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11  
12 IN THE UNITED STATES DISTRICT COURT  
13 FOR THE NORTHERN DISTRICT OF CALIFORNIA

14 ALEXANDER REDFOOT, a minor by and  
15 through his Guardian Ad Litem, MICHELL  
16 REDFOOT

17 Plaintiff,

18 vs.

19 B.F. ASCHER & COMPANY; and DOES 1  
20 through 10, inclusive,

21 Defendants.

) Case No. C05-02045 PJH  
)  
)  
)

) PLAINTIFF'S RESPONSE TO  
) DEFENDANTS' MOTION TO PRECLUDE  
) THE PROPOSED TESTIMONY OF  
) PLAINTIFF'S EXPERT WITNESSES  
) PURSUANT TO FRE 401, 702, 703 AND  
) DAUBERT  
)

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Ct: 3

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4 *Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 929-31 (8<sup>th</sup> Cir. 2001) ..... 25

5 *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993) ..... 5, 6, 10, 11, 24

6 *Daubert v. Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9<sup>th</sup> Cr. 1995) .....6, 24

7 *Eric Jeffries v. Centre Life Insurance Co.*, Civil Action No. C-1-02-351

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10 (W.D. WA 2005)(unpublished) ..... 9, 10

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12 *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998 (9<sup>th</sup> Cir. 2004) ..... 5, 9

13 *In re Paoli RR Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994) ..... 6

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1           Michell Redfoot respectfully requests that this Honorable Court deny the Defendants'  
2 Motion to preclude the causation opinion testimony of her retained expert witness, Dr. Mark  
3 Geier, as well as the testimony of her non-retained witnesses, Dr. James Bradstreet, Dr. George  
4 Lucier, Dr. Boyd Haley and Dr. Arthur Krigsman, as they have the requisite expertise and the  
5 reasoning and methodology utilized in reaching their opinions are valid, relevant and satisfy the  
6 requirements set forth in *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993), its progeny and  
7 the Federal Rules of Evidence 401, 702 and 703.  
8

9  
10 **I. INTRODUCTION**

11           It has been long known that mercury, like lead, is a powerful neurotoxin in all of its  
12 various forms. Prior to this litigation, cumulative scientific evidence – case reports, animal  
13 studies, pharmacokinetic studies, biological studies and epidemiological data – permitted  
14 scientists and physicians across the country to reasonably, reliably and validly infer that exposure  
15 to mercury caused neurological development disorders. Their findings were all subject to peer-  
16 review and published in reputable scientific and medical journals.  
17

18           Within the last decade, scientists and physicians have justifiably applied this scientific  
19 knowledge to children exposed to excessive concentrations of mercury as a result of their  
20 exposure to thimerosal, a preservative incorporated into vaccines, ophthalmic products and nasal  
21 products. Dozens of peer-reviewed published articles regarding mercury exposure in general and  
22 thimerosal in particular, and their contribution to the development of neurological disorders,  
23 including autism, form a reliable basis for the opinions expressed by Dr. Geier and Alexander's  
24 treating physicians, Dr. Arthur Krigsman and Dr. James Bradstreet linking Alexander Redfoot's  
25 autism to his exposure to thimerosal from Ayr Saline Nasal Mist, a product that was  
26 administered to Alexander on a repeated basis from the time he was two months old until he  
27 reached his fourth birthday.  
28

1 **2. PLAINTIFF'S EXPERTS ARE WELL QUALIFIED.**

2 Federal Rule of Evidence (FRE) 702 provides that "if scientific, technical, or other  
3 specialized knowledge will assist the trier of fact to understand the evidence or to determine a  
4 fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or  
5 education, may testify thereto in the form of an opinion or otherwise." Drs. Geier, Lucier, Haley,  
6 Bradstreet and Krigsman all have extensive experience with mercury and thimerosal and their  
7 toxic neurological effects. These experts came to their conclusions regarding the capability of  
8 the mercury in thimerosal to cause neurological injuries long before this litigation. They have  
9 published those opinions in peer-reviewed medical and scientific journals and have presented  
10 them to both the Government Reform Committee of the United States Congress addressing  
11 Mercury in Medicine and to the Institute of Medicine ("IOM") of the National Academy of  
12 Sciences investigating hazards of thimerosal-containing vaccines.

- 13
- 14 • Mark R. Geier, M.D., PhD: a medical doctor who specializes in obstetrical genetics, he  
15 holds a PhD in genetics and is Board-certified in medical genetics and forensic  
16 medicine. Currently in clinical practice, he was a researcher at the National Institutes  
17 of Health for 10 years as well as a professor at Johns Hopkins University. He has  
18 studied vaccines for over thirty years and has published more than 50 peer-reviewed  
19 scientific/medical papers on vaccine safety, efficacy, contamination and policy,  
20 including over a dozen dedicated to the issue of thimerosal, mercury and neurological  
21 disorders, including autism<sup>1</sup>. He is a peer reviewer for the journals Vaccine, Expert

22

23 <sup>1</sup> "Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief Communication", EXP BIOL MED  
24 228:660-664 (2003)(Defendant Exhibit D-9); "Thimerosal in Childhood Vaccines, Neurodevelopment Disorders,  
25 and Heart Disease in the United States", J AMER PHYS SUR 8(2):6-11 (2003)(Defendant Exhibit D-10); "An  
26 assessment of the impact of thimerosal on childhood neurodevelopmental disorders", PEDIATRIC REHABILITATION  
27 6(2):97-102 (2003)(Defendant Exhibit D-8); "A comparative evaluation of the effects of MMR immunization and  
28 mercury doses from thimerosal-containing childhood vaccines on the population prevalence of autism", MED SCI  
MONIT, 10(3):PI33-9 (2004); "An evaluation of serious neurological disorders following immunization: a  
comparison of whole-cell pertussis and acellular pertussis vaccines", BRAIN DEV, 26(5):296-300 (2004)(Exhibit 1);  
"Neurodevelopmental Disorder Following Thimerosal-Containing Childhood Immunizations: A Follow-Up  
Analysis", INTERNATIONAL JOURNAL OF TOXICOLOGY 23:369-376 (2004)(Exhibit 2); "The potential importance of  
steroids in the treatment of autistic spectrum disorders and other disorders involving mercury toxicity", MED  
HYPOTHESES, 64(5):946-54 (2005)(Exhibit 3); "A two-phased population epidemiological study of the safety of  
thimerosal-containing vaccines: a follow-up analysis", MED SCI MONIT, 11(4):CR160-70 (2005)(Exhibit 4); "An  
assessment of downward trends in neurodevelopment disorders in the United States following removal of  
Thimerosal from childhood vaccines", MED SCI MONIT, 12(6):CR231-9 (2006)(Exhibit 5); "An evaluation of the

1 Review of Vaccine, *Annals of Internal Medicine*, Expert Opinion on Emerging Drugs,  
 2 Clinical and Experimental Rheumatology and Environmental Health Perspectives. Dr.  
 3 Geier was instrumental in convincing governmental authorities to switch from the  
 4 whole-cell Diphtheria-Tetanus-Pertussis (DTP) vaccine to the much safer acellular  
 5 version (DTaP). In fact, Dr. Geier's article, "The True Story of Pertussis Vaccination:  
 6 A Sordid Legacy?" *J Hist Med Allied Sci* 57:249-84 (2002) won the first annual  
 7 Stanley W. Jackson prize for the best paper published in the *Journal of the History of  
 8 Medicine and Allied Sciences* during the period of 2000 to 2002.<sup>2</sup> Dr. Geier has been  
 9 invited to make presentations to the Institute of Medicine on multiple occasions  
 10 regarding the adverse consequences vaccines including a presentation of his  
 11 epidemiologic work on thimerosal in 2004.<sup>3</sup> Dr. Geier was invited by Dan Burton,  
 12 Chairman of the U.S. House of Representatives Committee on Government Reform  
 13 Investigating Vaccines and the Autism Epidemic to critique the Hviid study, the first  
 14 epidemiological study conducted in Denmark of autism and thimerosal exposure.<sup>4</sup> Dr.  
 15 Geier has also addressed the Food and Drug Administration Advisory Committee  
 16 regarding vaccine safety and he has also given numerous presentations on vaccine  
 17 issues, including thimerosal, to various scientific, health department and parent groups  
 18 in the United States and around the world. Finally, Dr. Geier qualified and testified as  
 19 an expert witness in approximately 100 cases before the National Vaccine Injury  
 20 Compensation Program (NVICP) of the United States Court of Federal Claims.

21 effects of thimerosal on neurodevelopmental disorders reported following DTP and Hib vaccines in comparison to  
 22 DTPH vaccine in the United States", *J TOXICOL ENVIRON HEALTH A*, 69(15):1481-95 (2006)(Exhibit 6); "A meta-  
 23 analysis epidemiological assessment of neurodevelopmental disorders following vaccines administered from 1994  
 24 through 2000 in the United States", *NEURO ENDOCRINOL LETT*, 27(4):401-13(2006)(Exhibit 7); "A clinical and  
 25 laboratory evaluation of methionine cycle-transsulfuration and androgen pathway markers in children with autistic  
 26 disorders", *HORM RES*, 66(4):182-8 (2006)(Exhibit 8); "A prospective assessment of porphyrins in autistic disorders:  
 27 a potential marker for heavy metal exposure", *NEUROTOX RES*, 10(1):57-64 (2006)(Exhibit 9); "A clinical trial of  
 28 combined anti-androgen and anti-heavy metal therapy in autistic disorders", *NEURO ENDOCRINOL LETT*, 27(6):833-8  
 (2006)(Exhibit 10).

<sup>2</sup> The *Journal of the History of Medicine and Allied Sciences* is a publication of the Oxford University Press and is associated with Duke University. See Letter from Margaret Humphreys, MD, PhD to David Geier and Mark Geier announcing the award, October 10, 2003 (Exhibit 11).

<sup>3</sup> See Letter from Christopher Howson, Ph.D., Institute of Medicine, January 12, 1990 (thanking Dr. Geier for his presentation to the committee reviewing the adverse consequences of the pertussis and rubella vaccines); Letter from Dr. Howson, March 26, 1990 (inviting Dr. Geier to make a presentation on the neurotoxic effects of the pertussis and rubella vaccines at the May 1990 meeting); Table of Contents to Transcript of Vaccine Safety Committee meeting January 16, 1993 (Noting that Dr. Geier presented by phone); E-mail from Alicia Gable, Program Officer, Institute of Medicine, December 8, 2003 (inviting Dr. Geier to present his findings from his studies, "Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief Communication" and "An assessment of the impact of thimerosal on childhood neurodevelopmental disorders"); Letter from Alicia Gable, Program Officer, Immunization Safety Review Committee (thanking Dr. Geier for sharing his thoughts and expertise regarding the potential role of vaccinations in autism with Committee on February 9, 2004); and Letter from Andrea Anason, Study Director, August 30, 2004 (thanking Dr. Geier for sharing his expertise to the committee reviewing the NIP's Research Procedures and Data Sharing Program related to the Vaccine Safety Datalink Sharing Program), collectively attached as (Exhibit 12); see also Dr. Geier's presentation to the Institute of Medicine on Thimerosal in Vaccines (Exhibit 13).

<sup>4</sup> See Letter from Dan Burton, Chairman, December 6, 2002 (Exhibit 14).

- 1 • George Lucier, PhD: retired from the National Institute of Environmental Health  
2 Sciences in 2000 where he was Director of the Environmental Toxicology program and  
3 Associate Director of the National Toxicology Program where he was responsible for  
4 coordinating toxicological research and testing across federal agencies as well as  
5 conducting risk assessments for exposure to various substances including  
6 methylmercury. He was head of a research group in molecular epidemiology and risk  
7 assessment and has authored approximately 250 scientific publications, book chapters  
8 and conference proceedings monographs involving toxicology, pharmacology and risk  
9 assessment. Included among his publications, are ten articles involving the toxicity of  
10 mercury. In 1998, he was appointed the Chair of the Organizing Committee for the  
11 White House Workshop on Scientific Issues Relevant to Assessment of Health Effects  
12 from Exposure to Methylmercury. He has presented his opinions regarding mercury  
13 toxicity on numerous occasions including, "Pharmacokinetics and Toxicity of Ethyl and  
14 Methylmercury," Workshop on Thimerosal Containing Vaccines; "Interagency  
15 Agreement on Risk Assessments for Methylmercury," U.S. Department of Health and  
16 Human Services; "Comparative Toxicology of Ethyl and Methylmercury," National  
17 Academy of Sciences Committee on Vaccine Safety (IOM); "Risk Assessments for  
18 Methylmercury," North Carolina Environmental Management Commission; as well as  
19 during a briefing on the health effects of methylmercury to the United States Senate  
20 Health and Environment Forum. He was also the co-editor in chief of the prestigious  
21 scientific journal, Environmental Health Perspectives, for 28 years.
- 22 • Boyd Haley, PhD: currently a Professor and Chairman of the Department of Chemistry  
23 with a joint appointment in the College of Pharmacy at the University of Kentucky.  
24 One of the classes he teaches at the University of Kentucky is on mercury toxicology.  
25 He has published over 120 articles in the peer-reviewed literature including three  
26 involving mercury, thimerosal and autism.<sup>5</sup> Since 1989, his laboratory has been  
27 actively involved in research regarding the relationship between mercury toxicity and  
28 neurological diseases, primarily Alzheimer's disease. He has also performed  
experiments with thimerosal. In 2001, he presented on "*In Vitro* Studies of Thimerosal  
Toxicity" to the Institute of Medicine.
- Jeffery Bradstreet, M.D., FAAFP: a Fellow of the American Academy of Family  
Physicians, is a practicing physician who treats children with autism and other  
neurological developmental disorders. He has been actively engaged in research  
regarding autism and childhood developmental disorders with scientists including Dr.  
Jane El-Dahr of the Tulane University Medical Center; Dr. V.K. Singh of the Utah  
State University Biotechnology Center and the University of Michigan Department of  
Pharmacology; Dr. Vas Aposhian of the University of Arizona; Dr. Anne Connolly of  
the Washington University Hospital; Dr. Walter Spitzer of McGill University; the  
Department of Pediatrics at Robert Wood Johnson Medical School; Dr. Jim Adams of  
the University of Arizona; and Dr. Jill James with the University of Arkansas,  
Department of Pediatrics. Dr. Bradstreet, a Harvard University Certified Continuing

<sup>5</sup> "Mercury and autism: accelerating evidence? NEURO ENDOCRINOL LETT, 26(5):439-46 (2005); "Baby hair, mercury toxicity and autism," INT J TOXICOL, 23(4):275-6 (2004); "Reduced levels of mercury in first baby haircuts of autistic children," INT J TOXICOL., 22(4):277-85 (2003)

1 Medical Education Instructor in autism, has published two peer reviewed papers  
 2 regarding mercury and children with autism.<sup>6</sup> Over the last five years, has been an  
 3 invited speaker at symposiums all over the globe regarding the neuroimmunobiology of  
 4 autism and developmental disorders including presentations at the Institute of Medicine  
 meeting in 2001 and 2004.

- 5 • Arthur Krigsman, MD: holds dual board certification in General Pediatrics and  
 6 Pediatric Gastroenterology and is a Clinical Assistant Professor of pediatrics at New  
 7 York University Medical Center. Dr. Krigsman specializes in the evaluation and  
 8 treatment of gastrointestinal pathology common in children with autistic spectrum  
 9 disorders. He has presented his findings relating to the symptomatology and  
 endoscopic/histopathologic character of what has become known as “autistic  
 enterocolitis” to the U.S. House Committee on Government Reform as well as other  
 scientific and lay meetings in the United States and Canada.

10 Clearly, based on their credentials and experience, each of the Plaintiff’s witnesses  
 11 possess the requisite “knowledge, skill, experience, training, or education” regarding thimerosal,  
 12 mercury and autism, to satisfy Federal Rule of Evidence 702.<sup>7</sup>

13  
 14 **3. THE PROPER LEGAL STANDARDS**

15 The Federal Rules of Evidence adopt a general approach of relaxing the traditional  
 16 barriers to opinion testimony and embody a governing principle favoring admissibility. *Daubert*  
 17 *v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587-88 (1993)(citing Fed. R. Evid. 401, 402 and  
 18 702). Expert testimony is admissible under Rule 702 if: (1) the reasoning or methodology  
 19 underlying the testimony is scientifically valid (the “reliability” prong); and (2) the reasoning or  
 20 methodology can properly be applied to the facts in issue (the “relevancy” prong). *Daubert*, 509  
 21 U.S. at 592-593. The trial court must make a preliminary determination that expert testimony is  
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 26 <sup>6</sup> “Metabolic endophenotype and related genotypes are associated with oxidative stress in children with autism,”  
 27 *AMM J MED GENET B NEUROPSYCHIATR GENET.*, 141(8):947-56 (2006); “A Case-Control Study of Mercury Burden  
 in Children with Autistic Spectrum Disorders”, *J AM PHYS SURG* 8(3):76-79 (2003)

28 <sup>7</sup> The Defendants, taking a very narrow interpretation of FRE 702 argue that none of the Plaintiff’s witnesses can  
 testify because they are not epidemiologists, biostatisticians, toxicologists, immunologists, pediatricians, or pediatric  
 neurologists. Defendants’ Motion to Preclude the Proposed Testimony of Plaintiff’s Expert Witness (“Defendants’  
 Motion to Preclude”) at pp. 4, 9, and 18. FRE 702, however, “contemplates a broad conception of expert  
 qualifications.” *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1016 (9<sup>th</sup> Cir. 2004). It is not the  
 title that an expert possesses that is important, it is his knowledge and experience.

1 both reliable and relevant before it may be admitted. *Id.* at 581. As the Supreme Court  
2 emphasized, the *Daubert* standard is a flexible one. *Id.* at 594. Pertinent evidence based on  
3 scientifically valid principles will satisfy those demands. *Id.* at 597.

4  
5 The focus is on principles and methodology, not conclusions. As the court stated in *In re*  
6 *Paoli RR Yard PCB Litigation*, 35 F.3d 717, 744 (3d Cir. 1994), proponents "do not have to  
7 demonstrate to the judge by a preponderance of the evidence that the assessments of their experts  
8 are correct, they only have to demonstrate by a preponderance of evidence that their opinions are  
9 reliable.... The evidentiary requirement of reliability is lower than the merits standard of  
10 correctness." *See also Daubert v. Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1318 (9<sup>th</sup> Cir. 1995)  
11 (scientific experts might be permitted to testify if they could show that the methods they used  
12 were also employed by "a recognized minority of scientists in their field."); *Riuz-Trocher v.*  
13 *Pepsi Cola*, 161 F.3d 77, 85 (1<sup>st</sup> Cir. 1998) ("*Daubert* neither requires nor empowers trial courts  
14 to determine which of several competing scientific theories has the best provenance.").

15  
16  
17 By citing the alphabet soup of organizations, FDA, AAP, IOM, WHO, CDC, CSM and  
18 EMEA, who have discounted the link between thimerosal and autism without discussing the  
19 motivation for or foundations of their conclusions, the Defendants, in essence, are arguing that  
20 their experts are "right" and the Plaintiff's experts are "wrong."<sup>8</sup> This simplistic approach,  
21 which completely ignores the reliable science on which the Plaintiff's experts' opinions are  
22 based, is irrelevant to a *Daubert* inquiry.

23  
24 The Supreme Court has recognized that there is a range in which experts might  
25 reasonably differ on issues of science, and that such conflicting evidence should be admitted to  
26 aid the jury in deciding those issues. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 1953  
27 (1999); *Ambrosini v. Labarraque*, 101 F.3d 129, 138-139 (D.C. Cir. 1996) ("there is nothing in  
28

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<sup>8</sup> Defendants' Motion to Preclude at p. 2.

1 *Daubert* to suggest that judges become scientific experts, must less evaluators of the  
 2 persuasiveness of an expert's conclusion"); *Globetti v. Sandoz Pharm. Corp.*, 111 F.Supp. 2d  
 3 1174, 1176 (N.D. Ala. 2000)(role of fact finder, not judge, is to decide whether opinion is correct  
 4 or worthy of credence). As the Ninth Circuit explained in *Kennedy v. Collagen Corp.*, 161 F.3d  
 5 1226, 1230-31 (9<sup>th</sup> Cir. 1998):

7 Judges in jury trials should not exclude expert testimony simply  
 8 because they disagree with the conclusions of the expert. The  
 9 *Daubert* duty is to judge the reasoning used in forming an expert  
 10 conclusion. The test is whether or not the reasoning is scientific  
 11 and will assist the jury. If it satisfied these two requirements, then  
 12 it is a matter for the finder of fact to decide what weight to accord  
 13 the expert's testimony. In arriving at a conclusion, the fact-finder  
 14 may be confronted with opposing experts, additional test,  
 experiments, and publications, all of which may increase or lessen  
 the value of the expert's testimony. But their presence should not  
 preclude the admission of the expert's testimony – they go to the  
 weight, not the admissibility.

#### 15 4. FEDERAL COURT ACCEPTANCE OF DR. GEIER'S OPINIONS

16 In their brief, Defendants unfairly attack Dr. Geier's credibility and credentials by  
 17 selectively presenting quotes from a handful of the hundred NVCIP cases in which he has  
 18 testified.<sup>9</sup> The unfairness of this type of collateral attack is amplified due to Plaintiff's inability,  
 19 given the confines of this brief, to adequately set the proper context of each decision. For  
 20 example, Defendants cite Special Master French's opinion in Eric Jefferies v. Secretary of HHS,  
 21 criticizing Dr. Geier, but then deliberately omit Special Master French's November 25, 2003  
 22 opinion in which he lauded Dr. Geier's credentials as an epidemiologist with substantial special  
 23  
 24  
 25  
 26

27 <sup>9</sup>Defendants Motion to Preclude, pp 9, 10, fn 31. The Defendants also mistakenly assert that Dr. Geier's testimony  
 28 in the NVCIP is "often on behalf of claimants alleging that TCVs caused their autism." In fact, Dr. Geier has not  
 offered such testimony. All of the autism cases within the NVCIP have been consolidated in a single Omnibus  
 proceeding which has yet to convene a hearing on causation which is tentatively set for June 11-29, 2007. See,  
 United States Court of Federal Claims. *In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or  
 a Similar Neurodevelopment Disorder*, Autism Master File, Autism Update – January 19, 2007 at p. 5 (Exhibit 15)

1 experience regarding vaccinations and autism.<sup>10</sup> In that opinion, the Special Master French  
2 found:

3  
4 Dr. Geier is not a neurologist, but is a board certified geneticist  
5 who has been deeply involved in the field of vaccine  
6 epidemiology. He ranks high among those who have studied  
7 vaccine issues through the medical literature on vaccines,  
8 databases, studies, articles and information on vaccine safety and  
9 efficacy in vaccine policy. He has published many articles  
10 involving vaccine matters. The tenor of his testimony in this case  
11 addressed the importance of statistical databases in providing  
12 statistical reliability and validity in interpreting the epidemiology  
and issues relating to autism and various vaccines. . . . Dr. Geier  
has recently proposed a data-sharing process that would improve  
the reliability of present statistical data that would include the  
present VAERS statistical database. It would be helpful in  
interpreting the epidemiology and issues relating to the autism  
controversy.

13 More importantly, Defendants also neglect to inform the Court of the companion case  
14 involving the same claimant, Eric Jeffries, that was filed in the of the United States District  
15 Court, Southern District of Ohio, Western Division against his insurance company while his  
16 NVCIP claim was pending. There, Judge Sandra Beckwith overruled a *Daubert* challenge to Dr.  
17 Geier's testimony and his use of the VAERS database:  
18

19 Dr. Geier's opinion is based on more than the VAERS database.  
20 He admits that the VAERS database analysis would not alone  
21 provide a reliable diagnosis. According to Dr. Geier, he relied on  
22 the following combination of factors [sic] which leads him to the  
23 conclusion that plaintiff had an adverse reaction to the Hepatitis B  
24 vaccine: medical plausibility; studies in peer-reviewed literature  
documenting a connection between Hepatitis B vaccine and  
adverse reactions; case studies reporting similar reactions;  
Plaintiff's reaction occurred in an acceptable time period following  
the vaccination; all of this in conjunction with the VAERS  
database association. In addition, Dr. Geier testified at the hearing  
26 that the Hepatitis B vaccine contains mercury and aluminum

27  
28 <sup>10</sup> Dixon v. HHS, No. 01-0605V (November 25, 2003)(Published) (Exhibit 16). Defendants' failure to cite this  
opinion in light of their attack on Dr. Geier's credentials as an expert in epidemiology is unconscionable. Moreover,  
this is not the only time Dr. Geier's credentials and experience have been found to be laudatory. See McClendon v.  
HHS, No. 90-579V (1991) at pp. 13, 16 (Exhibit 17) (Judge Gibson reversing and remanding a Special Master's  
decision for refusing to give appropriate credence to Dr. Geier's expert opinion regarding the DPT vaccine).

1 compounds, and that these substances in vaccines have been shown  
2 to cause cognitive defects. The combination of factors provides a  
3 reasonably reliable basis for Dr. Geier to conclude that Plaintiff's  
4 cognitive impairments were caused by an adverse reaction to the  
5 Hepatitis B vaccine, and that opinion is, of course, relevant to the  
6 issues in this case. Therefore, the motion to exclude Dr. Geier's  
7 testimony is not well-taken and is denied. His opinion could be  
8 helpful to the jury.<sup>11</sup>

9 This was not the only time that Dr. Geier has survived a *Daubert* challenge. In *Francis v.*  
10 *Maersk Lines, Limited*,<sup>12</sup>, the plaintiff retained Dr. Geier as a causation witness for injuries he  
11 sustained as a result of being forced to take a vaccine for anthrax (AVA). The government filed a  
12 motion to exclude Dr. Geier's testimony maintaining he was not qualified to testify as a causation  
13 expert and arguing that his causation opinion was unreliable because it was based, in part, on his  
14 review of the Vaccine Adverse Event Reporting Service (VAERS) database.

15 Like the Defendants in this case, the government first claimed that Dr. Geier was not  
16 qualified because he was formally educated and had practiced in the field of genetics. Citing  
17 *Hangerter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1016 (9<sup>th</sup> Cir. 2004) and Federal  
18 Rule of Evidence 702, the court held Dr. Geier was qualified to testify about causation, noting  
19 that:

20 [w]hile Dr. Geier's formal degrees are in genetics, he has extensive  
21 experience with and knowledge of vaccines. Dr. Geier has worked  
22 in the area of vaccines for over thirty years, has published many  
23 articles relating to vaccines and their safety, has published two  
24 articles on AVA specifically, and has testified before Congress on  
25 matters relating to vaccine safety. (*citations omitted*)

26 With regard to the reliability of a foundation based upon a review of the VAERS  
27 database, another challenge raised by the Defendants in the instant case,<sup>13</sup> the *Francis* court held:  
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<sup>11</sup> *Eric Jeffries v. Centre Life Insurance Co.*, Civil Action No. C-1-02-351(S.D. Ohio)(March 3, 2004) (Exhibit 18).

<sup>12</sup> Case No. C03-2898C (W.D. WA 2005)(unpublished)(Exhibit 19).

<sup>13</sup> See Defendants' Motion to Preclude at pp.14-15.

1 . . . reliance on the VAERS database to ascertain the risks  
 2 associated with a given vaccine is generally accepted in the  
 3 scientific community. Dr. Geier has published an article  
 4 explaining this database and its use to evaluate vaccine safety  
 5 concerns. In addition, Dr. Geier's articles using the VAERS  
 6 database to ascertain the relative risks of vaccines have been  
 7 accepted by peer-reviewed scientific and medical journals. Also,  
 8 this method has been used by other researchers, including those at  
 9 the Center for Disease Control. Just as in *Kennedy [v. Collagen  
 Corp., 161 F.3d 1226 (9<sup>th</sup> Cir. 1998)]*, the reasoning behind Dr.  
Geier's general causation opinion is based on objective, verifiable  
 evidence and scientific methodology. Therefore, Dr. Geier's  
 methods used to form his causation opinion are generally accepted  
 in the scientific community. (*emphasis added*) (*citations omitted*)<sup>14</sup>

10 **5. DR. GEIER'S EPIDEMIOLOGICAL STUDIES ARE PEER-REVIEWED,  
 11 GENERALLY ACCEPTED AND RELIABLE**

12 Defendants, relying primarily on criticisms from the Institute of Medicine (IOM),  
 13 maintain that all of Dr. Geier studies are unreliable as a matter of law and move to prevent any  
 14 expert from relying on them, including Dr. Geier. The Defendants, however, only cite the four  
 15 studies of Dr. Geier that the IOM reviewed, and completely ignore the other many other studies  
 16 that he has published on the issue of thimerosal and autism.<sup>15</sup>

18 In *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993), the United States Supreme  
 19 Court listed four non-exclusive factors to consider in determining whether scientific evidence is  
 20 reliable: (1) whether the scientific theory or technique can be (and has been) tested; (2) whether  
 21 the theory or technique has been subjected to peer review and publication; (3) whether a  
 22 particular technique has a known potential rate of error; and (4) whether the theory or technique  
 23 is accepted in the relevant scientific community. 509 U.S. at 593-594. That the research is  
 24 accepted for publication in a reputable scientific journal after being subjected to the usual rigors  
 25 of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it

28 <sup>14</sup> See also *Estep v. HHS*, No. 90-1062V (1993) (Exhibit 20) (Judge Margolis finds no basis to disturb the Special  
 Master's finding that Dr. Geier's methodology was generally accepted in the scientific community).

<sup>15</sup> See Defendants' Motion to Preclude, pp. 14-15, 24. For a complete listing of the dozen articles that Dr. Geier has  
 published on thimerosal and autism, see *supra* note 1.

1 meets at least the minimal criteria of good science. *Id.* at 593. When these *Daubert* factors are  
2 applied to the body of Dr. Geier's, it is clear that Dr. Geier's studies are sufficiently reliable to  
3 adequately form the foundation for an expert opinion on general causation and to be considered  
4 by a jury.  
5

6 First, Dr. Geier's hypothesis that increasing amounts of thimerosal cause a significant  
7 increase in the incidence of neurodevelopmental disorders including autism has been repeatedly  
8 tested in his many peer-reviewed publications. In addition, as shown below, the totality of his  
9 studies demonstrate the validity of the results since the increased risk of neurodevelopmental  
10 disorders was confirmed with three different data sources, the VAERS, the Department of  
11 Education and the Vaccine Safety Database (VSD). Moreover, Dr. Geier has shown that the rate  
12 of such impairments has declined steadily since the removal of thimerosal from vaccines.  
13

14 Second, all of Dr. Geier's articles containing his opinion relating thimerosal exposure to  
15 autism have been subject to peer-review and have been published. In addition, many other  
16 competent researchers have published peer-review articles involving toxicokinetic, molecular,  
17 clinical and animal model studies that are consistent with the opinion that thimerosal exposure  
18 can result in neurodevelopmental disorders in some children.<sup>16</sup> Third, the known rate of error is  
19 minimal as the results regarding autism are statistically significant and expressed with at a 95%  
20 confidence interval and control outcomes yielded no increased risks. Fourth, peer review  
21 publication of his findings in ten different journals covering varied disciplines including  
22 toxicology, pediatrics, hormone research, neuroendocrinology and experimental biology  
23 demonstrates their wide acceptance in the medical community.  
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<sup>16</sup> See, *supra* at note 1, Geier, NEURO ENDOCRINOL LETT, 27(4):401-13(2006)(Exhibit 7) at p. 411, and references 4, 13, 14, 15, 20, 41, 45, 46, 49, 51, 52, 53, 54, 65, 66, and 68.

1 The acceptance and reliability of Dr. Geier's work on thimerosal and autism is further  
2 supported by the selection of some of his articles for inclusion in the Hazardous Substances Data  
3 Bank (HSBD) of the United States National Library of Medicine (NLM).<sup>17</sup> The HSDB is a  
4 toxicology file containing 4700 records on the toxicology of potentially hazardous chemicals and  
5 is part of the NLM's Toxicology Data Network. According to the HSBD Fact Sheet, all of the  
6 data are derived from "a core set of books, government documents, technical reports and  
7 **selected primary journal literature.**" Furthermore, the HSDB is "peer-reviewed by the  
8 Scientific Review Panel (SRP), a committee of experts in the major subject areas with the data  
9 bank's scope." Review status tags are associated with each data statement indicating the quality  
10 review. If a data statement is tagged with the statement "PEER REVIEWED," it represents data  
11 which has undergone peer review by the Scientific Review Panel or other high level group. In  
12 essence, the HSDB is a "super" peer reviewed source that desires to insure that users of their  
13 service receive reliable information.

14 Under the section on Thimerosal, the data is broken down into various categories, for  
15 example: Human Exposure Studies, Case Reports, Epidemiology Studies, Genotoxicity, etc.  
16 Among the data listed under Epidemiology Studies are two of Dr. Geier's publications.<sup>18</sup> Also  
17 listed are three articles that the Defendants experts purportedly rely upon written by Stehr-Green,  
18 Verstraeten, and Hviid.<sup>19</sup> All five of the articles were tagged with the statement "PEER  
19 REVIEWED" indicating that they had undergone an additional level of peer-review after  
20 publication.

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27 <sup>17</sup> See United States National Library of Medicine Fact Sheet and excerpt on Thimerosal (Exhibit 21).

28 <sup>18</sup> Id. The two Geier publications are: "Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief Communication", EXP BIOL MED 228:660-664 (2003)(Defendant Exhibit D-9) and Geier, "An assessment of the impact of thimerosal on childhood neurodevelopmental disorders", PEDIATRIC REHABILITATION 6(2):97-102 (2003)(Defendant Exhibit D-8).

<sup>19</sup> These studies are discussed in more detail below.

1 Ignoring the fact that all of Dr. Geier's publications are peer-reviewed, the Defendants  
2 imply that the requirement of general acceptance of the "relevant scientific community" is  
3 somehow inextricably tied to acceptance by scientific organizations like the IOM, AAP and the  
4 CDC. The Defendants have not, and cannot, offer any legal support for their assertion that the  
5 IOM committee's opinions on reliability somehow trump all of the editors and peer-reviewers  
6 associated with scientific and medical periodicals.  
7

8 Instead, the Defendants assert that Dr. Geier's epidemiological studies on thimerosal and  
9 autism are unreliable and biased because they were conducted solely for the purposes of  
10 litigation.<sup>20</sup> The sole support for this contention is Judge Beaty's erroneous statement in his July  
11 2006 opinion in *Doe v. Ortho Clinical Diagnostics* that Dr. Geier's research into the cause of  
12 autism began "only in the last two and a half years, a time period that also represents the  
13 pendency of this lawsuit."<sup>21</sup> As demonstrated by the first page of Defendant Exhibit D-9,  
14 however, Dr. Geier's first article, "Neurodevelopmental Disorders after Thimerosal-Containing  
15 Vaccines: A Brief Communication," was submitted for publication on August 14, 2002, a year  
16 and half before the *Ortho* lawsuit was filed. Obviously, the research underlying the article was  
17 begun well before the date it was submitted for publication. In fact, all four of Dr. Geier's  
18 papers that the Defendants address in their motion were either published or accepted for  
19 publication prior to the *Ortho* litigation.<sup>22</sup>  
20  
21  
22

23 Given the rigor of the peer review process, the consistency of the results obtained and the  
24 limited potential for any rate of error, Dr. Geier's publications are reliable and authoritative and  
25 can properly be relied upon by any expert, with any internal flaws fodder for cross-examination.  
26  
27

28 <sup>20</sup> Defendants' Motion to Preclude, p. 17 ("Dr. Geier's interest in autism coincides neatly with his employment as an expert witness in vaccine litigation.")

<sup>21</sup> Judge Beaty's Opinion at p. 17 (Defendant Exhibit E-1).

<sup>22</sup> Given when the Opinion was written, the *Ortho* lawsuit must have been filed sometime early in 2004.

1 **6. DR. GEIER'S RELIABLE AND PEER-REVIEWED EPIDEMIOLOGICAL**  
2 **STUDIES SUPPORT GENERAL CAUSATION - EXPOSURE TO THIMEROSAL**  
3 **IS A CAUSE OF AUTISM**

4 There are some inherent limitations to investigating the causal relationship between  
5 thimerosal and adverse events like neurological developmental disorders in children. First, once  
6 an adverse event becomes known, it is not possible to conduct any type of randomized, placebo-  
7 controlled clinical studies since it would be unethical to experiment on children. Second,  
8 because of the recommendations for universal immunization of the pediatric population and the  
9 extensive use of thimerosal in various products in the United States beginning in the 1930s, there  
10 are no historical populations of children with zero exposure to act as a control group for the  
11 traditional exposure/no exposure epidemiologic study. Accordingly, researchers have  
12 determined that the two most practical methods for assessing the association epidemiologically  
13 are 1) to conduct ecologic studies looking at comparisons involving large populations, before and  
14 after the introduction of thimerosal in vaccines and 2) to perform case/control studies that  
15 compare differing doses of thimerosal and outcomes to ascertain the presence of a dose-response  
16 relationship that would indicate causation.  
17  
18

19 The ecologic studies involve the Vaccine Adverse Event Reporting System (VAERS)  
20 database, a passive reporting system, and the California Department of Developmental Services  
21 database. The two best sources for case/control studies in a vaccine setting are VAERS and the  
22 Vaccine Safety Datalink (VSD), a large-linked active database that covers millions of children  
23 and links medical records and vaccination records. While each of these data sources and  
24 methods have limitations, consistent results, when coupled with other evidence including  
25 toxicology studies, animal experiments, and laboratory *in vitro* and *in vivo* experiments, are a  
26 sufficient basis to meet the *Daubert* standard of reliability regarding general causation.  
27  
28

1 The Defendants devote a considerable portion of their motion to attacking Dr. Geier's use  
 2 of the VAERS to gather information on the association between thimerosal and autism.<sup>23</sup> While  
 3 it is well recognized that, as a passive-reporting system, the VAERS reporting may be limited by  
 4 under-reporting, erroneous reporting, frequent multiple exposure, multiple outcomes, and lack of  
 5 precise denominators,<sup>24</sup> VAERS has been repeatedly utilized by the CDC and the FDA to  
 6 epidemiologically evaluate the safety of vaccines.<sup>25</sup> In fact, prior to his first published paper on  
 7 thimerosal, Dr. Geier had published a review of the VAERS system<sup>26</sup> as well as four peer-  
 8 reviewed papers where he used VAERS to investigate various vaccines and outcomes.<sup>27</sup>

9 Moreover, the methodology employed by Dr. Geier, comparing the incidence rate of  
 10 reported adverse events following one vaccine with the incidence rate of the reported adverse  
 11 events of another vaccine administered to a similarly aged population was developed by  
 12 scientists working for the Center for Disease Control ("CDC").<sup>28</sup> Using this approved technique  
 13 tends to ameliorate the documented weakness of VAERS since they would apply with equal  
 14 force to events reported for both vaccines.  
 15  
 16  
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 18  
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20 <sup>23</sup> Motion to Preclude, pp. 13-15.

21 <sup>24</sup> See "An evaluation of the effects of thimerosal on neurodevelopmental disorders reported following DTP and Hib  
 22 vaccines in comparison to DTPH vaccine in the United States", J TOXICOL ENVIRON HEALTH A, 69(15):1481 at p.  
 1487 (2006)(Exhibit 6); Varricchio, "Understanding vaccine safety information from the Vaccine Adverse Report  
 System," PEDIATR INFECTION DIS J 23:287-94 (2004)(Exhibit 24).

23 <sup>25</sup> See e.g., Haber, et al., "An analysis of rotavirus vaccine reports to the vaccine adverse event reporting system:  
 24 more than intussusception alone?", PEDIATRICS, 113(4):E353-9 (2004); Lloyd, "Adverse event reporting rates  
 following tetanus-diphtheria and tetanus toxic vaccinations: data from the Vaccine Adverse Event Reporting System  
 (VAERS), 1991-1997", VACCINE 21:3746-3750 (2003)(Exhibit 23); DuVernoy & Braun, "Hypotonic-  
 25 hyporesponsive episodes reported to the Vaccine Adverse Event Reporting System (VAERS), 1996-1998",  
 PEDIATRICS, 106:E52 (2000); "Braun, et al., "Infant immunization with acellular pertussis vaccines in the United  
 26 States: assessment of the first two years' data from the Vaccine Adverse Event Reporting System (VAERS)",  
 PEDIATRICS, 106:E51 (2000); Rosenthal, "The Safety of Acellular Pertussis Vaccine vs Whole-Cell Pertussis  
 27 Vaccine", ARCH PEDIATR ADOLESC MED 150:457-460 (1996)(Exhibit 22).

28 <sup>26</sup> Geier, "A review of the Vaccine Adverse Event Reporting System database", EXPERT OPIN PHARMACOTHER,  
 5:691-8 (2004)(Exhibit 25)

<sup>27</sup> See references 2 through 5, Geier, "Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A  
 Brief Communication", EXP BIOL MED 228:660 at pp. 663-664 (2003)(Defendant Exhibit D-9).

<sup>28</sup> See Rosenthal, ARCH PEDIATR ADOLESC MED 150:457-460 (1996)(Exhibit 22); Lloyd, VACCINE 21:3746-3750  
 (2003)(Exhibit 23), *supra* at note 25.

1 Before conducting the first epidemiological study designed to examine the relationship  
2 between exposure to thimerosal and the subsequent development of autism and other  
3 neurodevelopmental disorders, Dr. Geier, while conceding the hypothesis was biologically  
4 plausible, remained “highly skeptical” that the differences in the amounts of thimerosal received  
5 by children in the United States would have any affect on their incidence of neurological  
6 developmental disorders.<sup>29</sup> To test the hypothesis, Dr, Geier applied the CDC method to the  
7 VAERS database to identify reported instances of autism, mental retardation, and speech  
8 disorders among children who had received a Diphtheria-Tetanus-acelluar-Pertussis (DTaP)  
9 vaccination that contained thimerosal from 1992 through 2000 and compare the results to  
10 children who had received the thimerosal-free DTaP from 1997 to 2000.  
11  
12

13 If the thimerosal had no effect on neurological development disorders, then the incidence  
14 of reported adverse events should have been similar for both groups. Instead, he was “extremely  
15 surprised” by the results. While recognizing that the VAERS database tended to underreport the  
16 incidence of disease and that factors other than thimerosal may be playing a role in the difference  
17 between the two groups of children. Dr. Geier found a statistically significant six-fold increased  
18 relative risk of autism following receipt of an additional 75 to 100 µg of thimerosal from the  
19 thimerosal containing DTaP vaccines. He also found increased relative risks ranging from two-  
20 fold for speech disorders and six-fold for mental retardation. Although an association was found  
21 between autism and thimerosal, Dr. Geier was not totally convinced that is was a causal  
22 relationship and, therefore, recommended that additional studies be conducted to confirm and  
23 extend the results of the study.  
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25  
26  
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<sup>29</sup> “Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief Communication”, EXP BIOL MED 228:660-664 (2003)(Defendant Exhibit D-9)

1 In the first of his follow-up studies,<sup>30</sup> Dr. Geier re-evaluated the comparison of DTaP  
2 with and without thimerosal and also sought to determine whether increasing doses yield  
3 increasing rates of neurological development disorders including autism. Expanding the study,  
4 Dr. Geier looked at three sources of cases, the VAERS database, the Department of Education  
5 database and the VSD database. For each data source, the relative risk of autism and other  
6 neurological disorders increased with the increased thimerosal exposure. Finally, Dr. Geier  
7 conducted a MEDLINE “search for the terms merthiolate and thimerosal and found almost 1,500  
8 references primarily about various adverse outcomes following exposure.”<sup>31</sup> Dr. Geier then  
9 related how his findings were consistent with the biological mechanism of mercury induced  
10 diseases and concluded that there was now strong epidemiological evidence of a link between  
11 thimerosal and autism.  
12

13  
14 In 2004, Dr. Geier updated his prior analyses noting that more children in the original  
15 study had a chance to further mature and could have potentially been diagnosed with  
16 neurological developmental disorders<sup>32</sup>. Dr. Geier again expanded the outcomes examined to  
17 include autism, mental retardation, ataxia, speech disorders, thinking abnormalities, and  
18 personality disorders. He also included a series of control events including fevers, seizures, and  
19 encephalitis/encephalopathy and total reports to address the issue of reporting bias based on the  
20 publicity that the thimerosal issue had generated and to further verify that the results were not an  
21 artifact of his methodology.  
22

23  
24 The results of the study found statistically significant increased odds ratios (OR) for  
25 autism (1.8); speech disorders (2.1); mental retardation (2.6); personality disorders (2.6); and  
26

27  
28 <sup>30</sup>Geier, “Thimerosal in Childhood Vaccines, Neurodevelopment Disorders, and Heart Disease in the United States”,  
J AMER PHYS SURG 8(1):6-11(2003)(Defendant Exhibit D-10).

<sup>31</sup> *Id.* at 9.

<sup>32</sup> “Neurodevelopmental Disorders Following Thimerosal-Containing Childhood Immunization: A Follow-Up  
Analysis”, INT J TOX 23:369-376 (2004)(Exhibit 2)

1 thinking abnormalities (8.2). None of the control outcomes had a statistically significant  
 2 increased odds ratio. As with his previous study, Dr. Geier reviewed the current literature  
 3 regarding thimerosal and found that his results were consistent with “the recently emerging  
 4 clinical, molecular, and animal model observations concerning thimerosal and its relationship  
 5 with neurodevelopmental disorders in the United States.”<sup>33</sup> Dr. Geier concluded that his results,  
 6 taken with the recently published studies of a number of other researchers, “demonstrate a  
 7 connection between mercury exposure via infant vaccinations and the dramatic increase in  
 8 autism and other neurodevelopmental disorders in the United States.”<sup>34</sup>

9  
 10  
 11 In subsequent publications, Dr. Geier has retested the hypothesis using the thimerosal  
 12 containing DTaP with the non-thimerosal DTaP across two different databases, VAERS versus  
 13 the VSD.<sup>35</sup> He has also tested comparisons of vaccines with differing levels of thimerosal.<sup>36</sup> In  
 14 each instance, he confirmed the presence of consistent significantly increased risks of autism and  
 15 other neurological development disorders associated with thimerosal exposure, even when  
 16 adjusted for sex, age, vaccine type and vaccine manufacturer.<sup>37</sup>

17  
 18 In addition, Dr. Geier has evaluated the effects of the removal of thimerosal on the  
 19 proportion of neurological development disorders reported in VAERS and the California  
 20  
 21  
 22  
 23

24 <sup>33</sup> Geier, INTR J TOX at p. 374. (Exhibit 2).

25 <sup>34</sup> Id. at 375.

26 <sup>35</sup> “A two-phased population epidemiological study of the safety of thimerosal-containing vaccines: a follow-up  
 analysis”, MED SCI MONIT, 11(4):CR160-70 (2005)(Exhibit 4)

27 <sup>36</sup> “An evaluation of the effects of thimerosal on neurodevelopmental disorders reported following DTP and Hib  
 vaccines in comparison to DTP vaccine in the United States”, J TOXICOL ENVIRON HEALTH A, 69(15):1481-95  
 (2006)(Exhibit 6); “A meta-analysis epidemiological assessment of neurodevelopmental disorders following  
 28 vaccines administered from 1994 through 2000 in the United States”, NEURO ENDOCRINOL LETT, 27(4):401-  
 13(2006)(Exhibit 7)

<sup>37</sup> *Supra*, note 34, MED SCI MONIT, 11(4):CR160-70 (2005)(Exhibit 4)(VAERS autism relative risk of 1.8 (95% CI  
 1.1 to 3.0); *supra*, note 35, NEURO ENDOCRINOL LETT, 27(4):401-13(2006)(Exhibit 7)(autism ratio 1.56 (95% CI  
 1.05 to 2.34)

1 Department of Developmental Services (CDDS) databases.<sup>38</sup> Based upon the FDA's  
 2 recommendation in 1999, many of the manufacturers of childhood vaccines removed the  
 3 thimerosal preservative from their formulation. The last thimerosal-containing childhood  
 4 vaccines were manufactured in 2000-2001 with an expiration date of the end of 2002 or early  
 5 2003.<sup>39</sup> Taking into consideration that the age at which autism is typically diagnosed, Dr. Geier  
 6 was performing a corollary to his previous research, *i.e.*, did the risk for autism decrease as the  
 7 thimerosal was being removed from the vaccines – did decreasing dose result in decreased  
 8 incidence of neurodevelopmental disease. Consistent with his prior findings, significant  
 9 decreasing trends in newly diagnosed neurodevelopmental disorders were observed in both  
 10 databases in relation to reducing amounts of thimerosal exposure.

13 **7. EPIDEMIOLOGIC STUDIES CITED BY DEFENDANTS ARE IRRELEVANT**  
 14 **AND CARRY LITTLE WEIGHT**

15 The Defendants, citing the Andrews (2004) and Jick (2004) studies of English children;  
 16 the Hviid (2003), Madsen (2003) and Stehr-Green (2003) studies of Danish children; and the  
 17 Verstraeten (2003)<sup>40</sup> study of children in the United States, argue that any association between  
 18 thimerosal exposure and autism has been conclusively refuted, thereby, preventing any contrary  
 19 opinions as a matter of law. Apparently, it is their belief that because the IOM found that these  
 20 studies did not detect an association, Dr. Geier's findings are invalid and irrelevant because he  
 21 found an association. This syllogism is fatally flawed for a variety of reasons.

27 <sup>38</sup> "An assessment of downward trends in neurodevelopment disorders in the United States following removal of  
 28 Thimerosal from childhood vaccines", MED SCI MONIT, 12(6):CR231-9 (2006)(Exhibit 5); "Early Downward  
 Trends in Neurodevelopmental Disorders Following Removal of Thimerosal-Containing Vaccines," J AMER PHYS  
 SURG, 11(1):8-13 (2006)(Exhibit 26).

<sup>39</sup> *Supra*, at note 27, J AMER PHYS SURG, 11(1):8-13 (2006)(Exhibit 26).

<sup>40</sup> Defendant Exhibits. D-14, D-15, D-12, d-16, D-17 & D-13. respectively from Defendants' brief.

1 Stehr-Green collected data on cases of autism in Sweden and Denmark for an ecological  
2 study.<sup>41</sup> From the text of his article, it is clear that Stehr-Green attempted to refute any  
3 association between thimerosal-containing vaccines and autism by offering evidence that the rate  
4 of autism in Denmark and Sweden when thimerosal was being used was exceedingly low and,  
5 after thimerosal was removed<sup>42</sup> from the vaccines, actually began to rise instead of decline. The  
6 article, however, suffers from serious methodological limitations which affect its conclusions.  
7 With regard to the data from Denmark, the authors conceded that several external events “may”  
8 have spuriously increased the apparent rise in autism cases after thimerosal was removed from  
9 vaccines. What they fail to mention is that these same external events seriously under-reported  
10 the number of cases of autism that occurred when thimerosal was being used in vaccines.  
11

12  
13 One significant confounder contributing to the under-reported thimerosal exposed  
14 autistics and over-reporting the post-thimerosal cases occurred in 1992, the year thimerosal was  
15 removed from vaccines. After the removal of thimerosal, the national register began collecting,  
16 for the first time, data from a large clinic in Copenhagen which accounted for 20% of all autism  
17 cases occurring in Denmark. The second confounder occurred in 1993 when Denmark switched  
18 coding for autism from ICD-8 to ICD-10 which had a compound effect on increasing the number  
19 of post-thimerosal cases - first, it increased awareness among clinicians from training in the new  
20 coding system that likely stimulated an increased reporting of autism cases and, second, the  
21 definition of disease under ICD-10 was a more inclusive then ICD-8.<sup>43</sup> Finally, in 1994, two  
22 years after thimerosal was eliminated, the autism case definition was expanded to include cases  
23  
24  
25  
26

27 <sup>41</sup> Stehr-Green, “Autism and Thimerosal-Containing Vaccines, Lack of Consistent Evidence for an Association”,  
28 AM J OF PREV MED 25(2):101-106 (2003)(Defendant Exhibit D-17).

<sup>42</sup> Thimerosal was eliminated in Denmark in 1992 and in Sweden in 1993.

<sup>43</sup> Lauritsen, “The incidence and prevalence of pervasive developmental disorders: a Danish population-based study”, PSYCHOLOGICAL MEDICINE 34:1-8 (2004)(Exhibit 27)(degree of coverage of ICD-10 in Denmark was high while the ICD-8 diagnoses were believed to much lower).

1 of Rhett's syndrome, Asperger's syndrome and childhood disintegrative disorders which had not  
2 previously been counted.

3  
4 The most telling evidence of under-reporting was that during the entire time thimerosal  
5 was being used in Denmark, the only cases of autism being recorded by the national registry  
6 were those serious enough to require hospitalization. It was not until 1995, three years after  
7 thimerosal was removed from vaccines, that the registry began recording out-patient cases.  
8 Since other researchers reported that the proportion of outpatient cases was 4 to 6 times greater  
9 than the inpatient, hospitalized cases<sup>44</sup>, it is not surprising that there was a significant increase in  
10 the number of the post-thimerosal cases. Certainly, the combination of these "external events" is  
11 sufficient to account for the increase in autism after the thimerosal was removed, a finding that  
12 significantly undermines the author's conclusion that the rise in autism after removal of  
13 thimerosal is strong evidence of the lack of an association between thimerosal exposure and  
14 autism.  
15  
16

17 The Swedish data was not much better. During the entire time frame of the Swedish  
18 cohort, Stehr-Green only collected data on children hospitalized for autism and no outpatient  
19 data was ever included. Moreover, unlike children in the United States who receive received a  
20 237.5 µg cumulative dose of ethylmercury by age 2, the maximum cumulative dose for Swedish  
21 children was 75 µg. Instead of seeking means to control or account for any of these "external  
22 events," Stehr-Green simply blamed the ecologic methodology for the study's limitations,  
23 permitting him to conclude that his results were "inconsistent" with the thimerosal hypothesis.  
24  
25  
26

27 <sup>44</sup> Madsen, "Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-  
28 Based Data", PEDIATRICS 112(3):604-606 (2003)(Defendant Exhibit D-16). Even this number is misleading since  
this very same lead author published a paper in 2002 wherein they reported for autistic children born between 1991  
and December of 1998, 93.1% of the children were treated only as outpatients, and 6.9% percent were at some point  
treated as in-patients at the psychiatric clinic. Madsen, "A population-based study of measles, mumps, and rubella  
vaccination and autism", N ENGL J MED 347(19):1477-1482 (2002) at p. 1478 (Exhibit 28).

1 Hviid (2003)<sup>45</sup> and Madsen (2003)<sup>46</sup> studied the same Danish population as Stehr-Green  
 2 and therefore suffer from all of the defects outlined above regarding Stehr-Green's evaluation of  
 3 the Danish children. In addition, the Danish population evaluated by Hviid (2003), Madsen  
 4 (2003) and Stehr-Green (2003), received about one-half the cumulative dose of ethylmercury  
 5 that US children got, prompting Madsen to concede "[o]ur data cannot, of course, exclude the  
 6 possibility that thimerosal at doses larger than used in Denmark may lead to neurodevelopmental  
 7 damage."<sup>47</sup>

8  
 9 Andrews (2004)<sup>48</sup> and Jick (2004)<sup>49</sup> both used the General Practice Research Database  
 10 (GPRD) in the United Kingdom which, again unlike children in the United States who receive  
 11 received a 237.5 µg cumulative dose of ethylmercury,<sup>50</sup> includes children who received a  
 12 maximum cumulative dose of 75 µg. When comparing the population he studied to that of the  
 13 United States, Andrews conceded:  
 14

15  
 16 [t]he exposure in the United Kingdom by 4 months of age was  
 17 similar to the United States by the same age; however, in the  
 18 United States, exposure increased further from 4 to 7 months. If  
 19 the increased risk in the US study were attributable only to the  
 20 additional thimerosal exposure after 4 months of age, then it is  
 21 possible that our study may not have been able to detect the risks  
 22 found in the US study.<sup>51</sup>

23  
 24 The final study cited by the Defendants, Verstraeten (2003)<sup>52</sup>, is the only study, besides  
 25 those of Dr. Geier, that involved a population of US children. While the 2004 IOM review

26 <sup>45</sup> Defendant Exhibit D-12

27 <sup>46</sup> Defendant Exhibit D-16

28 <sup>47</sup> *Id.* at 605.

<sup>48</sup> Defendant Exhibit D-14

<sup>49</sup> Defendant Exhibit D-15

<sup>50</sup> Alexander, however, received a dose in excess of what was experienced by most children in American since he received the thimerosal from the Ayr Saline Nasal Spray on top of whatever thimerosal he received from his vaccinations.

<sup>51</sup> Defendant Exhibit D-14 at 590.

<sup>52</sup> Defendant Exhibit D-13

1 asserted that Verstraeten (2003) is a negative study offering evidence that disproves any  
 2 association between thimerosal and autism, Verstraeten, the principal author of the study, wrote a  
 3 letter to the Editor of Pediatrics, the journal where the study was published, and stated:  
 4

5 Surprisingly, however, the study is being interpreted now as  
 6 negative by many, including the antivaccine lobbyists. The article  
 7 does not state that we found evidence against an association, as a  
 8 negative study would. It does state, on the contrary, that additional  
 9 study is recommended, which is the conclusion to which a neutral  
 study must come. . . . A neutral study carries a very distinct  
 message: the investigators could neither confirm nor exclude an  
 association, and therefore more study is required.<sup>53</sup>

10 **8. DR. GEIER'S SPECIFIC CAUSATION OPINION IS BASED UPON PROPER**  
 11 **METHODOLOGY AND RELIABLE DATA**

12 In reaching his opinion that Alexander Redfoot suffers from toxic encephalopathy  
 13 manifested as an autistic disorder that was caused, in significant part, by mercury exposure from  
 14 Ayr saline nasal spray he inhaled during his early childhood, Dr. Geier reviewed Alexander's  
 15 past medical history, performed a physical evaluation, had a series of tests conducted to rule out  
 16 known genetic causes of autism, and reviewed biochemical and genomic markers.<sup>54</sup> With this  
 17 evidence and his experience<sup>55</sup>, Dr. Geier was able to engage in "a differential diagnosis, the  
 18 process of elimination that physicians use to identify the most likely cause of a particular  
 19 individual's illness."<sup>56</sup> As Defendants properly concede, the methodology of utilizing a  
 20 differential diagnosis is acceptable under *Daubert* for determining specific causation. *See e.g.*,  
 21 *Kennedy v. Collagen Corp.*, 161 F.3d 1226 (9<sup>th</sup> Cir. 1998).  
 22  
 23  
 24  
 25

26 <sup>53</sup> Verstraeten, "Thimerosal, the Centers for Disease Control and Prevention, and GlaxoSmithKline", PEDIATRICS  
 27 113(4):932 (2004)(Exhibit 28)

<sup>54</sup> Geier Report, pp. 17-23, Defendant Exhibit A-2.

28 <sup>55</sup> Dr. Geier has medically evaluated and treated hundreds of patients with autistic disorders and has written peer  
 reviewed articles on clinical studies of autistics with mercury exposure. Geier Report, p. 1, Defendant's A-2; *see* "A  
 case-series of children with apparent mercury toxic encephalopathies manifesting with clinical symptoms of  
 regressive autistic disorders," J TOXICOL ENVRION HEALTH A (in press); *supra* note 1, Exhibits 3, 8, 9 and 10.

<sup>56</sup> Motion to Preclude, p. 12.

1 Utilizing this technique, Dr. Geier obtained reliable data upon which to formulate his  
2 opinion on specific causation. First, through the use of brain CT-Scan, Wood's Lamp  
3 examination, abdominal ultrasound, urine organic acid testing & plasma amino acid testing,  
4 DNA testing, physical examination and clinical observation, Dr. Geier was able to eliminate a  
5 series of potential alternative causes for Alexander's autism.<sup>57</sup> Second, laboratory testing  
6 performed during the time that the nasal spray was used on fecal matter and urine output after  
7 chelation challenge yielded results consistent with an increased body burden of mercury.  
8 Finally, biochemical and genomic testing revealed markers indicating that Alexander had an  
9 impaired ability to detoxify the increased mercury in his body resulting in a heightened  
10 sensitivity to mercury's detrimental neurological impact.<sup>58</sup>

11  
12  
13 In their Motion for Summary Judgment, the Defendants complain that Dr. Geier's failure  
14 to rule out an unknown causes of Alexander's illness renders his specific causation opinion  
15 unreliable.<sup>59</sup> Defendants, however, fail to explain how a physician would go about ruling out a  
16 cause to a disease that is "unknown." Fortunately, the law does not require such an absurd  
17 exercise. As the Court in *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230 (1998) explained:  
18

19 The Supreme Court stressed that, "[i]t would be unreasonable to  
20 conclude that the subject of scientific testimony must be "known"  
21 to a certainty; arguably, there are no certainties in science.  
22 *Daubert*, 509 U.S. at 590 . . . On remand, we stated: "Not knowing  
23 the mechanism whereby a particular agent causes a particular  
24 effect is not always fatal to a plaintiff's claim. Causation can be  
25 proved even when we don't know precisely *how* the damage  
26 occurred, if there is sufficiently compelling proof that the agent  
27 must have caused the damage *somehow*." *Daubert*, 43 F.3d at  
28 1314.

<sup>57</sup> For the list of eliminated potential causes see Geier Report, p. 22, Defendant Exhibit A-2.

<sup>58</sup> Geier Report, p. 23, Defendant Exhibit A-2.

<sup>59</sup> Defendants' Memorandum of Points and Authorities in Support of Summary Judgment, or in the Alternative, Motion for Summary Adjudication Claims, p. 8

1 Defendants further complain about "Dr. Geier's complete lack of making any  
 2 calculations of ethylmercury exposure and dose in this case."<sup>60</sup> Calculating an exact dose that  
 3 was actually absorbed in Alexander's nose is an impossibility and is an exercise that is not  
 4 legally necessary.<sup>61</sup> From Dr. Geier's epidemiologic research, he has established that the level of  
 5 thimerosal in vaccines is more than sufficient to cause autism in dose dependent manner. Here,  
 6 regardless of the exact dose of thimerosal Alexander received from the Ayer product, it was a  
 7 additional exposure that substantially contributed to the total dose of mercury that caused his  
 8 autism.  
 9

## 10 9. CONCLUSION

11 Dr. Geier's multiple peer-reviewed published epidemiologic studies are sufficiently  
 12 reliable to satisfy the *Daubert* requirements and serve as a suitable foundation for his opinion on  
 13 general causation. The laboratory studies performed on Alexander Redfoot documenting the  
 14 presence of an excess burden of mercury, a susceptibility to mercury because of an impaired  
 15 ability to excrete it and the absence of any other genetic and environmental factors normally  
 16 associated with autism is sufficient to meet Plaintiff's burden on specific causation.  
 17

18 Dated: March 14, 2007

19 C. Andrew Waters  
 20 WATERS & KRAUS, LLC

21 By: /s/C. Andrew Waters  
 22 C. Andrew Waters  
 23 Attorneys for Plaintiff

24 William Levin  
 25 LEVIN SIMES KAISER & GORNICK, LLP

26 <sup>60</sup> Defendants' Motion to Preclude, p. 18. Interesting the footnote to that statement goes on to discuss how Dr. Geier  
 27 calculated his estimate of Alexander's total dose from the Ayer nasal spray.

28 <sup>61</sup> *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262-63 (4<sup>th</sup> Cir. 1999) (holding that differential diagnosis may be  
 independently reliable without epidemiological studies, peer-reviewed studies, or laboratory data of dosage amount);  
*Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 929-31 (8<sup>th</sup> Cir. 2001) (holding that for an expert providing  
 differential diagnosis it is not necessary that expert "quantify the amount" of substance to which plaintiff was  
 exposed to demonstrate plaintiff was exposed to a toxic level).