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13 UNITED STATES DISTRICT COURT
14 FOR THE NORTHERN DISTRICT OF CALIFORNIA

15 ALEXANDER REDFOOT, a minor by and) CASE NO. C05-02045 PJH
through his Guardian Ad Litem, MICHELL,)
16 REDFOOT; MICHELL REDFOOT,)
Plaintiff,) DEFENDANTS' MOTION TO PRECLUDE THE
17) PROPOSED TESTIMONY OF PLAINTIFFS'
v.) EXPERT WITNESSES PURSUANT TO FRE
18) 401, 702, 703 and DAUBERT
B.F. ASCHER & COMPANY; and DOES 1) (Separate Exhibits and Declarations)
19 through 10, inclusive,)
20 Defendants.) Hearing Date: April 4, 2007
21) Time: 9:30 a.m.
22) Courtroom: 3

23 TO THE PARTIES HEREIN AND TO THEIR ATTORNEYS OF RECORD:

24 PLEASE TAKE NOTICE that on April 4, 2007, at 9:30 a.m., defendants B.F. Ascher &
25 Company, Inc. (öB.F. Ascherö) and Kolmar Laboratories, Inc. (öKolmarö), will move this Court for
26 an Order precluding the testimony of plaintiffs' experts. Concurrently, defendants will move the
27 court for summary judgment/summary adjudication of the plaintiffs' claims in their entirety,
28 because plaintiffs cannot establish general causation.

1 Defendants' Motion is to preclude the proposed opinion testimony of plaintiffs' sole retained
2 expert witness, Mark R. Geier, M.D., Ph.D., as well as the testimony of plaintiffs' non-retained
3 experts, James Jeffrey Bradstreet, M.D., FAAFP, George W. Lucier, Ph.D., Boyd Haley, Ph.D. and
4 Arthur D. Krigsman, M.D. pursuant to Federal Rules of Evidence ("FRE") 401, 702, and 703 and
5 Daubert v. Merrell Dow Pharm., 509 U.S. 579, 113 S.Ct. 2786 (1993) ("Daubert").

6
7 Dated: February 28, 2007

Robert B. Leck III
LECK & ASSOCIATES

8 Mark F. Hazelwood
9 LOW, BALL & LYNCH

10
11 By: /s/Robert B. Leck III
12 Robert B. Leck III
13 Attorneys for Defendants B.F. Ascher & Co., Inc.
14 and Kolmar Laboratories, Inc.
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I. FACTUAL BACKGROUND AND INTRODUCTION

Plaintiff Michell Redfoot alleges she administered Ayr Saline Nasal Mist (öAyrö) on a daily basis, two-to-three times per day, to her infant son, plaintiff Alexander Redfoot, from the time Alexander was two months old until he reached the age of three. Plaintiffs further allege that the trace amount (0.00025%, or 2.5 ppm) of the preservative thimerosal contained in Ayr, produced by B.F. Ascher, and manufactured for it by Kolmar, between the years 2000 and 2002 caused Alexander Redfoot to develop autism. Defendants believe this to be the first lawsuit filed anywhere alleging that thimerosal in a saline nasal product caused autism. All of plaintiffs' claims hinge upon establishing a causal link between exposure to thimerosal at these (or any) levels and the onset of autism.

Historically, many biologic products (including vaccines and nasal air saline products like Ayr) have included a preservative to prevent the growth of harmful microbial contaminants. Thimerosal, still an approved microbial and listed in the USP, has been used extensively in biologicals since 1930. In the body, thimerosal breaks down to ethylmercury and another compound.

In July of 1999, the Federal Food and Drug Administration (öFDAö) noted that the total ethylmercury exposure from routine childhood thimerosal-containing vaccines (öTCVsö) could exceed the U.S. Environmental Protection Agency ("EPA") guidelines for average daily exposure to methylmercury in seafood.¹ Concurrently, the American Academy of Pediatrics (öAAPö) issued a notice stating a preference for thimerosal-free vaccines, but expressly approving TCVs if thimerosal-free versions were unavailable, as the potential for harm was deemed theoretical only.² A flood of litigation followed in the U.S. Court of Federal Claims (öVaccine Courtö). The claims are based on the allegation that exposure to thimerosal from recommended childhood vaccines

¹ There is no reference dose for ethylmercury. (Guzelian Report, p. 12, Ex. B-4.)
² CDC, Notice to Readers: Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service, MMWR (July 9, 1999); 48 (26):563-65, Ex. C-1. This statement of theoretical harm made no mention of autism.

1 causes a "novel" form of mercury poisoning that manifests as autism.³ Prior to bringing the instant
 2 action, plaintiffs herein filed such a claim in the Vaccine Court, alleging that thimerosal in
 3 Alexander Redfoot's childhood vaccines caused his neurological problems.

4 After much debate on the potential for harm from TCVs, respected scientific and medical
 5 organizations worldwide have rejected the hypothesis that thimerosal-containing pediatric vaccines
 6 cause or contribute to autism. These include: FDA;⁴ AAP;⁵ the Institute of Medicine of The
 7 National Academies of Science ("IOM");⁶ the World Health Organization ("WHO");⁷ the U.S.
 8 Centers for Disease Control and Prevention ("CDC");⁸ the U.K. Committee on the Safety of
 9 Medicines ("CSM");⁹ and, the European Agency for the Evaluation of Medicinal Products
 10 ("EMA").¹⁰ See also Katona Report, p. 5, Ex. B-2 and Rodier Report, p.7, ¶ 20, Ex. B-3.

11 The National Institutes of Health (NIH) and CDC requested that the IOM review the
 12 issues raised by the vaccine litigation. Ultimately, in May 2004, after an exhaustive review of the
 13 available evidence on both sides, including presentations by three of plaintiffs' expert witnesses and
 14 the researchers upon whose studies they rely, the IOM's Immunization Safety Review Committee
 15 ("IOM Committee") concluded that "the evidence favors rejection of a causal relationship between
 16 thimerosal containing vaccines and autism."¹¹ The IOM Committee went one step further,

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 18 ³ Rodier Report, p. 3, ¶, Ex. B-3.

19 ⁴ Official Dept. of Health & Human Services, FDA response to citizen petition of CoMed
 20 Coalition for Mercury-Free Drugs dated Sept 26, 2006, signed by FDA Assistant Commissioner
 21 for Policy Jeffrey Shuren, M.D., J.D., and addressed to Paul G. King, PhD (FDA Response to
 22 Citizen Petition). A copy is shown to plaintiffs' expert, Mark Geier, Ex. C-2.

23 ⁵ American Academy of Pediatrics, Study Fails to Show a Connection Between Thimerosal and
 24 Autism (posed May 16, 2003) (AAP Statement), Ex. C-3.

25 ⁶ Immunization Safety Review Committee, Board on Public Health Promotion and Disease
 26 Prevention, Institute of Medicine, Immunization Safety Review: Vaccines and Autism. (National
 27 Academies Press 2004 [IOM Report]), Ex. C-4, and IOM Executive Summary (2004) Ex. C-5.

28 ⁷ WHO, Position of the Global Advisory Committee on Vaccine Safety, May 13, 2004, regarding
 concerns raised by recent paper about the safety of thimerosal-containing vaccines. Ex. C-6.

⁸ CDC, Thimerosal & Vaccines, Q & A, May 18, 2004, Ex. C-7.

⁹ Committee on the Safety of Medicines, Annual Report 2003, Ex. C-8.

¹⁰ EMA Public Statement on Thimerosal in Vaccines for Human Use ó Recent Evidence
 Supports Safety of Thimerosal-Containing Vaccines, March 24, 2004, Ex. C-9.

¹¹ IOM Executive Summary, p. 7, Ex. C-5.

1 recommending that available funding for autism research should be channeled to the most
2 promising areas.¹²

3 Despite these consensus opinions, plaintiffs' proffered expert asserts that TCVs and, by
4 some unsubstantiated inferential leap of faith, therefore Ayr - cause autism in a vulnerable
5 subpopulation of children.

6 The term "autism" is sometimes used to refer only to Autistic Disorder and sometimes to
7 the broader umbrella of Autism Spectrum Disorder ("ASD") or Pervasive Developmental Disorders
8 ("PDD").¹³ Alexander Redfoot has been diagnosed with mild autism.¹⁴

9 It is clear from twin and family studies there is a strong genetic basis for autism.¹⁵ Plaintiffs
10 claim that a postnatal environmental insult caused Alexander Redfoot's autism. However, there are
11 only five known environmental risk factors for autism, each of which involves prenatal exposure.
12 These known environmental risk factors for autism all act in the first trimester of pregnancy, and
13 not from postnatal exposure of mother or child. None of these factors includes ethylmercury or
14 mercury of any form.¹⁶

15 Moreover, the symptoms of ethylmercury poisoning are different from those of autism.¹⁷
16 Little is known about what symptoms might result from prenatal exposure to ethylmercury. It is
17 known that postnatal exposure to ethylmercury, as plaintiffs allege, does not produce the stigmata of
18 autism.¹⁸ Because the symptoms of ethylmercury poisoning are not similar to those of autism,
19 proponents of the thimerosal-autism theory have set forth a new (novel) hypothetical kind of
20 mercury poisoning with symptoms of toxicity different from other mercury species.¹⁹

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23 ¹² Id., p. 16, Ex. C-5.

24 ¹³ Under the DSM-IV-TR, a diagnosis of Autistic Disorder requires the presence of three types
25 of symptoms (1) impairment in social interaction; (2) problems in communication; and (3)
26 unusual or severely limited activities or interests (such as repetitive or stereotyped behaviors).

27 ¹⁴ Fisher IME Report, January 3, 2007, Ex. B-5.

28 ¹⁵ IOM Executive Summary, p. 9, line 6, Ex. C-5.

¹⁶ Rodier Report, pp. 4-5, Ex. B-3.

¹⁷ Id., p. 3, ¶ 11, Ex. B-3.

¹⁸ Id., p. 3, ¶ 13, Ex. B-3.

¹⁹ Id., pp. 3-4, ¶ 13, Ex. B-3.

1 The scientific evidence leading the IOM, FDA, WHO, AAP, CDC, CSM, and EMEA to
 2 reject the plaintiffs' claim of a TCV-autism link is now beyond debate. These organizations have
 3 found that there is no reliable, peer-reviewed, scientific evidence that (1) children exposed to TCVs
 4 are at a greater risk for autism than children who do not receive TCVs; (2) exposure to an amount of
 5 thimerosal received through childhood vaccines is associated with autism, or with any form of
 6 mercury neurotoxicity; or (3) the amount of thimerosal exposure from a standard vaccination
 7 schedule causes neurological injury. Conversely, there is reliable, peer-reviewed scientific evidence
 8 refuting the claims of a causal association.²⁰ Lacking reliable epidemiological or scientific evidence
 9 of any association between TCVs and autism (or mercury-induced neurotoxicity), plaintiffs' expert
 10 witnesses attempt to Frankenstein together a causation argument by extrapolating from in vitro
 11 experiments, animal data, and poorly controlled observational studies, while ignoring valid
 12 scientific methods. In doing so, plaintiffs' experts breach the boundaries of legitimate science by
 13 employing improper scientific methodology and relying on unproven or improper studies.

14 II. PLAINTIFFS' EXPERTS

- 15 • Mark R. Geier, M.D.: is an ObGyn by training and a geneticist. He is not a pediatrician,
 16 immunologist, or neurologist. His opinions on the subject of TCVs causing autism have
 17 been rejected numerous times.
- 18 • George Lucier, Ph.D.: is a retired toxicologist whose doctorate is in entomology. He is not
 19 a toxicologist, geneticist, neurologist or epidemiologist. He is an expert on methylmercury,
 20 not ethylmercury.
- 21 • Boyd Haley, Ph.D.: is a chemistry professor, with no special training in toxicology,
 22 epidemiology, genetics or neurology. His opinions about mercury and neurodevelopmental
 23 injuries have been rejected by at least two courts.
- 24 • James J. Bradstreet, M.D., FAAFP: is a family practitioner who is not board-certified in any
 25 specialty, does not maintain hospital privileges, and has no specialized training in
 26 epidemiology, neurology, toxicology or genetics.
- 27 • Arthur Krigsman, M.D.: is a gastroenterologist. No CV was provided but he apparently is
 28 involved in the evaluation of gastrointestinal symptoms of autistic children.

²⁰ IOM Executive Summary, p. 16, Ex. C-5. 4

1 Plaintiffs have designated Dr. Geier as their sole retained causation expert.²¹ Dr. Geier's
 2 Report (Ex. A-2) is the only causation report provided by plaintiffs. Although plaintiffs designated
 3 four other (non-retained) experts to provide opinions virtually identical to those in the broad-
 4 sweeping designation for Dr. Geier, two (Dr. Lucier and Dr. Haley) are not non-retained experts as
 5 they never treated Alexander Redfoot and no reports have been provided by them.

6 In a recent civil court vaccine case, the court's Memorandum Opinion relegated the
 7 dismissal of the opinions of Dr. Haley and Dr. Lucier to a footnote and focused instead on Dr.
 8 Geier's lack of qualifications and improper scientific methods.²² Dr. Geier offers three main
 9 opinions. It is believed that, if allowed to testify, the remaining non-retained experts will rely on
 10 the same body of "evidence" to reach the same conclusions. The three key components of plaintiffs'
 11 general causation opinion are that (1) thimerosal-containing nasal spray causes autism (2) in the
 12 same manner and at the same doses as thimerosal-containing vaccines (3) in a genetically
 13 vulnerable subpopulation of children whose ability to excrete mercury is impaired.

14 As the methodology employed by Dr. Geier is flawed, his opinions are based on flawed
 15 analyses without valid scientific support, and therefore fail to meet any of the Daubert standards.
 16 Plaintiffs have not cited any reliable, peer-reviewed epidemiological studies purporting to establish
 17 a causal link between the administration of thimerosal-containing nose spray and the onset of
 18 autistic disorder. Multiple reliable epidemiologic studies consistently have found no evidence of
 19 any association between TCVs and autism. There is no reliable scientific evidence (1) that
 20 thimerosal is toxic to humans at the incremental doses delivered by nasal sprays;²³ (2) that
 21 thimerosal is toxic to humans at the doses delivered by TCVs;²⁴ (3) that there is an identified

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 25 ²¹ Plaintiffs' Expert Designation, Ex. A-1.

26 ²² Memorandum Opinion, p. 4, fn. 3 in Doe v. Ortho Clinical Diagnostics, U.S.D.C. Middle
 District of North Carolina, 1-03CV00669 (July 6, 2006) (Ortho Memorandum Opinion), Ex. E-1.

27 ²³ FDA Response to Citizen Petition, p. 6, ¶ B.2., Ex. C-2. FDA believes that the mercury
 exposure from such products is minimal, and the products are safe.

28 ²⁴ Id., p. 7, no. 2, Ex. C-2.

1 subpopulation of children who are genetically vulnerable to mercury neurotoxicity;²⁵ (4) or that
2 mercury can cause neurological damage that manifests as autism.²⁶

3 III. DEFENDANTS' EXPERTS

4 In contrast, defendants offer opinions from highly-qualified experts, utilizing generally
5 accepted methodology in their respective fields and reliable scientific evidence to support their
6 opinions.

- 7 • Patricia Rodier, Ph.D.: Dr. Rodier is a medical research scientist, and a Professor of
8 Obstetrics and Gynecology in the School of Medicine at the University of Rochester. The
9 Director of the National Institutes of Health (NIH) Collaborative Program of Excellence in
10 Autism, and the NIH's STAART (Studies to Advance Autism Research and Treatment)
11 Center at the University of Rochester, Dr. Rodier has served both as the President of the
12 Behavioral Teratology Society and on the Governing Council of the Teratology Society.
13 (Teratology is the branch of embryology and toxicology dealing with abnormal development
14 and congenital malformations.) Dr. Rodier has published over 50 articles related to
15 neurological injury in general, and autism in particular, in many peer-reviewed scientific
16 journals, including Pediatrics, Environmental Health Perspectives, Teratology,
17 Developmental Brain Research and The Journal of Comparative Neurology. Rodier Report,
18 Ex. B-3.
- 19 • Philip Guzelian, M.D.: Dr. Guzelian is a Clinical Professor of Medicine and Chief of the
20 Section of Medical Toxicology, at the University of Colorado Health Sciences Center in
21 Denver. He served as a Professor of Medicine and Pharmacology. He is also board
22 certified in Internal Medicine, and belongs to numerous societies including the Academy of
23 Toxicological Sciences and the Society of Toxicology. He served as a member of both the
24 National Academy of Sciences Committee on Toxicology and the U.S. EPA's Scientific
25 Advisory Board. Dr. Guzelian served/serves on the editorial boards of several
26 publications, including: Hepatology; Toxicology and Applied Pharmacology; Drug
Metabolism and Disposition; and Human & Experimental Toxicology. He has authored or
co-authored over 150 abstracts, peer-reviewed articles, or book chapters in the area of
toxicology. Guzelian Report, Ex. B-4.
- Paul G. Fisher, M.D.: Dr. Fisher is an Associate Professor in Neurology and Pediatrics,
Neurosurgery and Human Biology at Stanford University. He completed residencies in both
pediatrics and neurology at the Johns Hopkins Hospital, and a fellowship in Neuro-
Oncology at Children's Hospital of Philadelphia. Dr. Fisher is board-certified in Neurology,
with special competence in both Child Neurology and Pediatrics. He conducted an
independent medical examination of Alexander Redfoot and evaluated Alexander for

27 ²⁵ Id., p. 13, ¶ B, Ex. C-2. The argument that thimerosal-containing products harm a susceptible
28 population of humans is not supported by the evidence.

²⁶ Rodier Report, p. 3, ¶ 10, Ex. B-3.

mercury-induced neurology. Dr. Fisher also holds a master's degree in Epidemiology from the Johns Hopkins University School of Hygiene and Public Health. Fisher Report, Ex. B-5.

- Peter Katona, M.D.: Dr. Katona is a medical doctor and Fellow in the American College of Physicians. He is board certified in both Internal Medicine and Infectious Disease, and received extensive epidemiology training at the Centers for Disease Control. Dr. Katona served as Chairman of the Infection Control Committee & Hospital Epidemiologist at UCLA Medical Center. He is a reviewer for the American Journal of Epidemiology and Journal of American Medical Association (JAMA). Katona Report, Ex. B-2.

IV. ARGUMENT

POINT I - The Daubert Standards.

Daubert v. Merrell Dow Pharm., 509 U.S. 579, 113 S.Ct. 2786 (1993) (Daubert) and the Federal Rules of Evidence require, at a minimum, that plaintiffs demonstrate that each expert witness offered to testify (1) is properly qualified in the field in which he seeks to offer opinions, (2) offers opinions that are based on reliable science and methodology, and (3) offers opinions that have a sufficient nexus to the present case to constitute relevant evidence. Plaintiffs cannot meet these requirements.

A. The District Courts Act as “Gatekeepers” Under Daubert

The U.S. Supreme Court has bestowed upon the district court judges the role of gatekeepers, charged with the task of excluding unreliable scientific evidence and opinion testimony from the courtroom. Daubert, supra. Daubert requires a two-part analysis: First, the court must determine whether an expert's testimony reflects "scientific knowledge," whether the findings are "derived by the scientific method," and whether the work product is "good science." Id. at 590 & 593, 113 S.Ct. at 2795 & 2797. Second, the court must determine whether the expert's testimony is "relevant to the task at hand." Id. at 597, 113 S.Ct. at 2799. This gate-keeping requirement recognizes the powerful and potentially misleading influence that expert scientific testimony may have upon jurors. Id. at 595, 113 S.Ct. at 2786. The trial court's gate-keeping function requires more than simply taking the expert's word for it. Any step that renders the expert's analysis unreliable renders the expert's testimony inadmissible. Cagle v. Cooper Cos. (In re Silicone Gel Breasts Implants), 318 F. Supp. 2d 879 (9th Cir. 2004).

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1 **B. Daubert Provides Factors for Assessing the Reliability of Testimony Proffered**
 2 **by Plaintiffs' Expert Witnesses**

3 In Daubert and related cases, the U.S. Supreme Court has elucidated a number of non-
 4 exclusive factors for district courts to consider when determining whether to admit expert testimony
 5 under FRE 702.²⁷ The FRE 702 factors focus on the methodology employed by the witness and the
 6 conclusions flowing therefrom, and asks, as to the theory or technique employed by the expert,
 7 whether it (1) is generally accepted in the relevant scientific community; (2) has been subjected to
 8 peer-review and publication; (3) can be and has been tested; (4) has an acceptable or known rate of
 9 error; and (5) includes and maintains standards and controls. Daubert, 509 U.S. at 593-94; 113 S.
 10 Ct. at 2796-98. These factors are neither exclusive nor dispositive. Since Daubert, the U.S.
 11 Supreme Court and lower courts have also identified additional factors that may be considered, such
 12 as whether an expert has unjustifiably extrapolated from an accepted premise to an unfounded
 13 conclusion (see GE v. Joiner, 522 U.S. 136, 146, 118 S. Ct. 512, 519 (1997)); whether an expert has
 14 adequately accounted for obvious alternative explanations (see Claar v. Burlington N.R.R., 29 F.3d
 15 499, 502 (9th Cir. 1994); or whether an expert is proposing to testify about matters growing
 16 naturally and directly out of research they have conducted independent of the litigation, or whether
 17 they developed their opinions expressly for the purposes of testifying. Daubert v. Merrell Dow
 18 Pharm., 43 F.3d 1311, 1317 (9th Cir. 1995) (Daubert II). See Ortho Memorandum Opinion, pp. 5-
 19 6, Ex. E-1.

20 Where proffered expert testimony is based on a literature review and not independent
 21 research, the proffering party must come forward with objective, verifiable evidence that the

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 24 ²⁷ FRE 702 provides that if scientific, technical, or other specialized knowledge will assist the
 25 trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an
 26 expert by knowledge, skill, experience, training, or education, may testify thereto in the form of
 27 an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the
 28 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.

1 testimony is based on scientifically valid principles. This can be by proving that the research and
 2 analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny
 3 through peer review and publication. Daubert II, 43 F.3d at 1318. While a Daubert analysis must
 4 focus solely on principles and methodology, not the conclusions they generate, the Court later
 5 recognized that conclusions and methodology are not entirely distinct from one another. GE, 522
 6 U.S. at 146, 118 S. Ct at 519. In other words, trained experts commonly extrapolate from
 7 existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a district
 8 court to admit opinion evidence which is connected to existing data only by the ipse dixit of the
 9 expert. A court may conclude that there is simply too great an analytical gap between the data and
 10 the opinion proffered. Id. Finally, a bold statement of the experts' qualifications, conclusions, and
 11 assurances of reliability are not enough to satisfy the Daubert standard. Daubert II, 43 F.3d at 1319.

12 **POINT II - Analysis of Daubert As Applied To Dr. Mark Geier**

13 **A. Dr. Geier Lacks the Requisite Qualifications**

14 Dr. Geier is a medical doctor and has a Ph.D. in genetics. He is not board certified in
 15 pediatrics or pediatric neurology. He is also not certified as an epidemiologist or biostatistician.²⁸
 16 Dr. Geier is not a toxicologist either. Although he has published more than 50 peer-reviewed
 17 papers, none of these publications addressed the specific issue of whether thimerosal-containing
 18 nasal sprays cause autism.

19 Dr. Geier has testified as an expert witness in approximately 100 cases²⁹ before the National
 20 Injury Compensation Program of the U.S. Court of Federal Claims (the "Vaccine Court"), often on
 21 behalf of claimants alleging that TCVs caused their autism. In more than ten of these cases,
 22 particularly the more recent ones, Dr. Geier's opinion has either been pointedly excluded or
 23 accorded no weight based upon a determination that he was testifying beyond his expertise.³⁰
 24 Jeffries v. Secretary of HHS, 2004 U.S. Claims LEXIS 273 (Fed.Ct. 2004).³¹

25
 26 ²⁸ Geier Deposition, pp. 62-63, Ex. A-4.

27 ²⁹ Id., p. 52, line 21 - p. 53. (Ex. A-4)

28 ³⁰ Ortho Memorandum Opinion, p. 9, fn. 5, Ex. E-1. See, e.g., 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,

1 **B. Dr. Geier Employed Unacceptable Methodology**

2 Subject to the court's ruling on this Daubert motion, plaintiffs seek to offer Dr. Geier's
3 testimony in support of his ultimate conclusion that thimerosal in Ayr caused Alexander Redfoot's
4 autism. At issue here is Dr. Geier's methodology of using a review of relevant literature and his
5 own studies relating to the incidence of autism to support a conclusion of general causation.

6 **C. Dr. Geier's Literature Review Does Not Establish That Ayr Causes Autism**

7 A properly performed literature review can be an appropriate part of a method of
8 determining general cause. Here, however, Dr. Geier relied on a number of disparate and
9 unconnected studies, including some by Dr. Haley and Dr. Lucier, to rig together a conclusion as to
10 general causation ó that the undetermined but small amount of thimerosal received by Alexander
11 Redfoot could cause autism. Dr. Geier attempts to extrapolate from various studies in vitro, animal
12 and observational studies finding that (1) mercury exposure could destroy neurons;³² (2) high levels

13
14
15 No. 99-436V, 2003 WL 21439672 (Fed. Cl. May 23, 2003) (finding Dr. Geier was not qualified
16 because his causation theory was filled with **speculation that is directly contrary to the**
17 **conclusions reached in well-respected and numerous epidemiologic and medical studies**
18 **ranging over two decades**); Bruesewitz v. Sec'y of HHS, No. 95-0266V, 2002 WL 31965744
19 (Fed. Cl. Dec. 20, 2002) (finding Dr. Geier unqualified to diagnose neurological diseases); Raj v.
20 Sec'y of HHS, No. 96-294V, 2001 WL 963984 (Fed. Cl. July 31, 2001) (finding Dr. Geier
21 **wholly unqualified to testify concerning the two major issues in this case [encephalopathy**
22 **and infantile spasms]...because he is neither board certified nor has formal training in**
23 **pediatrics and pediatric neurology**); Haim v. Sec'y of HHS, No. 90-1031V, 1993 WL 346392
24 (Fed. Cl. Aug. 27, 1993) (finding that Dr. Geier's testimony did not reach "the level of evidentiary
25 reliability that Daubert requires because it is **not based upon scientific validity, valid**
26 **methodology, peer review or testing, and more than minimal support within the scientific**
27 **community**"); Marascalo v. Sec'y of HHS, No. 90-1571V, 1993 WL 277095 (Fed. Cl. July 9,
28 1993) (finding Dr. Geier's testimony "intellectually dishonest" and that his affidavit was "**nothing**
29 **more than an egregious example of blatant, result-oriented testimony**"). [Emphasis added]

30 ³¹ In Jeffries v. Secretary of HHS, Special Master French determined that Dr. Geier's testimony
31 was not probative of the causation issue and completely discounted it, "adding the present matter
32 to a long line of vaccine cases finding little or no value in Dr. Geier's testimony." LEXIS 273 at
33 69. Noting that Dr. Geier has been trained as an obstetrician and a geneticist, but not in
34 epidemiology, the court concluded that "Dr. Geier does not meet the AMA's guidelines for expert
35 witnesses," which require, first and foremost, "that the testifying doctor be an expert in the field for
36 which he opines, and that formal training in that field is essential." Id. at 69-70.

37 ³² Baskin DS, et al., Thimerosal induces DNA breaks, capsae-3 activation, membrane damage and
38 cell death in cultured human neurons and fibroblasts. Toxicol Sci 2003;74:361-8. Ex. D-1.

1 of prenatal mercury exposure may cause developmental defects³³; (3) mercury can be transmitted
 2 through a mother's milk to her child;³⁴ (4) thimerosal can cross the blood-brain and placental
 3 barriers (at doses of 1,000 micrograms of thimerosal);³⁵ (5) direct and multiple injections of 50
 4 milligrams (50,000 micrograms) can kill or deform embryonic chickens;³⁶ (6) topical use of
 5 thimerosal as an antimicrobial by pregnant women may have caused birth defects; (7) a mouse
 6 model exposed to thimerosal mimicking a childhood immunizations schedule developed symptoms
 7 allegedly similar to autism;³⁷ (8) a paper suggesting that TCVs cause a novel form of mercury
 8 poisoning in some children;³⁸ and (9) a hair study of children with autism showing a statistically
 9 significant correlation between RhoD immunoglobulin administration and autism.³⁹ See Ortho
 10 Memorandum Opinion, pp. 10-11, Ex. E-1.

11 In the Holmes study (a pillar of Dr. Geier's opinion), mercury content in first baby haircuts
 12 from a group of autistic children was found to be lower than the mercury content of the baby hair
 13 from a group of purportedly "normal" controls. The authors hypothesized the autistic children's
 14 impaired ability to "excrete" mercury meant they must have retained mercury in their tissues,
 15 including the brain, where it could exert neurotoxic effects. The IOM specifically dismissed the
 16 Holmes study noting numerous methodological problems, including that the selection of both cases
 17

18 ³³ Faroe Islanders Studies, Grandjean P, Weihe P, White RF, Debes F, Cognitive deficit in 7-year-
 19 old children with prenatal exposure to methylmercury. Neurotoxicol. Teratol. 1997; 19:417-28,
 20 Ex. D-3; and Grandjean P, Weihe P, White RF, Debes F, Cognitive performance of children
 21 prenatally exposed to safe levels of methylmercury. Environ. Res. 1998, 77:165-72, Ex. D-2.

22 ³⁴ Iraq Study of Amin-Zaki, L.S. Elhassani, et al. (1974). Intra-uterine methylmercury poisoning in
 23 Iraq. Pediatrics 54(5):587-95. See Ortho Memorandum Opinion, p. 11, Ex. E-1.

24 ³⁵ Slikker W. Developmental neurotoxicology of therapeutics: survey of novel recent findings.
 25 Neurotoxicology 2000; 21:250, Ex. D-4.

26 ³⁶ Digar A, Sensharma GC, Samal SN. Lethality and teratogenicity of organic mercury
 27 (thimerosal) on the chick embryo. J. Anat. Soc. India 1987; 36:153-9. See Ortho Memorandum
 28 Opinion, p. 11, Ex. E-1.

29 ³⁷ Hornig M, Chian D, Lipkin Wi. Neurotoxic Effects of Postnatal Thimerosal are Mouse Strain
 30 Dependent. Mol. Psychiatry 2004; 9:833-45, Ex. D-5.

31 ³⁸ Bernard, S., et al. (2001) Autism: a novel form of mercury poisoning. Medical Hypotheses.
 32 56:462-71, Ex. D-6.

33 ³⁹ Holmes, A.S., Blaxill M.F., Haley, B.I. (2003). Reduced Levels of Mercury in First Baby
 34 Haircuts of Autistic Children. Int. J. Toxicol. 22(4):277-85, Ex. D-7.

1 and controls were biased.⁴⁰ Dr. Holmes concludes: "Our study provides further insight into one
2 possible mechanism by which early mercury exposures could increase the risk of autism."⁴¹ Such a
3 conditional statement ("could") cannot meet the preponderance of the evidence standard that
4 plaintiffs need to meet to show that thimerosal in Ayr can cause autism.

5 **D. Dr. Geier's Studies Have an Unknown and Indeterminate Rate of Error**

6 The methodology employed in the Geier studies cannot be fully discerned, and the rate of
7 error is potentially quite high. The IOM found that Dr. Geier's description of the analytical methods
8 employed omitted important details such as "regression models were not specified, the frequency
9 distribution of variables was not provided, and actual calculation of statistics were not clear or not
10 reported."⁴²

11 Accordingly, Dr. Geier's studies have an unknown and indeterminate rate of error.

12 **E. Dr. Geier's Differential Diagnosis**

13 Dr. Geier undertook a differential diagnosis of Alexander Redfoot and concluded he had
14 toxic encephalopathy from mercury exposure.⁴³ Differential diagnosis, the process of elimination
15 that physicians use to identify the most likely cause of a particular individual's illness, is an
16 acceptable source of data on specific causation. However, differential diagnosis cannot demonstrate
17 general causation, because "differential diagnosis assumes that general causation has been proven
18 for the list of possible causes it eliminates." Cagle, supra at 892 citing Hall v. Baxter Healthcare
19 Corp., 947 F. Supp. 1387 (1996) (emphasis added). Thus, Dr. Geier's differential diagnosis,
20 whatever its strengths and flaws may be, cannot provide evidence of general causation.

21 **F. The Peer-Reviewed Literature Flatly Contradicts Dr. Geier's Conclusions**

22 Dr. Geier's conclusion that the peer-reviewed literature supports his theory that autism can
23 be caused by thimerosal is flatly contradicted by all of the reliable epidemiological studies available
24 at this time. Dr. Geier's theory that Ayr could cause autism is based on "with no data or calculations
25

26 ⁴⁰ IOM Report at 133-134, Ex. C-4.

27 ⁴¹ Holmes, fn. 35 above at 285, Ex. D-7.

28 ⁴² IOM Report at 57-58, Ex. C-4.

⁴³ Geier Report, p. 23, Impressions 3-4, Ex. A-2.

1 provided- on extrapolation from his "evidence" that TCVs cause autism. The theory that TCVs
 2 cause autism has been tested in multiple well-designed, well-conducted epidemiologic studies, all of
 3 which have found no evidence of any association.⁴⁴ The IOM concluded:

4 "Given the lack of direct evidence for a biological mechanism and
 5 the fact that all well-designed epidemiological studies provide
 6 evidence of no association between thimerosal and autism, the
 7 Committee recommends that the cost-benefit assessments
 8 regarding the use of thimerosal-containing versus thimerosal-free
 9 vaccines and other biological or pharmaceutical products **should**
 10 **not include autism as a potential risk.**" IOM Executive
 11 Summary, p.13, Ex.C-5.

12 Thus, while Dr. Geier's recitation of the literature as part of his methodology might at first
 13 blush appear convincing, the disconnected literature he presents does not add up to the opinion and
 14 conclusion he is offering. See Domingo v. T.K., 289 F.3d 600, 606 (9th Cir. 2002).⁴⁵

15 **G. Dr. Geier's Studies are Not Generally Accepted**

16 General acceptance in the relevant scientific communities is the hallmark of the fourth
 17 reliability factor. After Daubert, the U.S. Court of Appeals for the Ninth Circuit routinely has
 18 considered the reliability of expert testimony against the backdrop of other scientists' opinions.
 19 Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc., 55 F. Supp. 2d 1024, 1999 U.S. Dist. LEXIS
 20 16051 (9th Cir. 1999).

21 Dr. Geier has published articles purporting to find a statistically significant link between
 22 TCVs and autism. (See infra, CONCLUSION, p. 24, ¶ 2.) These studies utilize data from the
 23 Vaccine Adverse Event Reporting System ("VAERS") database or the Department of Education
 24 ("DOE") database, neither of which contain sufficient or appropriate data to test a hypothesized
 25 association between TCVs and autism. Dr. Geier has also performed an analysis of Vaccine Safety
 26 Datalink ("VSD") data. All of these studies are methodologically unsound.⁴⁶

27 ⁴⁴ Rodier Report, p. 7, ¶ 20, Ex. B-3.

28 ⁴⁵ "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. Domingo v. T.K., at 606.

⁴⁶ Katona Deposition, p. 47, lines 5-10; p. 49 lines 2-9, Ex. B-7.

1 Dr. Geier relies heavily on his own VAERS studies to support his conclusions.⁴⁷ However,
 2 far from gaining general acceptance, Dr. Geier's VAERS studies have met almost universal scorn
 3 from the scientific community. The VAERS database is a passive reporting system that accepts
 4 voluntary reports regarding potential adverse events. The IOM concluded "the data in VAERS
 5 cannot support a determination of whether a vaccine was more likely than not to have caused an
 6 adverse event." The limitations of the system include "variability in reporting standards, reporting
 7 bias, unconfirmed diagnoses, lack of information on people who were immunized but did not report
 8 an adverse event, lack of an unbiased comparison group, and variable and potentially significant
 9 underreporting of adverse events."⁴⁸ Nor could any individual child's total thimerosal exposure be
 10 discerned. Even well-designed studies cannot reach conclusions about cause and effect
 11 relationships from VAERS data.

12 After reviewing Dr. Geier's VAERS studies, the IOM Committee concluded:

13 "the studies by Geier and Geier cited above have serious
 14 methodological flaws and their analytic methods were
 15 nontransparent making their results uninterpretable, and therefore
 16 non-contributory with respect to causality... Thus, based on this
 17 body of evidence, the committee concludes that the evidence favors
 18 rejection of a causal relationship between thimerosal-containing
 19 vaccines and autism."⁴⁹

18 The IOM Committee deemed the fact that Dr. Geier's calculations were based on passive
 19 reporting data a "major problem,"⁵⁰ and identified further flaws in Dr. Geier's VAERS studies,
 20 including: (1) The lack of a complete and transparent description of methods and underlying data;
 21 (2) Use of inappropriate methodology for analysis of VAERS data; (3) Baseless assumptions
 22 regarding vaccine history and total thimerosal exposure for any individual; (4) Arbitrary
 23 identification of exposure groups; and (5) Improper application of epidemiological measures.⁵¹

24
 25
 26 ⁴⁷ The VAERS internet site specifically warns that VAERS data cannot be used to determine
 27 causal relationships. See www.vaers.hhs.gov, Ex. C-10.

28 ⁴⁸ IOM Report at 61, Ex. C-4.

⁴⁹ *Id.* at 65, Ex. C-4.

⁵⁰ *Id.* at 61, Ex. C-4.

⁵¹ *Id.* at 59-62, Ex. C-4.

1 Dr. Geier has authored new studies since the IOM report, but they are also based on the
2 VAERS database. They, therefore, suffer from the same inherent problems owing to the passive
3 reporting nature of the VAERS database.⁵²

4 The American Academy of Pediatrics issued a scathing official statement criticizing Dr.
5 Geier's 2003 VAERS study, stating his study "uses data from the Vaccine Adverse Event Reporting
6 System (VAERS) inappropriately and contains numerous conceptual and scientific flaws, omissions
7 of fact, inaccuracies, and misstatements."⁵³ In addition, the WHO concluded that the same study
8 "has a number of limitations which leave an independent reader of the article unable to reach the
9 same conclusions as the authors."⁵⁴

10 At least three of Dr. Geier's published articles reference his analyses of DOE data.⁵⁵ These
11 ecological studies suffer from similar flaws to the VAERS studies. In his DOE analyses, Dr. Geier
12 purports to compare the number of autism cases in DOE's special education program database in
13 various years to the estimated doses of mercury that children might have received based upon data
14 from Biologic Surveillance Summaries ("BSS").⁵⁶ The IOM Committee found these DOE studies
15 were "characterized by serious methodological problems" that rendered them wholly
16 uninformative.⁵⁷

17 The IOM Committee also identified significant flaws, including Dr. Geier's use of DOE data
18 to estimate autism prevalence, his method of manipulating that data, and the inherent potential for
19 bias.⁵⁸ A further methodological problem is that "description of analytic methods was not
20

21 _____
22 ⁵² Katona Deposition, p. 47, ll. 5-10; p. 49, ll. 2-9, Ex. B-7.

23 ⁵³ AAP Statement, Ex. C-3.

24 ⁵⁴ WHO, Ex. C-6.

25 ⁵⁵ Geier DA & Geier MR, An assessment of the impact of thimerosal on childhood
26 neurodevelopmental disorders, Ex. D-8; Geier DA & Geier MR, Thimerosal in childhood vaccines,
27 neurodevelopmental disorders, and heart disease in the United States, Ex. D-10; Geier DA & Geier
28 MR, A comparative evaluation of the effects of MMR immunization and mercury doses from
thimerosal-containing childhood vaccines on the population prevalence of autism, Ex. D-11.

⁵⁶ These are voluntary reports from vaccine manufacturers to CDC of the number of vaccine doses
distributed and returned during the reporting periods maintained by the CDC. See IOM Report at
55, fn. 11, Ex. C-4.

⁵⁷ IOM Report at 57-58, Ex. C-4.

⁵⁸ Id. at 57, Ex. C-4.

1 transparent and important details were omitted.⁵⁹ Consequently, the IOM Committee concluded
2 that Dr. Geier's DOE studies were "uninterpretable and, therefore, non-contributory with respect to
3 causality."⁶⁰

4 Given that these studies by Dr. Geier are methodologically flawed and have been deemed
5 "uninterpretable" by the relevant scientific community, they cannot and do not constitute reliable
6 epidemiological evidence prerequisite to the admission of expert opinions on general causation.
7 Plaintiffs' allegation that thimerosal in nasal spray causes autism is based entirely on the earlier
8 and now completely discredited hypothesis of a link between thimerosal in vaccines and autism,⁶¹
9 and thus plaintiffs' allegations must also be rejected.

10 **H. Permissible Opinion Testimony Regarding General Causation Must Be**
11 **Grounded in Reliable Epidemiologic Studies**

12 When numerous epidemiological studies spanning a significant period of time are available,
13 they are important in determining questions of causation. Because epidemiology is concerned with
14 the incidence of disease in populations, epidemiology is probative of general causation. Cagle,
15 supra at 879. Here, however, there are no peer-reviewed epidemiological studies demonstrating a
16 link between thimerosal in nasal spray and autism. Similarly, there are no reliable studies
17 demonstrating a link between TCVs and autism.

18 Several controlled, epidemiological studies that examined the alleged link between exposure
19 to thimerosal-containing vaccines and the development of autism have been published in peer-
20 reviewed journals.⁶² These studies all reached the same conclusion that their results showed no
21

22
23 ⁵⁹ Id. at 58. Ex. C-4.

24 ⁶⁰ Id. at 58, Ex. C-4.

25 ⁶¹ Rodier Report, p.7, ¶ 21, Ex. B-3.

26 ⁶² Hviid, A et al., Association between Thimerosal-Containing Vaccine and Autism, JAMA 2003;
27 290 (13):1763-66 ("Hviid 2003"), Ex. D-12; Verstraeten, T et al., Safety of Thimerosal-Containing
28 Vaccines: A two-phased study of computerized health maintenance organization databases,
Pediatrics 2003,112(5):1039-48 ("Verstraeten 2003") Ex. D-13; Andrews N et al., Thimerosal
Exposure in Infants and Developmental Disorders: a retrospective cohort study in the United
Kingdom does not support a causal association, Pediatrics 2004;114(3):584-91 ("Andrews 2004")
Ex. D-14; Jick H & Kaye J, Autism and DPT Vaccination in the United Kingdom, Engl. J Med
2004; 350(26):2722-3 ("Jick 2004") Ex. D-15. ¹⁶

1 evidence of an association between TCVs and ASDs.⁶³ In addition, two published ecological
 2 studies, Madsen, et al.,⁶⁴ and Stehr-Green,⁶⁵ are consistent with the finding of no association
 3 between TCVs and autism.⁶⁶ Plaintiffs' expert witnesses essentially ignore the weight of reliable
 4 epidemiology demonstrating "no evidence of any association." After carefully considering the
 5 foregoing studies, and all other available scientific evidence (including the studies by Dr. Geier), the
 6 IOM Committee concluded that "the evidence favors rejection of a causal relationship between
 7 thimerosal-containing vaccines and autism."⁶⁷ The court's gate-keeping function requires more
 8 than simply taking the expert's word for it. Cagle, supra, at 890. Here, virtually every step renders
 9 Dr. Geier's analysis unreliable and renders his testimony inadmissible. Id. at 890.

10 **I. Dr. Geier's Opinions Were Formulated for Litigation, Are Not Based on Pre-**
 11 **Existing Independent Research, and He Has Demonstrated Bias.**

12 A factor as to whether expert testimony is based on scientific knowledge is whether the
 13 opinions are based on pre-existing independent research, or are expressly formed for the purposes of
 14 testifying. Where the expert testimony is not based on independent research, the party offering it
 15 must come forward with other objective, verifiable evidence that the testimony is based on
 16 scientifically valid principles, such as peer-reviewed publications. Alternatively, the experts must
 17 explain precisely how they went about reaching their conclusions and point to some objective
 18 source to show that they have followed the scientific method. Lopez v. Wyeth-Ayerst Labs., 1996
 19 U.S. Dist. LEXIS 22739. As noted by Judge Beaty in the Ortho case, Dr. Geier's interest in autism
 20 coincides neatly with his employment as an expert witness in vaccine litigation.⁶⁸

23 _____
 24 ⁶³ Fisher Report, p. 4, ¶ 6, Ex. B-5; Katona Report, p.5, Ex. B-2; Rodier Report, p. 7, ¶ 20,
 Ex. B-3.

25 ⁶⁴ Madsen K., et al, Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From
Danish Population-Based Data, Pediatrics Vol. 112 No.3 September 2003, Ex. D-16.

26 ⁶⁵ Stehr-Green Thimerosal and Thimerosal-Containing Vaccines, Lack of Consistent Evidence of
an Association, Am J Prev Med 2003; 25(2), Ex. D-17.

27 ⁶⁶ Fisher Report, p. 3, ¶ 6, Ex. B-5; and Katona Report, p. 4, Ex. B-2.

28 ⁶⁷ IOM Executive Summary, p. 7. Ex. C-5.

⁶⁸ See Ortho Memorandum Opinion, p.17, Ex. E-1.

1 Dr. Geier published no papers on thimerosal-containing nasal spray induced autism before
 2 this litigation. Moreover, Dr. Geier has called the highly-respected CDC a "rogue organization."⁶⁹
 3 He also has opined that "I think they are an organization out of control, the CDC and FDA,"⁷⁰
 4 underscoring his potential bias and conspiracy-theorist proclivities.

5 **POINT III - Plaintiffs' Other Expert Witnesses Are Not Qualified To Testify Regarding the**
 6 **Key Opinions Proffered**

7 FRE 702 permits the testimony of expert witnesses only under carefully controlled
 8 circumstances. The broad sweep of opinions plaintiffs' experts attempt to proffer requires each to
 9 be qualified as an expert in each of three disciplines: epidemiology, toxicology, and pediatric
 10 neurology. All have overstepped their expertise by offering such broad opinions. To the extent
 11 they venture past their expertise, plaintiffs' experts' testimony must be excluded. None of plaintiffs'
 12 expert witnesses is qualified by "knowledge, skill, experience, training or education," to testify in
 13 the area of epidemiology. Neither Dr. Geier, Dr. Bradstreet, Dr. Kringsman nor Dr. Haley is
 14 qualified as a toxicologist, a fact painfully evident in light of Dr. Geier's complete lack of making
 15 any calculations of ethylmercury exposure and dose in this case.⁷¹ In November 2004, the Superior
 16 Court of California in an enforcement action under Proposition 65 by the Attorney General, citing
 17 Dr. Haley's lack of qualifications in toxicology, rejected his testimony that the amount of thimerosal

18
 19 ⁶⁹ Geier Deposition, p. 165, l. 17, Ex. A-4.

20 ⁷⁰ Id., p. 165, ll. 17-18, Ex. A-4.

21 ⁷¹ Dr. Geier only estimated that the total amount of ethylmercury in the product administered (i.e.,
 22 total exposure to Alexander) to be "about 700 micrograms ethylmercury." See
 23 "Neurodevelopmental Disorder Assessment," p. 5, Plaintiffs' FRCP 26(a)(2) Supplemental Expert
 24 Disclosures (Documents Only) Ex. A-3. Dr. Geier indicates that Michell Redfoot administered Ayr
 25 Saline Nasal Mist to Alexander 2 to 3 times per day, every day, from age 2 months to 3 years.
 26 Further, he notes Michell used 2-4 bottles per year in this time. Apparently based on these data, Dr.
 27 Geier calculates the total exposure as approximately 700 micrograms ethylmercury. Dr. Geier
 28 makes no effort to calculate the amount of ethylmercury from Ayr Alexander Redfoot actually
 absorbed, which is essential in arriving at an accurate average daily dose. Michell Redfoot has
 testified in deposition that Alexander made administering the product difficult, so that some Ayr ran
 down his face. Michell Deposition, p. 19, line 15, Ex. A-5. Robert (Alexander's father) testified
 that they used a vacuum bulb to remove the Ayr Saline Nasal Mist shortly after it was administered.
 Robert Deposition, p. 83, ll. 14-20, Ex. A-6. When asked whether use of a vacuum extractor would
 change the ethylmercury exposure, Dr. Geier conceded "I don't know how to evaluate how much
 would come out." Geier Deposition p. 191, ll. 2-3.

1 contained in certain nasal sprays exceeded the maximum allowable dose level (MADL) under
 2 California law. People v. Altaire Pharmaceutical, Inc., No. 2001 ó 026727 (2004).⁷² This Court
 3 should not permit similar unreliable testimony by Dr. Haley.

4 **POINT IV - The Genetically Susceptible Argument**

5 The opinion that there exists a subpopulation of children genetically vulnerable to mercury
 6 toxicity, and therefore to a "unique" form of mercury poisoning that manifests as autism, lacks any
 7 reliable scientific foundation. This concept has been fully rejected by the FDA.⁷³

8 **A. The Symptoms of Mercury Poisoning and Autism are Not the Same**

9 The theory is based on a paper by Bernard, et al., (Ex. D-6) who posited that postnatal
 10 exposure in TCVs causes autism. The authors claimed incorrectly that the symptoms of autism are
 11 also those of mercury poisoning.⁷⁴ As pointed out by the experts on autism, the symptoms of
 12 autism used by the authors to find parallels to symptoms of mercury poisoning are not the
 13 characteristic symptoms used to diagnose autism. Instead, the authors include a long list of
 14 symptoms that occur in all children (e.g., nausea and vomiting, irritability and temper tantrums),
 15 or occur in other conditions as well as in some cases of autism (e.g., mental retardation, articulation
 16 problems, abnormal gait and posture.)⁷⁵ The most common symptoms of ethylmercury poisoning
 17 are muscle weakness, loss of appetite, and dizziness (Zhang, 1984). In fact, of the 35 symptoms of
 18 ethylmercury poisoning described by Zhang, not a single symptom is even vaguely related to the
 19 core symptoms of autism.⁷⁶

20 There is no reliable evidence that ethylmercury at the doses delivered by TCVs or Ayr has
 21 ever caused autism. Plaintiffs' expert witnesses' contrary opinions are based on the

22
 23 ⁷² Finding that Dr. Haley's proposed MADL calculations were "not credible," the court noted that
 24 he "is not a toxicologist" is not board certified, and has no hands-on toxicology experience. The
 25 court further observed that Dr. Haley's views on mercury's "potential like to conditions such as
 26 autism have been disproved or discredited." The court deemed irrelevant studies relied upon by Dr.
 27 Haley in proposing a MADL, or maximum human dose of thimerosal, People v. Altaire, Slip.
 28 Opinion at 11, Ex. E-2.

⁷³ FDA Response to Citizen Petition, pp. 13-19, Ex. C-2.

⁷⁴ Rodier Report, p.3, ¶ 10, Ex. B-3.

⁷⁵ Id., p. 3, ¶ 11, Ex. B-3.

⁷⁶ Id., p. 3, ¶ 11, Ex. B-3.

1 "epidemiologic" studies of Dr. Geier and his son, all of which have been severely criticized as
 2 methodologically unsound by numerous international bodies; on in vitro and animal studies, which
 3 are generally unreliable evidence of human causation; and on methodologically flawed hypothesis-
 4 generating human studies. Their testimony regarding the hypothesized causal link between TCVs
 5 and either mercury poisoning or autism must therefore be viewed as speculative, at best.⁷⁷ In
 6 fulfilling its mandated gatekeeping function, this Court should therefore preclude any such
 7 testimony from reaching the jury.

8 **1. In vitro Experiments are Unreliable Indicators of Human Response to a**
 9 **Potential Toxin**

10 In its May 2004 report, the IOM Committee reviewed a number of the in vitro studies that
 11 plaintiffs' expert witnesses rely on, but found that the relevance of the effects of thimerosal in cell
 12 culture "to a causal pathway in autism, is theoretical."⁷⁸ Dr. Geier cites a study by Baskin, et al.,
 13 (Ex. D-1) that found that thimerosal at sufficient concentrations (1 micromolar and higher) at
 14 killed cultured neurons. The authors recognized there is no scientific evidence that mercury reaches
 15 concentrations in the human brain anywhere near this level following vaccination with thimerosal-
 16 containing vaccines.⁷⁹

17 In a second in vitro study cited by plaintiffs' expert, it was found that insulin-like growth
 18 factor and dopamine stimulated the activity of a specific enzyme (methionine synthase) in tumor
 19 cells, but that this increased enzymatic activity was suppressed by thimerosal.⁸⁰ The authors
 20 speculated that thimerosal might suppress this enzyme in the human brain, leading to a series of
 21 speculative changes that were hypothesized to lead, potentially, to autism. The study authors
 22 themselves explicitly recognized the limitations of their study and ultimately concluded that:

23 biochemical studies under controlled cultured conditions do not
 24 replicate the complex in vivo environment, in terms of ambient

25
 26 ⁷⁷ FDA Response to Citizen Petition, p. 8, Ex. C-2.

27 ⁷⁸ IOM Report at 136, Ex. C-4.

28 ⁷⁹ Baskin at pp. 361-8, Ex. D-1.

⁸⁰ Waly, et al., Activation of methionine synthase by insulin-like growth factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal, Mol. Psychiatry (2004), pp. 1-13, Ex. D-20.

1 metal ion concentrations, redox conditions and other factors that
2 could influence [their observations].⁸¹

3 **2. Animal Studies**

4 To the extent plaintiffs' expert witnesses rely on animal studies, their opinions are
5 methodologically flawed and inadmissible. An expert's mere citation to animal studies, without
6 more, is not enough to show that the expert's opinion is based upon scientific knowledge. Lopez v.
7 Wyeth-Ayerst Labs., 1996 U.S. Dist. LEXIS 22739, at 12; see also Daubert II, 43 F.3d at 1319.
8 When animal studies are offered to demonstrate causation in a tort case, experts also need to
9 provide additional information to justify the extrapolation to humans. Expert opinions based on
10 animal data have been excluded where the expert did not review similarities and differences
11 between humans and the animal species in which the compound was tested. Cagle, supra at 891.

12 Dr. Geier has made no effort to justify extrapolation to humans from these studies. He has
13 not indicated or calculated a dose at which thimerosal causes autism in humans. He has not
14 discussed the similarities and differences between humans and the animals in which the compounds
15 were tested. Not surprisingly, as referenced above, neither did he calculate the average daily dose
16 of ethylmercury Alexander received. (See supra, fn. 73.)

17 Plaintiffs' expert witnesses also rely on a study in mice published by Hornig, et al., in 2004.
18 Ex. D-5. Inbred newborn neonatal mice genetically susceptible to mercury-induced autoimmune
19 reactions unknown in humans were injected with thimerosal-containing vaccines. Because
20 autoimmune reactions are not implicated in the etiology of autism the study is irrelevant.⁸² The
21 Hornig study does not describe a mouse model for autism. Even Dr. Hornig does not claim her
22 animal study establishes that TCVs can cause autism. The IOM concluded "the connection between
23 these models and autism is theoretical."⁸³

24 **B. The Genetic Predisposition Argument is Unfounded**

25 Plaintiffs' experts' opinions are predicated on the theory that there is a subpopulation of
26 children genetically rendered unable to eliminate mercury. As a result, administration of TCVs (or

27
28 ⁸¹ Id., p.11.

⁸² See IOM Report at 138, Ex. C-4.

⁸³ IOM Report at 138, Ex. C-4.

1 Ayr), plaintiffs claim, results in a mercury build-up in the brain, where it exerts toxic effects
2 resulting in a "unique" form of mercury poisoning that manifests as autism.

3 The IOM recognized this line of reasoning as a theoretical explanation of the data
4 presented, but found no corroborating data in the laboratory, in animals, or in humans linking
5 vaccines or vaccine components to autism based on genetic susceptibility.⁸⁴

6 Dr. Geier relies on an unpublished study by Jill James.⁸⁵ As the James study failed to ensure
7 that the cases and controls be properly matched, and the results have not been replicated, it cannot
8 be viewed as scientifically reliable.⁸⁶ Dr. Geier also relies on two human observational studies
9 authored by plaintiffs' expert witnesses. Neither study is methodologically sound or probative of
10 the issue of impaired mercury elimination. There is no evidence that mercury, retained or
11 otherwise, could give rise to a condition resembling autism.

12 Dr. Geier cites a study by Bradstreet, Geier, & Geier, et al.,⁸⁷ to support the proposition that
13 impaired mercury excretion results in higher mercury retention of vulnerable children, leading to
14 mercury toxicity that manifests as autism. Neither the Bradstreet study nor the Holmes study
15 referenced above provides information regarding a potential association between Ayr or mercury
16 and the development of autism. After examining the Holmes and Bradstreet studies, the 2004 IOM
17 Committee concluded that they "do not provide evidence of a relationship between vaccines or
18 thimerosal and autism."⁸⁸ Thus, the in vitro, animal and human observational studies comprising
19 the non-epidemiologic evidence on which plaintiffs' expert witnesses rely do not support their
20 conclusion that Ayr can cause a "unique" form of mercury poisoning that manifests as autism in a
21 subpopulation of children with impaired ability to excrete mercury.

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25 ⁸⁴ See IOM Report at 139, Ex. C-4.

26 ⁸⁵ See Slide Presentation at Fall DAN! Conference, October 1-3, 2004, Ex. D-18.

27 ⁸⁶ FDA Response to Citizen Petition, p. 16, Ex. C-2.

28 ⁸⁷ Bradstreet, Geier, et al., A Case-Control Study of Mercury Burden in Children with Autistic Spectrum Disorders, J. Amer. Phys. and Surgeons, Vol. 8, No. 3, (2003), Ex. D-19.

⁸⁸ IOM Report at 132-134, 140-141, Ex. C-4

1 **POINT V - Plaintiffs' Expert Witnesses Have Not Excluded Other Likely Causes of Alexander**
2 **Redfoot's Condition**

3 Assuming that plaintiffs' proposed expert testimony is deemed reliable, that testimony must
4 still be relevant to be admissible. See Daubert, 509 U.S. at 591. As the Supreme Court held in
5 Daubert, the FRE 702 "helpfulness standard requires a valid scientific connection to the pertinent
6 inquiry as a precondition to admissibility." Plaintiffs claim that Ayr caused Alexander's autism is
7 not relevant unless their experts establish that the condition did not pre-exist exposure to the
8 product.

9 None of plaintiffs' experts can prove that Alexander Redfoot's autism or underlying causes
10 did not pre-exist his exposure to Ayr. That is, none can prove he developed autism after his
11 exposure to thimerosal-containing Ayr Saline Nasal Mist. That the child was not diagnosed with
12 autism until the age of three does not mean that he was not autistic prior to that time. In fact, Dr.
13 Fisher indicated that Alexander Redfoot was "macrocephalic from birth onward with occipital
14 circumference at birth of 38.5 cm (greater than 95th percentile)" indicating some abnormal
15 development from birth.⁸⁹

16 Accordingly, Dr. Geier's opinion that Alexander Redfoot sustained "toxic encephalopathy
17 (that) was significantly contributed to by mercury exposure from Thimerosal-containing nasal
18 spray"⁹⁰ is contrary to the competent evidence in this case, wholly speculative and unreliable, and
19 must therefore be excluded under FRE 702.

20 **V. CONCLUSION**

21 Daubert requires that plaintiffs demonstrate that each expert they designate to testify is
22 properly qualified in the field in which he or she seeks to offer opinions, offers opinions that are
23 based on reliable science and methodology, and offers opinions that have a sufficient nexus to the
24 case at issue to constitute relevant evidence. In this case, plaintiffs have failed to meet their burden
25 of establishing that any of the Daubert requirements are met.

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28 ⁸⁹ Fisher IME Report, p. 2, Ex. B-5.

⁹⁰ Geier Report, p. 23, Ex. A-2.

1 Plaintiffs' experts seek to wear many hats (e.g., epidemiologist, pediatric neurologist,
2 toxicologist), but they are obviously unqualified for these tasks. Plaintiffs' experts' proclivities for
3 "junk science" cannot be ignored. The available epidemiology demonstrates that TCVs are not
4 associated with either autism or ASDs. There simply is no reliable epidemiological evidence that
5 thimerosal in nasal products causes autism.

6 The opinions offered by plaintiffs' experts are, therefore, unsupported, contrary to the
7 available epidemiology and to the general accepted consensus in the scientific community,
8 including the IOM, WHO, CDC, EMEA, CSM, and AAP. Lacking any epidemiological support,
9 they instead base their opinions on conjecture, speculation, and unsupported extrapolation.

10 For the forgoing reasons, defendants' motion should be granted and the court should enter an
11 order:

12 1. Precluding plaintiffs' expert witnesses, Mark R. Geier, M.D., Ph.D., James Jeffrey
13 Bradstreet, M.D., FAAFP, Boyd Haley, Ph.D., Arthur Krigsman, M.D. and George W. Lucier,
14 Ph.D., from offering any testimony or opinions that (a) thimerosal in Ayr Saline Nasal Mist can
15 cause or contribute to autism or ASDs; and (b) there is a genetically vulnerable subpopulation of
16 children whose ability to excrete mercury is impaired, resulting in an increased risk of autism from
17 exposure to thimerosal-containing nasal spray;

18 2. Precluding any expert witness from relying on any Geier DA & Geier MR, An
19 assessment of the impact of thimerosal on childhood neurodevelopmental disorders, Pediatr Rehabil
20 2003a;97-102 (Ex. D-8); Geier MR & Geier DA, Neurodevelopmental disorders after thimerosal-
21 containing vaccines: a brief communication, Exp. Biol. Med. 2003b;228(6):660-4 (Ex. D-9); Geier
22 DA & Geier MR, Thimerosal in childhood vaccines, neurodevelopmental disorders, and heart
23 disease in the United States J Amer Phys Sur 2003d;8(2):6-11 (Ex. D-10); Geier DA & Geier MR,
24 A comparative evaluation of the effects of MMR immunization and mercury doses from thimerosal-
25 containing childhood vaccines on the population prevalence of autism, Med Sci Monit
26 2004a;10(3):PI33-09 (Ex. D-11); or James SJ, Slide presentation at Fall DAN! 2004 Conference,
27 October 1-3, 2004 at 156 (Ex. D-18); or the data results, or conclusions contained therein, as the
28 basis for any opinion testimony in this case; and

1 3. Precluding (a) Dr. Bradstreet, Dr. Haley and Dr. Krigsman from offering any opinion
2 in the areas of epidemiology, genetics, neurology, or toxicology; (b) Dr. Geier from offering any
3 opinion in the areas of epidemiology, neurology, or toxicology; (c) Dr. Lucier from offering any
4 opinion in the areas of epidemiology, neurology, or genetics; and (4) granting such other and further
5 relief as this Court may deem just and appropriate.

6
7 Dated: February 28, 2007

Robert B. Leck III
LECK & ASSOCIATES

8 Mark F. Hazelwood
9 LOW, BALL & LYNCH

10
11 By: /S/Robert B. Leck III
12 Robert B. Leck III
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14 and Kolmar Laboratories, Inc.
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