicol. 22(4): 277-85. This study has been criticized, among other reasons, because its findings have not been duplicated and are not consistent with two other studies that used better methods. (See Def. Reply Brief, Document #102, Expert Report of Susan E. Folstein, Ex. 2 at 4 ("Thus, the study by Holmes is highly suspect – it used a peculiar sample, a suspect laboratory (IOM 2004) and uncertain methods of statistical analysis, and it offered a highly idiosyncratic interpretation of data.").)

determined that any amount of mercury could cause the specific neurological disorder of autism.[14] Even with respect to the Holmes study, which was an important part of Dr. Geier's methodology and ultimate conclusion, Holmes states the following in the last sentence of the paper: "Our study provides further insight into one *possible* mechanism by which early mercury exposures *could* increase the risk of autism." (emphasis added). Such a conditional statement cannot meet the preponderance of the evidence standard that Plaintiffs need to meet to show that the thimerosal in RhoGAM could cause autism. This Court must find more than the "hypothesis and speculation," engaged in by Dr. Geier in this instance, in order to allow Dr. Geier to rely upon the methodology he used in forming a conclusion based upon his review of the literature presented to the Court. See Cavallo v. Star Enter., 100 F.3d 1150, 1159 (4th Cir. 1996) . In any event, Dr. Geier's conclusion in this matter is not supported even by the literature

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[14] The Court is applying a definition of autism which is "a complex and severe set of developmental disorders characterized by sustained impairments in social interaction, impairments in verbal communication, and stereotypically restricted or repetitive patterns of behaviors and interests." (See Def. Apx. Tab 6, Institute of Medicine of The National Academy of Sciences, Immunization Safety Review: Vaccines and Autism, p. 32 (2004).) Thus, a patient must exhibit a number of specific symptoms in order to receive an "autism" diagnosis, symptoms that fall on a "continuum of related cognitive and neurobehavioral disorders." Id.; see also Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV-TR) (APA, 2000). Plaintiffs often appear to argue that the mercury in thimerosal could cause some specific neurological or developmental disorder, such as the delayed motor development seen in the Amin-Zaki study of Iraqi suckling infants. However, these studies also suggest that mercury poisoning can cause many symptoms different than the symptoms that most often characterize autism. (See Def. Reply Brief, Document #102, Expert Report of Susan E. Folstein, Ex. 2 at 27-30 (comparing descriptions of mercury poisoning with autism symptoms and finding some similarities and some differences but stating that "any claimed similarities are based on an imprecise use of words.").)

he presented to the Court. Moreover, Dr. Geier's conclusion that the peer-reviewed literature he has relied upon supports his theory that autism can be caused by thimerosal is flatly contradicted by all of the epidemiological studies available at this time. (Def. Apx. Tab 6, Institute of Medicine of The National Academy of Sciences ("IOM Report"), Immunization Safety Review: Vaccines and Autism, p.13 (2004) ("Given the lack of direct evidence for a biological mechanism and the fact that all well-designed epidemiological studies provide evidence of no association between thimerosal and autism, the Committee recommends that cost-benefit assessments regarding the use of thimerosal-containing versus thimerosal-free vaccines and other biological or pharmaceutical products, whether in the United States or other countries, should not include autism as a potential risk.").)[15] While this Court notes that the Fourth Circuit Court of Appeals has clearly held that epidemiological studies are not required to establish causation, see Benedi, 66 F.3d at 1384, in this case, all of the available peer-reviewed and generally accepted epidemiological studies refute causation. See Norris v. Baxter Healthcare Corp., 397 F.3d 878, 882 (10th Cir. 2005) (distinguishing Benedi by stating in that case there was no body of epidemiological evidence demonstrating the absence of a causal relationship and finding that "where there is a large body of contrary epidemiological evidence, it is necessary to at least

[15] The Court notes that Dr. Geier also exhibited some bias against health agencies that have criticized his methodology on other issues to such an extent that he has publicly accused the Centers for Disease Control ("CDC"), the World Health Organization, the American Academy of Pediatrics, and the National Academy of Sciences of deceiving the American public as to the dangers of mercury and specifically called the CDC a "rogue organization." (Def. Apx. Tab 15, Transcript of Videotape Deposition of Dr. Mark R. Geier in Civil Action No. 5:03-CV-141, E.D. Tex. 2004.)

address it with evidence that is based on medically reliable and scientifically valid methodology"). Thus, while Dr. Geier's presentation of the literature as part of his methodology might at first glance appear convincing, the disconnected literature he presents does not add up to the opinion and conclusion that Dr. Geier is offering. See Domingo v. T.K., 289 F.3d 600, 606 (9th Cir. 2002) ("A further problem is that the studies that were cited do not provide support for every necessary link in [the expert's] theory of causation. Some of the studies relied upon by [the expert] support various aspects of his theory . . . The studies . . . do not, however, provide support for his conclusion . . . nor is this a probable conclusion from the studies cited.") Accordingly, the Court finds that Dr. Geier's literature review, in this instance, does not meet the Daubert standard of being both derived by the scientific method and relevant to the "task at hand."

Beyond the literature review, Dr. Geier also relied upon the results of his own studies of the Vaccine Adverse Event Reporting System ("VAERS") database,[16] and his currently non-published studies showing an increased frequency of maternal Rh negativity in children with autistic disorder in comparison with the general population. The VAERS database is a passive reporting system for physicians and others to report adverse events after the administration of vaccines. Although Dr. Geier is neither an epidemiologist or biostatistician, Dr. Geier's studies

[16] Geier DA, Geier MR (2003a). "An assessment of the impact of thimerosal on childhood neurodevelopmental disorders." Pediatr. Rehabil. 6(2): 97-102; Geier M, Geier D. (2003b). "Neurodevelopmental disorders after thimerosal-containing vaccines: a brief communication." Exp. Biol. Med. (Maywood) 228(6): 660-4; Geier MR, Geier DA (2003d). "Thimerosal in childhood vaccines, neurodevelopmental disorders and heart disease in the United States." J. Am. Phys. Surg. 8: 6-11.

examined the incidence of autism by comparing reported incidents of adverse events after the administration of the Diphtheria, Tetanus & Pertussis ("DTP") vaccine that contained thimerosal against reported incidents of adverse events after thimerosal was removed from the DTP vaccine. However, the Court finds that Dr. Geier's published VAERS studies have been severely criticized by The Institute of Medicine as having "serious methodological flaws," analytic methods that were "non-transparent," and generally "non-contributory with respect to causality." (See Def. Apx. Tab 6, IOM Report at pp. 7, 52, 55-58, 60-62, 119-120). More specifically, one of the particular criticisms leveled at Dr. Geier's study was that, as a passive reporting system, it would be inappropriate to calculate incidence rates based upon the data in VAERS because it "does not have complete reporting of all adverse events and because many report events lack a confirmed diagnosis or confirmed attribution to vaccine." (Id. at p. 59 n.18.) Finally, the Court also finds that Dr. Geier's two most recent papers, concerning the incidence of autism among Dr. Geier's own Rh-negative patients, that were presented to the Court during the hearing, have not yet been published nor peer-reviewed, making their own relevance and scientific validity difficult, if not impossible, to assess. Nevertheless, looking at these studies in conjunction with Dr. Geier's literature review, the Court remains unpersuaded that Dr. Geier's testimony meets the Daubert test, particularly because Plaintiffs have failed in each instance to show: (1) that the theory employed by Dr. Geier is generally accepted in the scientific community; (2) that Dr. Geier's most recent and most applicable work concerning RhoGAM has been subjected to peer review and publication; and (3) that Dr. Geier properly controlled his studies and maintained

standards: particularly, that he failed to take into account that RhoGAM is not the only Rho D immunoglobulin on the market and RhoGAM's competitor did not contain thimerosal, and Dr. Geier admittedly has not separately analyzed which of his patients received Defendant's product RhoGAM and which received some other Rho D immunoglobulin to determine respective autism rates. Moreover, the Court is particularly concerned as to a potential bias in Dr. Geier's methodology and ultimate conclusion given the recency of Dr. Geier's research into the cause of autism, which he admittedly began in only the last two and a half years, a time period that also represents the pendency of this lawsuit. Therefore, after a thorough consideration of all of the issues involved in this matter and the positions taken by the parties, the Court finds that Plaintiffs have failed to present evidence showing that Dr. Geier's testimony should be admissible under Federal Rule of Evidence 702 concerning the general causation question of whether the exposure to thimerosal in RhoGAM could cause autism.

B. Dr. Geier's Differential Diagnosis of Minor Child Doe

As previously noted, the Court has found that Dr. Geier's methodology, concerning the general causation question, that is, whether the thimerosal in RhoGAM could cause autism, has not met the Daubert standard. Based upon this finding, the Court need not go further. See Dunn, 275 F. Supp. 2d at 676. Nevertheless, for sake of completeness, the Court will also examine Dr. Geier's methodology concerning specific causation, that is, whether RhoGAM specifically caused Minor Child Doe's autism. Dr. Geier is Plaintiffs' sole expert to opine that RhoGAM in fact caused Minor Child Doe's autism. In order to do this, Dr. Geier testified that

he relied upon the medical records and testimony of Minor Child Doe's treating physicians, as well as some specific genetic testing that he performed, in order to rule out other possible causes of Minor Child Doe's autism. Such a method is known as a "differential diagnosis," which may be an appropriate basis for an expert opinion as to causation. See Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) (finding that where properly applied, the methodology of differential diagnosis "has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results."); Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1384 (4th Cir. 1998).

However, "[a] differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion." Roche v. Lincoln Property Co., 278 F. Supp. 2d 744, 751 (E.D. Va. 2003), aff'd 2006 WL 910241, *5 (4th Cir. April 7, 2006) (unpublished) (intermediate history omitted). Stated differently, "[i]f other possible causes of an injury cannot be ruled out, or at least the probability of their contribution to causation minimized, then the 'more likely than not' threshold for proving causation may not be met." Cavallo, 892 F. Supp. at 771, aff'd on this ground, rev'd on other grounds, 100 F.3d 1150 (4th Cir. 1996). Generally, it is not appropriate to rely on a differential diagnosis to prove general causation. See Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005). Thus, the court in Ruggiero addressed the question of whether to allow an expert to testify that the plaintiff's cirrhosis was specifically caused by a particular drug, by applying a differential diagnosis, where that expert had not, with respect to general causation, also "offered any reliable

basis for concluding that [the drug] is capable of causing the cirrhosis that caused the liver failure that resulted in [the plaintiff's] death. In other words, he has offered no reliable ground upon which [the drug] may be 'ruled in' as a plausible cause of the cirrhosis." Ruggiero, 424 F.3d at 254 n.5. Indeed, the appellate court in Ruggiero ultimately affirmed the district court's exclusion of the expert based upon a faulty differential diagnosis. See id. at 254. Similarly, the court in Norris v. Baxter Healthcare Corp., 397 F.3d 878, 885 (10th Cir. 2005), considered whether a differential diagnosis would be valid where general causation had not been established to show that silicone breast implants could cause systemic disease. There, the court stated that "[w]e are unable to find a single case in which differential diagnosis that is flatly contrary to all of the available epidemiological evidence is both admissible and sufficient to defeat a defendant's motion for summary judgment." Id. at 885-86.

In this case, Plaintiffs have failed to show that applying a differential diagnosis is appropriate methodology, standing alone, given the possibility of a finding by the Court, as in this instance, that Plaintiffs' expert witness could not establish general causation with respect to RhoGAM and autism. However, even if the Court were to assume that general causation had been shown in this instance, the Court finds that Dr. Geier's application of the differential diagnosis technique suffers from its own irregularities. First, the Court notes that Dr. Geier is not a pediatrician or a pediatric neurologist. In fact, testimony was presented to the Court that Dr. Geier was not even successful in sitting for his Medical Board examination in the specific field of pediatric genetics. (See Transcript, Vol. II of III, Document #121, at 65.) Thus, there is

a threshold question as to whether Dr. Geier is even qualified to perform a differential diagnosis so as to give a causation opinion with respect to the cause of a neurological disorder such as autism in a child such as Minor Child Doe. More troubling, however, is that Dr. Geier's differential diagnosis failed to acknowledge the one conclusion that is generally accepted in the medical community with respect to the causation of autism, which is, that its cause is genetic, but that the exact genetic sequence of autism is unknown. See, e.g., McDougle CJ, et al., "Neurochemistry in the Pathophysiology of Autism." J. Clin. Psychiatry 2005; 66(suppl. 10); 9-18; Veenstra-VanderWeele J, et. al., "Autism as a Paradigmatic Complex Genetic Disorder." Annu. Rev. Genomics Hum. Genet., 2004; 5: 379-405 ("Autism is one of the most heritable complex disorders, with compelling evidence for genetic factors and little to no support for environmental influence."). From the evidence presented to the Court, this appears to be the prevailing medical view on the subject of autism among experts in the field. Dr. Geier does not even profess to be, nor has he or any other proposed expert witness for Plaintiffs tendered to the Court, an expert on autism. Although Dr. Geier apparently has considered a number of specific genetic disorders in performing his differential diagnosis, the Court finds that his failure to take into account the existence of such a strong likelihood of a currently unknown genetic cause of autism serves to negate Dr. Geier's use of the differential diagnosis technique as being proper in this instance. Therefore, were the Court to only consider the specific causation question, the result would be the same as with the Court's ruling on the issue of general causation, as the Court finds that Dr. Geier (1) was not specifically qualified to perform a differential diagnosis

of a pediatric neurological disorder, and, that (2) he did not properly perform the differential diagnosis given his failure to consider within his analysis the high probability that an unknown genetic cause cannot be ruled out as the specific cause of Minor Child Doe's autism. For these reasons, Dr. Geier's testimony on specific causation based upon a differential diagnosis must be excluded under Federal Rule of Evidence 702. Having thus addressed the admissibility of Dr. Geier's testimony, the Court will now turn to a consideration of Defendant's Motion for Summary Judgment.

IV. DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Summary judgment is appropriate when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A fact is considered "material" if it "might affect the outcome of the suit under the governing law . . . ." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 2510, 91 L. Ed. 2d 202 (1986). There can be "no genuine issue as to any material fact" if the non-moving party fails to "make a showing sufficient to establish the existence of an element essential to that party's case," since "a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 106 S. Ct. 2548, 2552, 91 L. Ed. 2d 265 (1986).

As the Court has found that testimony from Dr. Geier and as previously noted, relatedly, the proffered testimony of Drs. Haley and Lucier must be excluded, the Court further finds that Defendant's Motion for Summary Judgment must be granted as to all of Plaintiffs' claims. This