

PAMELA and ERNEST BLACKWELL
Individually, and as Parents
and Next Friends of
JAMARR BLACKWELL, a Minor

Plaintiffs

v.

SIGMA ALDRICH, INC., et al.

Defendants

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IN THE
CIRCUIT COURT
FOR
BALTIMORE CITY
Case No: 24-C-04-004829

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MEMORANDUM OPINION

The plaintiffs filed this action in the Circuit Court for Baltimore City on June 11, 2004 against several defendants, including Defendant Wyeth. The plaintiffs are parents and next friends of their son, Jamarr Blackwell, who has since reached the age of majority but is unable to manage his own legal and business affairs.

The plaintiffs allege that their son, Jamarr Blackwell, was injured in 1985 and 1986 by, among other things, the thimerosal preservative in FDA-approved vaccines manufactured by Wyeth. The plaintiffs maintain that the injuries suffered by Jamarr Blackwell were proximately caused by the administration of various childhood vaccines containing the preservative thimerosal, the composition of which contains mercury.

Defendant Wyeth has sought to preclude plaintiffs' proposed experts from offering testimony on general causation under both a

Frye-Reed analysis, and separately, under Md. Rule 5-702. The plaintiffs, as well, have moved to exclude certain defense experts and various expert testimony.

I. PROCEDURAL HISTORY

Pending before the Court are two motions: (1) Defendant Wyeth's Motion to Preclude Testimony of Plaintiffs' Expert Witnesses Pursuant to the Frye-Reed Test and Md. Rule 5-702; and (2) Plaintiffs' Motion to Exclude Certain Defense Experts and Certain Expert Testimony.

Both parties supplied the Court with extensive memoranda prior to the Court entertaining a ten-day evidentiary hearing from August 18-29, 2007. Thereafter, the parties filed post-hearing memoranda and proposed findings of fact and conclusions of law. On October 29, 2007, the parties submitted responsive memoranda in support of their oppositions to the extant motions to preclude the proposed expert testimony.

II. STANDARD OF REVIEW

In Reed v. State, 283 Md. 374 (1978), the Court of Appeals of Maryland adopted the standard set forth in Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), for determining the admissibility of scientific evidence and expert scientific testimony. Under Reed, the proponent of an expert witness bears the burden of proving the basis of the witness' opinion is generally accepted as reliable

within the relevant scientific field. Reed v. State, supra, 283 Md. at 389; Keene Corp. v. Hall, 96 Md. App. 644, 656 (1993).

In Reed, the Court of Appeals specifically noted that "Frye was deliberately intended to impose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles." Montgomery Mut. Ins. Co. v. Chesson, 399 Md. 314, 328 (2007) (quoting Reed, supra, 283 Md. at 386). Applying that standard, the Court in Reed held that testimony based on the novel technique of voiceprint analysis is inadmissible in Maryland because, if a new scientific technique's validity is in controversy in the relevant scientific community, or if it is generally regarded as an experimental technique, then expert testimony based upon its validity cannot be admitted into evidence. Id. at 327.

The Frye standard, as articulated in Reed, is the minimum threshold standard for the admissibility of scientific evidence in Maryland. Critically, satisfaction of the Frye-Reed standard does not automatically require admission of expert testimony into evidence. Trial courts nonetheless maintain the discretion to exclude such testimony on other grounds--such as lack of helpfulness to the jury, or the fact that an expert is not properly qualified. Reed, supra, 283 Md. at 389. However, if expert testimony fails to meet the Frye-Reed standard, it is inadmissible, and the analysis ends. Id.

Therefore, “[u]nder the Frye-Reed test, a party must establish first that any novel scientific method is reliable and accepted generally in the scientific community before the court will admit expert testimony based upon the application of the questioned scientific technique.” Id. at 327 (citing Wilson v. State, 370 Md. 191, 201 (2002)). In doing so,

[a] trial court may take judicial notice of the reliability of scientific techniques and methodologies that are widely accepted within the scientific community. A trial court may also take notice that certain scientific theories are viewed as unreliable, bogus, or experimental. However, when it is unclear whether the scientific community accepts the validity of a novel scientific theory or methodology, ... before testimony based on the questioned technique may be admitted into evidence, the reliability must be demonstrated.

Id. (internal citations omitted).

Accordingly, it is well settled that the preferable practice is for a court to address evidentiary challenges under Frye-Reed pre-trial and out of the presence of the jury. Id. at 328 (citing Clemons v. State, 392 Md. 339, 347-48 n. 6 (2006)). Frye-Reed challenges generally involve matters collateral to the substantive issues at trial and, for that reason alone, are better resolved outside of the presence of the jury. Id. (citing Clemons, 392 Md. at 348 n. 6). As a result, this Court held a status conference in this case, and, based on the agreement of counsel, converted the

trial date to a lengthy hearing on the opposing challenges regarding the competing expert testimony.

Recently, the Court of Appeals clarified the application of Frye-Reed to theories of disease causation, including diagnosis of medical doctors. See Montgomery Mut. Ins. Co. v. Chesson, 399 Md. 314 (2007). The Chesson case involved a Frye-Reed challenge to a doctor's testimony that exposure to toxic mold caused the illness. The trial court held that the Frye-Reed test did not apply to that testimony. The Court of Special Appeals affirmed, holding that "expert opinions concerning the cause or origin of an individual's condition are not subject to a Frye-Reed analysis." See Montgomery Mut. Ins. Co. v. Chesson, 170 Md. App. 551, 569 (2006). The Court of Special Appeals had adopted a narrow view of Frye-Reed as applying only to new scientific techniques such as lie-detector tests and breathalyzer tests, rather than to a doctor's causation opinion.

On certiorari, the Court of Appeals vacated the Court of Special Appeals' ruling and remanded the case for a Frye-Reed hearing. See Montgomery Mut. Ins. Co. v. Chesson, supra, 399 Md. at 336. In so doing, the Court of Appeals noted that the doctor in that case employed medical tests to reach a conclusion regarding toxic mold that was "not as widely accepted as to be subject to judicial notice of reliability" - unlike cases involving non-controversial opinions, such as the opinion that asbestos causes

cancer. Id. Given the controversial nature of the doctor's conclusion, the Court held that "both the theories regarding causation and the tests he used to diagnose respondents were subject to Frye-Reed analysis." Id. at 329.

Clearly, the Frye-Reed standard applies to the expert witnesses proffered in this case. Indeed, the Court of Appeals has indicated that the plaintiffs' proffered link between thimerosal and autism be evaluated under a Frye-Reed standard. See Aventis Pasteur v. Skevofilax, 396 Md. 405 (2007). The Skevofilax case involved virtually similar allegations of injury from vaccines that contained thimerosal. The Court of Appeals overturned the Court of Special Appeals' reversal of the trial court's granting of summary judgment to the defendants, where the plaintiffs were unable to produce an expert witness who could testify to specific causation. Id. at 443.

In Skevofilax, the Court of Appeals addressed (in dicta) an expert witness' opinion that certain genetic polymorphisms rendered the plaintiff particularly susceptible to thimerosal toxicity. The Court noted that such testimony would face a "daunting hurdle" under Maryland's Frye-Reed standard. Id. at 431, n. 18.¹

Clearly, when entertaining testimony at the Frye-Reed hearing, "the opinion of an expert witness should be admitted only if the

¹Plaintiffs' expert witnesses in this case advance several causation theories including the theory identified by the Court of Appeals in Skevofilax.

court finds that the basis of the opinion is generally accepted as reliable within the expert's particular scientific field." Montgomery Mut. Ins. Co. v. Chesson, *supra*, 399 Md. at 327 (quoting Wilson, *supra*, 370 Md. at 201). However, "an expert's opinion is of no greater probative value than the soundness of his [or her] reasons given therefore will warrant." Wood v. Toyota Motor Corp., 134 Md. 512, 525 (2000) (quoting Betty v. Trailmaster, 330 Md. 726, 741 (1993)).

III. THE FRYE-REED HEARING IN THIS CASE

The principal issue addressed at the comprehensive Frye-Reed hearing was whether the basis for the plaintiffs' expert witnesses respective opinions regarding causation are generally accepted to be reliable in the scientific fields relevant to the issue of general causation. Specifically, the issue addressed throughout the Frye-Reed hearing in this case is whether the childhood vaccines that contained thimerosal can cause autism.

Clearly, this issue of causation, i.e. whether thimerosal-containing vaccines can cause autism, is a hotly debated issue. Indeed, the discourse on this topic is, at a minimum, highly charged. Any person who comes into close contact with anyone who is diagnosed as autistic can clearly see why this topic engenders significant, and understandable, emotional and visceral reactions.

Nevertheless, this Court--and this judge--must determine initially whether the plaintiffs can support their claim of general

causation with science that utilized methods and theories that are generally accepted in the relevant disciplines. For the reasons that follow, plaintiffs fail to sustain their burden of proof. Accordingly, this Court grants Defendant Wyeth's Motion to Preclude Testimony of Plaintiffs' Expert Witnesses Pursuant to the Frye-Reed Test. Further, for the reasons that will follow, this Court denies Plaintiffs' Motion to Exclude Certain Defense Experts and Certain Expert Testimony.

Prior to the extensive ten-day evidentiary Frye-Reed hearing, the Court had been presented with extensive documents establishing the credentials of various proposed expert witnesses and many of the materials upon which each witness relied. Although those submissions were of some assistance to the Court, it was not until the presentation of live testimony that the Court could endeavor to cogently understand the basis of the witnesses' testimony. It is only upon this record that the Court can consider: (1) whether the witnesses have actual expertise in a given field; and (2) whether in reaching their opinions, the proffered experts relied upon generally accepted methodologies in those fields.

At the evidentiary hearing, testimony was adduced from each of plaintiffs' expert witnesses: Mark Geier, M.D., Ph.D.; Stephen Siebert, M.D., M.P.H.; Elizabeth A. Mumper, M.D.; Richard Carlton Deth, Ph.D.; and Boyd E. Haley, Ph.D. Wyeth's motion to preclude testimony challenged each witness pursuant to the Frye-Reed test

and Md. Rule 5-702. Testimony was also presented by five of Wyeth's proposed expert witnesses: Peter M. Layde, M.D., M.Sc.; Paul Kostyniak, Ph.D.; Joseph D. Buxbaum, Ph.D.; Kwame Anane-Yeboah, M.D.; and Bryna Siegel, Ph.D. Of those experts, only Dr. Buxbaum and Dr. Yeboah were challenged by the plaintiffs.²

During the course of the evidentiary hearing in this case, numerous issues were presented to the Court. However, the critical issue that both parties briefed, argued, and the focus of much of the testimony, concerned the causal connection (or lack thereof) between thimerosal-containing vaccines (hereinafter "TCV" or "TCV's") and autism.

The plaintiffs posit several different theories that, they maintain, support their position of a link between thimerosal-containing vaccines and autism. Alternatively, defendant Wyeth contends that the worldwide scientific community has rejected (what they claim) is the hypothesized link between TCV's and autism. The expert testimony that followed presented the methodology employed by each party's "experts" that either supported or rejected the alleged nexus between TCV's and autism.

²Wyeth's expert witness in neurodevelopmental disabilities, Paul H. Lipkin, M.D., was also challenged by plaintiffs, but he did not testify at the hearing.

THIMEROSAL

Thimerosal is an organic mercury-based compound. See plaintiffs' exhibit 10³ at 36, and defendant's exhibit 18⁴ at 1. Thimerosal is 49% mercury by weight and is metabolized to ethyl mercury and thioralicylate. DX 25 at 1039.

Thimerosal has been used as a preservative in various vaccines and other biological and pharmaceutical products since the 1930's. Id. In addition, thimerosal has been used as an agent in the manufacturing process of various vaccines. PX at 37. However, the use of thimerosal in the manufacturing process contributes only a "trace" amount to the ultimate concentration of thimerosal in the vaccine. PX at 37, 39 n. 6.

The Centers for Disease Control and Prevention (hereinafter "CDC"), through its Advisory Committee on Immunization Practices ("ACIP"), publishes a recommended schedule for the active immunization of normal infants and children. PX 37. Jamarr Blackwell was born on March 3, 1985. PX 103.

As of the date of Jamarr's birth, the ACIP recommended that normal infants receive: Diphtheria tetanus and whole-cell pertussis vaccine ("DTP") at 2 months, 4 months, 6 months and 18 months; oral

³The exhibits introduced by the plaintiff will be identified as "PX" followed by the exhibit number, and where appropriate, the page number of the exhibit.

⁴Similarly, the exhibits introduced by defendant Wyeth will be identified as "DX" followed by the exhibit number, and where appropriate, the page number of the exhibit.

polio vaccine ("OPV") at 2 months, 4 months, 6 months (however this was optional) and 18 months; and a measles mumps rubella vaccine ("MMR") at 15 months. PX 37 at 3. Of these vaccines, only DTP contained thimerosal. PX 10 at 37.

Jamarr Blackwell received a DTP vaccine on five occasions between May 21, 1985 and July 11, 1989. PX 103. Additionally, on April 7, 1987, Jamarr Blackwell received a hemophilia influenza type b ("Hib") vaccine. PX 103. Both the DTP vaccine and the Hib vaccine contained 50 micrograms of thimerosal, which results in approximately 25 micrograms of mercury in each vaccination. DX 49 at 113-114; PX 10 at 37.

In July 1999, the Public Health Service and the American Academy of Pediatrics issued a joint statement recommending the removal of thimerosal from vaccines. PX 10 at 37-38.⁵ The decision by the Public Health Service and the American Academy of Pediatrics to seek the removal of thimerosal from vaccines was a precautionary measure and was not based on any evidence that thimerosal is dangerous. DX 18 at 1 and DX 49 at 1.

By March 2001, all vaccines on the recommended childhood immunization schedule were available without thimerosal as its preservative. PX 10 at 39. According to the 2004 Institute of

⁵Plaintiffs' proposed expert, Mark Geier, M.D., testified that the FDA and the American public health officials requested that thimerosal be removed from all childhood vaccines.

Medicine⁶ ("IOM") Report, "[b]ased on information from vaccine manufacturers provided to the FDA, the lots of vaccines manufactured before [the publication of the report] that contained thimerosal as a preservative and had been released to the market had expiration dates in 2002." PX 10 at 39.

AUTISM

Autism or autism spectrum disorder ("ASD")⁷ are pervasive developmental disorders that are characterized by sustained impairments in social interaction, sustained impairments in verbal and nonverbal communication skills, and restricted, repetitive and stereotyped patterns of behaviors and interests. PX 10 at 32; PX 40 at 66-67. Although definitive diagnostic tests for autism do not exist (PX 29 at 152), the diagnosis of early onset cases of autism is usually not made until one's second year of life. PX 10 at 33. Under the American Psychiatric Association's Diagnostic and Statistical Manual's ("DSM") most recent version ("DSM IV"), the onset of autistic disorder is prior to three years of age. PX 40 at 69, 71.

It is generally accepted in the scientific community that autism is genetic in its origin. PX 80; PX at 33. In its 2004 Report, the Institute of Medicine ("IOM") stated that:

⁶The 2004 Institute of Medicine ("IOM") Report was relied upon heavily by both sides throughout this proceeding.

⁷"Autistic disorder" refers to a more narrow diagnosis.

The consensus of most scientific experts is that autism is generally caused by early prenatal exposures (such as valproic acid (Moore et al., 2000) or thalidomide (Stromland et al., 1994)) or is linked to early developmental genes (Ingram et al., 2000; Persico et al., 2001; Wassink et al., 2001).

PX 10 at 33.

After hearing extensive testimony regarding the 2004 IOM Report, this Court finds, unequivocally, that it is a credible, venerable and significant publication in the field of vaccines and autism. Accordingly, in that context, the history of the formation of the IOM committee that issued its initial report in 2001 is noteworthy.

In 1970, the National Academy of Sciences⁸ created the Institute of Medicine ("IOM") to advise the federal government on issues affecting public health and to act independently in identifying significant issues of medical care, research and education. PX 10 at ix; DX 49 at ix. The IOM has a long history of conducting independent analyses in connection with vaccine safety. DX 49 at ix. In 1999, the CDC and the National Institutes of Health (hereinafter "NIH") approached the IOM about developing the Immunization Safety Review project to address vaccine safety issues. DX 49 at 21-22.

The IOM gathered a panel of 15 members to form the Immunization Safety Review Committee that issued its report in

⁸The National Academy of Sciences is a private, nonprofit, self-perpetuating society of distinguished scholars, created by congressional charter in 1863 to advise the federal government on scientific and technical matters. DX 49 at iv.

2001. The members of the 2001 IOM Committee had significant expertise in a number of relevant fields including pediatrics, neurology, immunology, internal medicine, infectious diseases, genetics, epidemiology, biostatistics, risk perception and communication, decision analysis, public health, nursing and ethics. DX 49 at x. The Committee members were leading authorities in their respective fields, and were found to have no conflicts of interest. DX 49 at x.⁹

The 2001 IOM Committee evaluated the alleged connection between thimerosal-containing vaccines and a broad range of neurodevelopmental disorders including autism, ADHD, and speech or language delay. DX 49 at 27; PX 10 at 4. The 2001 IOM Committee issued its report (DX 49), which concluded that:

[T]he evidence is inadequate to accept or reject a causal relationship between thimerosal exposures from childhood vaccines and the neurodevelopmental disorders of autism, ADHD, and speech and language delay.

DX 49 at 13, 14.

The 2001 IOM Committee further found that "[t]he hypothesis that thimerosal exposure through the recommended childhood immunization schedule has caused neurodevelopmental disorders is

⁹The IOM established stringent criteria for committee membership, which precluded participation by individuals with financial ties to vaccine manufacturers or their parent companies, with previous service on major vaccine-advisory committees, or who had given prior expert testimony or published on issues of vaccine safety. DX 49 at x.

not supported by clinical or experimental evidence." DX 49 at 3.

The 2001 IOM Committee based this finding on:

- (a) low-dose thimerosal exposure in humans has not been demonstrated to be associated with effects on the nervous system;
- (b) neurodevelopmental effects have been demonstrated for prenatal but not postnatal exposures to low doses of ethylmercury;
- (c) the toxicological information regarding ethylmercury, particularly at low doses, is limited;
- (d) thimerosal exposure from vaccines has not proven to result in mercury levels associated with toxic responses;
- (e) signs and symptoms of mercury poisonings are not identical to autism, ADHD, or speech or language delay;
- (f) autism is thought primarily to originate from prenatal injury; and
- (g) there is no evidence that ethylmercury causes any of the pathophysiological changes known to be associated with autism, such as genetic defects, and there are no well-developed pathological markers of ADHD or delay of speech or language that could be compared to effects of ethylmercury on the nervous system.

DX 49 at 3-4.

After the publication of the 2001 IOM Report, additional epidemiological studies and biological mechanism theories emerged. PX 10 at 5. As a result, the IOM was asked to revisit the alleged causal connection between vaccines and autism and further update its conclusions and recommendations in its final report. PX 10 at 2. As it did in 2001, the IOM gathered a panel of 13 members with significant expertise in the same areas of expertise as those designated in 2001.¹⁰

The 2004 IOM Committee held an open scientific meeting in February, 2004 in an effort to hear presentations on the issue of vaccines and autism from scientists, and from individuals associated with or funded by representatives of parent advocacy groups. PX 10 at 23, 180-82. Four of the plaintiffs' five proposed experts in this case either testified before the 2004 IOM Committee or submitted materials to the committee.¹¹

In assessing causality, the 2004 IOM Committee used the categories of causal conclusions developed by previous IOM committees, namely: (1) no evidence; (2) evidence is inadequate to accept or reject a causal relationship; (3) evidence favors rejection of a causal relationship; (4) evidence favors acceptance of a causal relationship; (5) evidence establishes a causal

¹⁰All 13 members of the 2004 IOM Committee were members of the 2001 IOM Committee. PX 10 at v; DX 49 at v.

¹¹The only one of the five experts presented by the plaintiffs in this case who did not submit materials to the 2004 IOM Committee was Stephen Siebert, M.D., M.P.H.

relationship. PX 10 at 25. In that context, the 2004 IOM Committee began its assessment from a position of neutrality, i.e. that there was no presumption that thimerosal in vaccines either does or does not cause autism. PX 10 at 25.

After reviewing the vast body of literature and consideration of the extensive presentations and submission from scientists and other individuals associated with or funded by representatives of parent advocacy groups, the 2004 IOM Committee issued its report. PX 10 at 192-96. In assessing causality, the 2004 IOM Committee concluded:

[T]hat the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism.

PX 10 at 65 (emphasis in original).

The 2004 IOM Committee found that “[e]pidemiological studies examining TCVs and autism, including three controlled observation studies (Hviid et al., 2003; Miller, 2004; Verstraeten, et al. 2003) and two uncontrolled observational studies (Madsen, et al., 2003; Stehr-Green, et al., 2003), consistently provided evidence of no association between TCVs and autism, despite the fact that these studies utilized different methods and examined different populations (in Sweden, Denmark, the United States and the United Kingdom).” PX 10 at 65.

In assessing biological mechanisms, the 2004 IOM Committee opined that: “[i]n the absence of experimental or human evidence

that vaccination (either the MMR vaccine or the preservative thimerosal) affects metabolic, developmental, immune or other physiological or molecular mechanisms that are causally related to the development of autism, the committee concludes that the hypotheses generated to date are theoretical only." PX 10 at 152. As a result, the 2004 IOM Committee recommended that: "[g]iven the lack of direct evidence for a biological mechanism and the fact that all well-designed epidemiological studies provide evidence of no association between thimerosal and autism, the committee recommends that cost-benefit assessments regarding the use of thimerosal-containing versus thimerosal-free vaccines and other biological or pharmaceutical products, whether in the United States or other countries, should not include autism as a potential risk." PX at 13, 152.

The 2004 IOM Report is not the only publication that rejects any alleged link between thimerosal and autism. The Global Advisory Committee on Vaccine Safety (hereinafter "GACVS") advises the World Health Organization (hereinafter "WHO") on vaccine-related safety issues. DX 20 at 1926. GACVS "reviewed the issue and found no scientific evidence of toxicity from thimerosal-containing vaccines." DX 20 at 1929. In addition, the Center for Disease Control takes the position that "science does not support a causal association between thimerosal and autism." DX 19.

Moreover, the American Academy of Pediatrics (hereinafter "AAP") takes the position that thimerosal in vaccines does not cause or contribute to autism. DX 18; DX 35. The AAP presently advises parents and patients that "[t]here are no valid studies that show a link between thimerosal in vaccines and autistic disorder." DX 18 at 1. In addition, the AAP has also stated that "[n]o scientific data link thimerosal used as a preservative in vaccines with any pediatric neurologic disorder, including autism." DX 35 at 2.

Lastly, the National Institutes of Health takes the position that thimerosal in vaccines do not cause or contribute to autism. DX 55. The National Institute of Allergy and Infectious Diseases (hereinafter "NIAID"), a component of NIH, has sponsored several studies regarding any causal association between thimerosal-containing vaccines and neurological injury. Both NIH and NIAID currently state that as of May 2007, "[t]he only known side effects of receiving low doses of thimerosal in vaccines have been minor reactions such as redness and swelling at the injection site." DX 55 at 1.

Faced with the plethora of venerable publications rejecting the plaintiffs' theoretical link between thimerosal-containing vaccines and autism, plaintiffs request that this Court allow them to present their theories to a finder of fact. In Aventis Pasteur v. Skevofilax, 396 Md. 405 (2007), the Court of Appeals

discussed an expert witness' opinion that certain genetic polymorphisms rendered the plaintiff particularly susceptible to thimerosal toxicity. The Court noted that such testimony would face a "daunting hurdle" under Maryland's Frye-Reed standard. Id. at 431 n. 18. Similarly, the plaintiffs in this case face an equally daunting hurdle in this Frye-Reed hearing.¹² In an effort to overcome the hurdle, the plaintiffs presented the testimony from five proposed experts and presented 117 documents to the Court, 70 of which were received into evidence at the hearing.

After entertaining the lengthy evidentiary hearing in this case, one salient fact was undisputed, namely, the issue of whether thimerosal in vaccines cause autism is extremely contentious. PX 10 at 11. The 2004 IOM Committee specifically noted that "the anger of some families toward the federal government (particularly the CDC and FDA), vaccine manufacturers, the field of epidemiology, and traditional biomedical research" is pervasive. Id. Indeed, two of the plaintiffs' proposed expert witnesses, Mark Geier, M.D. and Dr. Boyd Haley, testified to a conspiracy or other criminal activity within the CDC and other entities to hide information from them and others that would support the theoretical link between thimerosal and autism.

¹²Plaintiffs' expert witnesses in this case advance several causation theories including the theory identified by the Court of Appeals in Skevofilax.

TESTIMONY OFFERED BY THE PLAINTIFFS

Plaintiffs offered the testimony of the following five witnesses on the issue of general causation: Drs. Boyd Haley, Richard Deth, Elizabeth Mumper, Mark Geier and Stephen Siebert.¹³

1. Dr. Boyd Haley

Dr. Boyd Haley is a professor of chemistry at the University of Kentucky. He has published a little less than 130 articles including a number of chemical and biochemical studies involving mercury. He testified that he teaches two courses on mercury toxicity. Plaintiffs offered Dr. Haley as an expert in the fields of mercury toxicology, biochemistry and physiology.

Dr. Haley discussed the adverse effect mercury has on the brain and the neuro-degeneration caused by mercury. Dr. Haley concluded that mercury is generally toxic to human brain cells. The conclusion reached by Dr. Haley is not disputed by any of the parties in this proceeding. He further testified that the thimerosal in vaccines injected in children results in exposure to a child's brain to mercury. In that context, Dr. Haley testified that autistic children do not metabolize and excrete mercury the way other children are able, and concluded that thimerosal in

¹³Drs. Geier and Siebert also testified as proposed expert witnesses regarding the specific causation issue as to Jamarr Blackwell.

childhood vaccines causes neurological damage in genetically susceptible children.

On cross-examination, he acknowledged that he conducted only studies of hair, and did not measure urinary, fecal excretion or blood. He accused the IOM committee of dishonesty and asserted that the CDC are bureaucrats that should be charged with criminal activity. He further stated that he had no respect for the science that was reported, and that the goal of the CDC was to find that thimerosal was not toxic. Therefore, he concluded that the goal was not to find the truth about the connection between thimerosal and vaccines.

2. Dr. Richard Deth

Plaintiffs' next witness was Dr. Richard Deth, who teaches pharmacology at Northeastern University. He was offered as an expert witness in the fields of physiology, neuropharmacology, and the effects of thimerosal on the human brain. Dr. Deth opined that the exposure to mercury from thimerosal-containing vaccines causes autism. He further testified that he firmly believed that the thimerosal in vaccines has made a causal contribution to the rates and occurrences of autism in the United States.

3. Dr. Elizabeth Mumper

Dr. Elizabeth Mumper is a general pediatrician in private practice in the Commonwealth of Virginia. She testified that she considers herself a clinician and a general physician who performs

clinical research. She was proffered as an expert in the field of pediatrics, in the diagnosis and treatment of children with neurodevelopmental disorders, including Attention Deficit Disorder, learning disabilities, and autism, and as an expert clinician in the field of diagnosing children with mercury toxicity, and treating children with mercury toxicity.

Dr. Mumper testified that, based on her clinical experience, mercury causes neurological effects on children. However, she--like Dr. Haley before her--carried that unassailable conclusion one step further. She opined that exposure to thimerosal-containing vaccines in genetically susceptible children causes neurological impairment in these children. Dr. Mumper further testified that she was "flabbergasted" by the conclusion rendered by the 2004 IOM Committee, because she found the epidemiological studies relied upon by the IOM to contain flaws.¹⁴

She further testified she bases her opinion on several facts including her review of approximately 150 articles published by others. As a result, she expressed disagreement with the American Academy of Pediatrics that concluded that there are no valid studies that show a link between thimerosal in vaccines and autistic spectrum disorder. Although she disagreed with the IOM

¹⁴It is noteworthy that Dr. Mumper is not an epidemiologist, nor does she hold herself out to be an expert in toxicology, genetics or neurology. Dr. Mumper is the medical director for the Autism Research Institute and the medical director for the clinical training program sponsored by the related organization, Defeat Autism Now ("DAN!").

and the American Academy of Pediatrics, she acknowledged that the medical community in terms of the IOM, the CDC, and the American Academy of Pediatrics have taken a position contrary to the testimony she presented.

4. Dr. Mark Geier

The critical witness relied upon by the plaintiff is Dr. Mark Geier. Indeed, Dr. Geier testified for three full days in the Frye-Reed hearing in this case. Dr. Geier is a genetic counselor and an obstetrician. He is in private practice, and for many years ran a laboratory known as Molecular Medicine. Since 2003, Dr. Geier has published approximately 15 articles concerning thimerosal, including 11 purported epidemiological studies. More recently, Dr. Geier has examined and treated autistic children, working on over 400 children by performing a differential analysis on each one, trying to determine the cause of autism.

5. Dr. Stephen Siebert

Lastly, Dr. Stephen Siebert was presented by the plaintiffs as their expert witness in the fields of psychiatry and forensic psychiatry. Dr. Siebert is a psychiatrist who has a masters degree in public health. He is board certified in the field of psychiatry. For the reasons that the Court will address infra, Dr. Siebert is clearly qualified as an expert witness in the areas of psychiatry and forensic psychiatry. Nevertheless, his expertise in the fields of psychiatry and forensic psychiatry does

not provide the appropriate basis for opinion testimony on the issue of whether thimerosal-containing vaccines can cause autism.

THE COURT'S ANALYSIS OF THE DEFENDANT'S FRYE-REED
CHALLENGE TO THE ADMISSIBILITY OF THE TESTIMONY
PRESENTED BY PLAINTIFFS' EXPERT WITNESSES

The plaintiffs fail to demonstrate that the bases of their expert witnesses' causation opinions are generally accepted to be reliable in the relevant scientific community. On this record, this Court finds that the plaintiffs have failed to establish that the hypothesized link between thimerosal and autism is generally accepted as reliable within the relevant scientific community. In that context, the methodologies used by the plaintiffs' experts are deeply flawed. As a result, this Court grants defendant Wyeth's Motion to Preclude Testimony of Plaintiffs' Expert Witnesses pursuant to the Frye-Reed Test. Critical to this analysis is the relevance of epidemiology to the issue of general causation.

Epidemiology is the science that studies the distribution of diseases within populations and determines diseases in populations. Accordingly, medical causality is central to the field of epidemiology. It is the finding of this Court that epidemiology is the single most relevant field of science to the general causation issue presented in this case, i.e., whether thimerosal-containing vaccines can cause autism. PX 10 at 26. The 2004 IOM Report specifically notes that "[e]pidemiologic studies carry the most

weight in a causality assessment.” Id. at 26. That is so because in epidemiology, an association between an exposure and a health outcome generally occurs more frequently in people with one type of exposure than in those who do not have the exposure.

This is not to suggest that one must be an epidemiologist or rely on epidemiological studies to testify on the issues associated with this proceeding. However, it is significant to note that Drs. Haley, Deth, Mumper and Siebert are not epidemiologists, and were not proffered to the Court that they were qualified in the field of epidemiology. Plaintiffs proffered Dr. Mark Geier as their lone expert witness in the field of epidemiology. For the reasons that follow, this Court rejects the methodology utilized by Dr. Geier pursuant to the Frye-Reed test, and further finds that Dr. Geier is not an expert in the field of epidemiology.

In that context, the only published epidemiological studies that purport to find an association between exposure to thimerosal-containing vaccines and autism were written by Dr. Mark Geier and his son, Dr. David Geier. The Geiers maintain that they have found epidemiological evidence of causation in all 11 of their studies. Wyeth contends that their articles were published generally in relatively obscure or unknown journals that are not typically used to report significant epidemiological studies. Accordingly, this Court must review these studies in order to address the issues associated in this Frye-Reed proceeding.

Each of the Geier and Geier epidemiology studies uses one or more of the following databases: the Vaccine Adverse Effect Reporting System ("VAERS"); the Vaccine Safety Datalink ("VSD"); the Department of Education database ("DOE"); and the California Department of Social Services. On the record established in this proceeding, this Court finds that Geier and Geier improperly use these databases and draw conclusions from the data that could not be drawn through the use of generally accepted principles of epidemiology.

Dr. Geier testified that the methodology that he and his son utilized in their VAERS studies strictly replicated the methodology used by the Centers for Disease Control ("CDC"). On the record established in this proceeding, this Court finds that to be facially incorrect; indeed, there are significant and material distinctions between the CDC studies and the Geier and Geier publications.

The Geier and Geier studies refer to two CDC publications, namely Niv, et al. (DX 41) and Rosenthal, et al. (DX 34). Both of these articles address the adverse events that were previously accepted to result in some cases from administration of the vaccines. Accordingly, unlike Dr. Geier, the CDC authors were not attempting to prove or disprove that such adverse events were caused by vaccination. Instead, the authors sought to compare the

relative frequency of the reporting of such events following vaccinations with two different vaccines.

Further, and significantly, while the CDC authors analyzed relative rates of reported reactions from different vaccines, they did not treat their findings as proof of causality. The CDC authors noted that a finding of a statistically significant difference in the reported rates of reactions between two vaccines does not allow one to conclude that one vaccine is more reactive than the other. Indeed, such a hypothesis, generated by VAERS data, can only be confirmed by use of a database that allows for a controlled study, such as VSD. As a result, Dr. Geier's claim that the Geier and Geier studies using the VAERS database were done in a manner that the CDC instructed is factually incorrect.

Dr. Geier's VAERS studies provide no competent evidence of causation. They use two different databases in one of their studies.¹⁵ See PX 48. The VAERS data reflects adverse event reports received by VAERS concerning thimerosal-containing DtaP vaccines administered from 1997-2000 and thimerosal-free DtaP vaccines administered from 1997-2000. In the conclusion of PX 48, the authors note that their study "provides strong epidemiological evidence for a link between increasing mercury from thimerosal-containing vaccines and neurodevelopmental disorders and heart disease." PX 10 at 10. At the Frye-Reed hearing in this case, Dr.

¹⁵The two databases are VAERS and the United States Department of Education.

Geier testified that PX 48 provided overwhelming evidence that neurological disorders are related to vaccines.

In PX 48, Geier and Geier purport to calculate and compare "the incidence rates of adverse events following thimerosal-containing DtaP and DtweP vaccines against thimerosal-free DtaP vaccines in order to determine relative risk." PX 48 at 7. It is significant to this Court that the IOM Committee criticized the technique utilized in PX 48. The IOM Committee noted expressly that:

VAERS cannot be used to calculate incidence rates because the VAERS database does not have complete reporting of all adverse events and because many report events lack a confirmed diagnosis or confirmed attribution to vaccine.

PX 10 at 59 n. 18.

Admittedly, Dr. Geier acknowledged that PX 48 is controversial. Indeed, the American Academy of Pediatrics ("AAP"), in a May, 2003 posting to their website, strongly denounced the Geier and Geier publication identified as PX 48 ("Study Fails to Show a Connection Between Thimerosal and Autism"). The AAP expressed the concern about using the VAERS database in the manner utilized by Geier and Geier, stating: "This paper uses data from the Vaccine Adverse Event Reporting System (VAERS) inappropriately and contains numerous conceptual and scientific flaws, omissions of fact, inaccuracies, and misstatements." DX 35 at 1.

The AAP commentary went on to note that Geier and Geier had "failed to acknowledge the inherent limitations of the VAERS database when drawing conclusions of adverse event associations contained in [PX 48] and their other publications", and had failed to clearly state "how their data were generated." DX 35 at 1. Several additional criticisms are also presented in the AAP commentary. Of significance to this Court is the criticisms of the AAP that addressed the methodologies utilized by the Geiers in PX 48. Among those criticisms included what was termed "control adverse events," about which the AAP states:

Comparing the occurrence of late onset, chronic conditions like autism by using acute vaccine reactions like fever, pain and vomiting (presumably attributable to other vaccine components) as controls makes no sense as a measure of relative adverse event rates.

DX 35 at 2.

Dr. Geier presented several additional publications (PX 49, 51, 53 and 55) that also contained studies in which the Geiers compared adverse event reports filed with VAERS with regard to thimerosal-containing and thimerosal-free vaccines. In each of the studies, Geier and Geier continued assigning (despite the absence of total mercury exposure data), a higher cumulative thimerosal total to one group of children (those who filed a VAERS report regarding a TCV) than the other group (those who filed a VAERS report regarding a thimerosal-free vaccine). As a result, Geier

and Geier concluded that the greater the total exposure to mercury from thimerosal, the greater the risk of neurological disorders.¹⁶

Critically, with regard to the pre-2004 published Geier and Geier VAERS database studies (PX 47, 48, and 49), the Institute on Medicine opined:

- (1) The three studies have serious methodological limitations that make their results uninterpretable. PX 10 at 61 [Emphasis added];
- (2) The results of their studies are likewise improbable. PX 10 at 62;
- (3) The articles also lack a complete and transparent description of their methods and underlying data, making it difficult to confirm or evaluate their findings. PX 10 at 62.

Accordingly, the 2004 IOM Committee concluded that the Geier and Geier VAERS studies were not helpful with regard to the causation issue it considered, that is, whether thimerosal-containing vaccines can cause autism or autistic spectrum disorders. The 2004 IOM Committee Report concluded:

As a result of these significant methodological limitations, the committee finds the results of [Geier and Geier's] studies to be uninterpretable and, as such, they are noncontributory with respect to causality.

PX 10 at 62.

¹⁶See e.g. PX 49 at 99 ("It was determined that the odds ratio of autism increased by 0.029 per mg of mercury.").

In addition, Geier and Geier analyzed the VSP database on no less than two occasions. The Geiers presented to the 2004 IOM Committee an unpublished analysis of USD data, but did not describe the basis for their calculation or their methods leading the 2004 IOM Committee to conclude that it "found the results of their analysis using VSP data uninterpretable, primarily due to the lack of a complete description of their methods." PX 10 at 52.

Finally, the 2004 IOM Report reviewed Geier and Geier's Department of Education database and found that "[t]hese studies are characterized by serious methodological problems." PX at 57. The source of the Geier's autism data was a 2001 United States Department of Education report that "analyzed the number of children of various ages who had developed various conditions." PX 48 at 7. Geier and Geier used that data to address birth cohort prevalence data for the years 1984-1985 and 1990-1994. The 2004 IOM Committee expressly disapproved of that methodology, and noted that:

Transforming the cross-sectional data by dividing by birth cohort creates the artificial impression of a cohort effect when the data are cross-sectional in nature....This is particularly problematic with respect to the older birth cohorts because 'prior to the addition of the autism category in 1990, IDEA served students with autism, but for reporting purposes they were reported in a different disability category.'

PX 10 at 57.

In sum, the plaintiffs rely on Dr. Geier's six epidemiological studies that purport to find an association between thimerosal in vaccines and autism. However, this Court finds that Dr. Geier's epidemiological studies do not constitute generally accepted bases for plaintiffs' causation opinions inasmuch as those studies have been rejected by the relevant scientific community due to severe methodological flaws that render them unreliable. Indeed, the venerable IOM Committee concluded that Dr. Geier's studies were not only flawed methodologically, but "uninterpretable," and therefore "noncontributory." PX 10 at 62.

The plaintiffs have not cited--and the Court has failed to unearth--any case in which a proffered expert has been permitted to offer a novel causation opinion that directly contradicts every generally accepted epidemiological study addressing the issue of causation. The Court fails to allow the plaintiffs to skirt the well-established mandate of the Frye-Reed test. As a result, this Court finds expressly that Dr. Geier's epidemiological studies are not generally accepted in the scientific community because they utilize a methodology that is fundamentally flawed.

THE PLAINTIFFS' GENETIC SUSCEPTIBILITY THEORY

One of the remaining theories advanced by the plaintiffs in this proceeding is that thimerosal in vaccines cause autism in certainly genetically susceptible individuals. It is well settled that even a large well-designed epidemiology study might fail to

detect "the possibility that vaccines contribute to autism in some small subset of cases or very unusual circumstances" (PX 10 at 12), such as a rare event caused by genetic susceptibility. However, the plaintiffs have presented no evidence that it is generally accepted in the relevant scientific community that there is any genetic susceptibility to vaccines or their components.

One of the plaintiffs' theories in this case is that the thimerosal used in TCVs caused autism in a so-called genetically susceptible subgroup. The 2004 IOM Committee found that a genetic susceptibility could indeed constitute a "theoretical explanation" for the fact that reliable epidemiological studies have not found any association between thimerosal exposure and autism. However, the 2004 IOM noted expressly that it:

[F]ound no corroborating data in the laboratory, in animals, or in humans, linking vaccines or vaccine components for autism based on genetic susceptibility.

PX 10 at 139.

Indeed, if plaintiffs' theory was based on generally accepted scientific principles, the autism allegedly caused in this subgroup would not be a "rare event." Dr. Geier testified that 80 to 90 percent of the cases of autism occurring in the late 1990's were due to exposure to mercury in childhood vaccines and Rhogam. If that were true, and those cases presented themselves in the genetically susceptible subgroup, then epidemiological principles would dictate that a large proportion of the population would have

that genetic susceptibility. Moreover, such an effect would have been detectable in epidemiological studies of the general population.

Autism is a highly genetic disorder that is generally believed to arise from multiple interacting genes. It is generally accepted that autism is genetic in origin, except in rare instances of certain prenatal exposures of defined periods during pregnancy. PX 10 at 33; DX 80. Indeed, autism is a disorder of the developing brain. DX 29 at 152.

The 2004 IOM Report noted that "[t]he consensus of the (sic) most scientific experts is that autism is generally caused by early prenatal exposures (such as valproic acid (Moore et al., 2000) or thalidomide (Stromland et al., 1994)) or is linked to early developmental genes (Ingram et al., 2000; Persico et al., 2001; Wassink et al., 2001)." PX 10 at 33. As noted in the 2004 IOM Report, prenatal onset of autism has been documented by several studies. PX 10 at 33.

Autism is likely to involve multiple genes. DX 29 at 157. Dr. Geier testified that the following genes are associated with autism: the A1298C polymorphism in the MTHFR gene; the null polymorphism of the GSTMI gene; the I105V polymorphism of the GSTPI gene; the I114T, R197Q, and K268R polymorphisms in the NATZ gene; and an unspecified variant in the CYP3A4 gene. There is no evidence that any of the polymorphisms identified by Dr. Geier are

associated with autism. None of the polymorphisms is generally accepted among clinical geneticists to be causes of autism. Further, despite the theories advanced by Dr. Geier, there is no evidence that the presence of these polymorphisms impairs the body's ability to excrete mercury.

More specifically, there is no evidence that the A1298C polymorphism in the MTHFR gene is associated with autism. A 2004 study by Boris, et al., and a follow-up study by one of the co-authors of that 2004 study, Jill James (among others), both showed no statistically significant association between the MTHFR 1298A/C polymorphism and autism. PX 28 at 107; PX 29 at 951.

Further, the MTHFR 1298A/C polymorphism is common, occurring on average, across different populations, in about 34 percent of the population. DX 69 at 2. In addition, the rate of occurrence of the MTHFR 1298A/C polymorphism varies significantly among different ethnic groups. It is well established that common genetic polymorphisms that vary across ethnic groups, such as the MTHFR 1298A/C polymorphism, are not considered by geneticists to be candidates for causation of a disease, such as autism, that has equal prevalence across ethnic groups.

Lastly, the plaintiffs posit that the GSTMI null polymorphism is associated with autism. The GSTMI null polymorphism refers to a condition in which the GSTMI gene is missing. The purported association between the GSTMI polymorphism and autism has been

investigated and rejected in several studies. PX 70; DX 29. No study has found an association between the GSTMI null polymorphism and autism. Further, there is no evidence that the absence of the GSTMI gene is associated with autism.

Dr. Geier performed a differential diagnosis in his analysis. A differential diagnosis is a methodology by which the cause of a medical problem is identified by considering and then ruling out the potential causes until the most probable cause remains. Inasmuch as Dr. Geier is neither a pediatrician nor a clinical geneticist, it is debatable whether he is qualified to perform a differential diagnosis in order to offer a causation opinion with respect to the cause of a neurological disorder such as autism.

In that context, Dr. Geier performed a urinary porphyrin test in connection with his differential diagnosis of Jamarr Blackwell. That test, as well as the mercury toxicity and testosterone tests, along with the polymorphisms tested by Dr. Geier, are not generally accepted by the medical community, including clinical geneticists and pediatricians, as appropriate tests for either the work-up of a patient with autism or to determine the underlying cause of autism.

It is noteworthy that Dr. Geier failed to even consider the single most important alleged cause of autism--idiopathic autism¹⁷--in his analysis. Causation opinions on the etiology of autism

¹⁷Idiopathic autism is defined as autism where the underlying genetic etiology has not yet been identified.

simply cannot be based on a differential diagnosis methodology that fails to even consider the most prevalent alleged cause of autism, namely, a gene or series of interacting genes that have not yet been identified. In short, causation opinions on the etiology of autism cannot be based on a differential diagnosis that includes thimerosal as a potential cause of autism because the science does not support the plaintiffs' purported theory of a causal connection between thimerosal-containing vaccines and autism.

IV. WYETH'S MOTION TO PRECLUDE TESTIMONY OF PLAINTIFFS' EXPERTS PURSUANT TO MARYLAND RULE 5-702

Inasmuch as the Court has granted Wyeth's motion to preclude testimony of the plaintiffs' expert witnesses pursuant to the Frye-Reed test, it is arguable that the Court's analysis is complete. See Reed v. State, supra, 283 Md. 374 (if expert testimony fails to meet the Frye-Reed standard, it is inadmissible, and the analysis ends). Id. at 389. However, both parties have spent considerable time and resources in an effort to preclude the other side's expert witnesses from testifying pursuant to Maryland Rule 5-702. The pertinent Maryland Rule provides that:

Expert testimony may be admitted, in the form of an opinion or otherwise, if the court determines that the testimony will assist the trier of fact to understand the evidence or to determine fact in issue. In making that determination, the court shall determine (1) whether the witness is qualified as an expert by knowledge, skill, experience, training, or education, (2) the appropriateness of the expert testimony on the particular subject,

and (3) whether a sufficient factual basis exists to support the expert testimony.

The qualification of an expert is generally "a matter wholly relative to the subject of the particular inquiry." Redman v. Harold, 267 Md. 167, 172 n.2 (1978) quoting Refrigerating Co. v. Kreiner, 109 Md. 361, 370 (1909). In the case sub judice, all of the plaintiffs' expert witnesses either: (1) offer opinions concerning a theory of causation that has been refuted in many credible epidemiological studies; or (2) base their opinions on the alleged toxicological properties of thimerosal. Further, as was demonstrated at the hearing, those witnesses lack expertise in the areas of epidemiology or cannot set forth a sufficient factual basis of their opinions.

1. Dr. Mark Geier

As identified previously in this Opinion, one of plaintiffs' proposed experts, Dr. Mark Geier, testified extensively in the hearing in this case. He is an obstetrician who also is a board-certified genetic counselor. He is in private practice and for many years ran a laboratory called Molecular Medicine. Plaintiffs proffered Dr. Geier as an expert witness in many areas, including: (i) genetics; (ii) "vaccine injuries"; (iii) "differential etiology of autism"; (iv) mercury toxicity; (v) medicine ; (vi) "urinary porphyrin analysis"; and (vii) epidemiology. Dr. Geier is not an epidemiologist or toxicologist. He has no degree or board certification in either field. This

Court finds that, pursuant to Md. Rule 5-702(1), he is not qualified to testify in any of those areas (with the limited exception of the area of medicine) by his knowledge, skill, training, experience or education.

The Court acknowledges that Dr. Geier has a background in genetics, and that genetics play a role in the opinions that he espouses. However, he is not board-certified by the American Board of Medical Genetics as a clinical geneticist. While he is a genetic counselor, he has neither the scientific basis nor the expertise to offer the opinion that thimerosal-containing vaccines cause autism in a genetically susceptible population.

Although not at all binding of this Court, it is noteworthy that many courts have strongly criticized Dr. Geier's testimony as a purported expert witness in cases involving alleged vaccine injuries. Dr. Geier has never been qualified to testify as an expert in a thimerosal case. One of those cases involved Rhogam, an immunoglobulin preserved with thimerosal (Doe 2 v. Ortho-Clinical Diagnostics, Inc., 440 F.Supp.2d 465, 468, 471-72 (M.D.N.C. 2006)). Another of those cases involved a thimerosal-containing over-the-counter nasal spray (Redfoot v. B.F. Ascher & Co., No. C 05-2045 PJR, 2007 WL 1593239, slip op. at 10-11 (N.D. Cal. June 1, 2007)). In those proceedings, Dr. Geier's causation testimony failed to satisfy the Daubert standard, and Dr. Geier's credentials were found to be inadequate and his qualifications to not be aligned with the subject matter of his intended testimony.

Dr. Geier's credentials as a medical doctor and genetic counselor are not a foundation sufficient for him to offer an opinion that thimerosal-containing vaccines cause autism. In Redfoot v. Ascher, supra, Dr. Geier opined that a child's autism was a result of exposure to thimerosal in nasal spray. The trial court excluded his testimony, finding that "Dr. Geier is not a pediatrician, a neurologist, a toxicologist, or an epidemiologist, either by background or training. He is a medical doctor and a geneticist, but has no specialization in any of the relevant areas."¹⁸

In the hearing in this case, Dr. Geier testified that he was qualified as an expert in a thimerosal case captioned as Easter v. Aventis Pasteur, 358 F.Supp.2d 574 (E.D. Tex. 2005). He testified that the judge in the Easter proceeding qualified him as an expert, purportedly stating in open court that defense counsel should use his time wisely by not challenging Dr. Geier's qualifications because he has so many publications. Despite this Court's review of the transcript of the Daubert hearing in Easter (DX 50) and the opinion of that Court on the Daubert motion (DX 51), this Court could unearth nothing to support Dr. Geier's statements pertaining to the Easter Court qualifying him as an expert in that proceeding.

¹⁸The Redfoot court further noted the severe criticism of Dr. Geier's epidemiological studies by the IOM, AAP and other entities, and of cases before the Special Masters of the Court of Federal Claims under the National Vaccine Compensation Program in which Dr. Geier's opinions had been excluded or accorded little weight. Redfoot, supra, at *11.

While this Court acknowledges the different standards utilized by the federal courts in deciding Daubert motions, the differing standard does not change the fact that Dr. Geier is not qualified by his knowledge, skill, experience, training or education to render the opinions he proffers in this case. Dr. Geier is clearly qualified to testify in the field of medicine. However, in light of this Court's findings addressed at pp. 24-38 in this Opinion, this Court does not find that there exists a sufficient factual basis to support his proffered testimony. Accordingly, this Court grants defendant Wyeth's Md. Rule 5-702 motion as to Dr. Geier's testimony.

2. Dr. Boyd Haley

Plaintiffs presented testimony of Dr. Boyd Haley, a Professor of Chemistry at the University of Kentucky at Lexington. He was offered as an expert in the fields of mercury toxicity, biochemistry and physiology. This Court finds that he is qualified in the areas of biochemistry and physiology by his knowledge, skill, experience, training and education.

This Court acknowledges that he has published a multitude of articles involving chemical and biochemical studies regarding mercury. Indeed, he is a professor of causes that address mercury toxicity. Clearly, he is qualified to testify as to the toxicity of mercury to human brain cells. However, his lack of expertise in genetics, epidemiology and child neurology make it impossible for him to supply the necessary factual basis to support his testimony

pursuant to Md. Rule 5-702(3).¹⁹ In light of the lack of expertise in the above-identified disciplines, the plaintiffs have failed to demonstrate a sufficient factual basis to support the proffered.

3. Dr. Richard Deth

Dr. Richard Deth teaches pharmacology at Northeastern University. He was offered by the plaintiffs as an expert in the areas of physiology, neuropharmacology and the effects of thimerosal in the human brain. Dr. Deth is clearly qualified to testify as an expert witness in the areas of physiology and neuropharmacology. However, there is no recognized field of science in the third proposed area of expertise, namely "the effects of thimerosal in the human brain."

Dr. Deth offered the opinion that exposure to mercury for thimerosal-containing vaccines causes autism, based on a molecular theory that he developed through his in vitro studies. Questions about the effect mercury has in the human brain necessarily come within the ambit of the field of toxicology. These questions, including any opinions about the absorption, distribution, metabolism, and the excretion of thimerosal or mercury all involve issues of toxicology.

Further, Dr. Deth is neither an epidemiologist, a neurologist nor a geneticist. That--vel non--would not operate to preclude his

¹⁹Indeed, at the hearing in this case, Dr. Haley accused the IOM Committee of dishonesty, and the CDC personnel of lack of honesty and asserted that the CDC should be charged with criminal activity.

testimony. However, he has never taken any courses in epidemiology, has published no papers in any epidemiological journal, and is not a member of any epidemiological societies. He relies on an epidemiology paper published by Dr. Geier as support for his opinions.²⁰ Further, he relies on several papers about the neurology of autism. He is not a medical doctor and is not an expert in the field of pediatric neurology. Lastly, although he relies on various studies in the field of genetics, he does not have a degree in genetics nor is he a member of any professional genetics organizations or societies. Accordingly, in light of his expressed reliance on Dr. Geier's studies (that the Court has addressed at pp. 24-38 of this Opinion), this Court finds that he lacks a sufficient factual basis to support his testimony.

4. Dr. Elizabeth Mumper

Dr. Elizabeth Mumper is a general pediatrician in private practice in Virginia. The plaintiffs proffered Dr. Mumper as an expert in the field of pediatrics, in the diagnosis and treatment of children with neurodevelopmental disorders, including Attention Deficit Disorder, learning disabilities and autism, and as an expert clinician in the field of diagnosing children with mercury toxicity; and treating children with mercury toxicity.

The Court recognizes that by her training and expertise, Dr. Mumper is qualified to testify in the diagnosis and treatment of

²⁰This Court has ruled that Dr. Geier does not possess a sufficient factual basis to support his testimony.

children with neurodevelopmental disorders. However, expertise in the diagnosis and treatment of children with neurodevelopmental disorders including autism is not relevant to any matter relating to general causation in this case.

Moreover, as to the other areas of proffered expertise, Dr. Mumper is not qualified by her knowledge, skill, experience, training or education. She is neither proffered as--nor is she--an expert in the areas of epidemiology, toxicology or genetics,²¹ and has no specialized expertise in any of these disciplines. The plaintiffs have sought to qualify Dr. Mumper as an expert based on several factors, including: (i) her review of toxicological and genetic-susceptibility literature (PX 24, 26, 32, and 34-36); (ii) her clinical experience with some autistic patients; and (iii) her contributions to certain advocacy organizations including the Autism Research Institute and the entity known as Defeat Autism Now. While this work is laudable, it nevertheless does not qualify Dr. Mumper "by knowledge, skill, experience, training or education" to allow her to testify on the causation issues the plaintiffs wish to present. Further, assuming arguendo that she would be so

²¹For example, Dr. Mumper, who does not hold herself out to be an expert in the areas of genetics or metabolic diseases, is not qualified to offer opinions or interpret the genetic susceptibility studies published by Jill James (PX 26), which she indicated at the hearing as support for her opinion. When she was questioned about her understanding as to what percentage of the normal population has a polymorphism in connection with a gene that was the subject of Dr. James' research, she responded that it is common, but that she did not recall the number. She further stated that she is not a geneticist.

qualified, there does not exist the necessary factual basis to support her testimony pursuant to Md. Rule 5-703(3).

5. Dr. Stephen Siebert

Dr. Stephen Siebert is a psychologist who has a masters degree in public health. He is board certified in the field of psychiatry. The plaintiffs proffered Dr. Siebert as an expert in two related fields: (i) psychiatry; and (ii) forensic psychiatry. Dr. Siebert is clearly qualified under Md. Rule 5-702 to testify as an expert witness in the fields of psychiatry and forensic psychiatry. However, neither field has any relevance to the issues in this case that include general or specific causation. Expertise in the fields of psychiatry and forensic psychiatry does not provide the appropriate basis for opinion testimony on the issue of whether thimerosal-containing vaccines can cause autism.

Dr. Siebert testified that he diagnosed Jamarr Blackwell as mentally retarded and autistic. Those diagnoses are not disputed. However, he further testified to non-psychiatric diagnoses including that Jamarr Blackwell has a history of mercury toxicity. Although Dr. Siebert admittedly is not a toxicologist, he testified to a number of opinions in the field of toxicology, including that Jamarr Blackwell's autism and mental retardation were caused by exposure to thimerosal-containing vaccines.

Dr. Siebert further rendered opinions in the fields of genetics (e.g. that Jamarr Blackwell's autism could not solely be explained as a genetic condition), epidemiology and neurology.

These disciplines go far beyond Dr. Siebert's area of expertise in the fields of psychiatry and forensic psychiatry.²² In sum, while Dr. Siebert's training in psychiatry could easily qualify him to diagnose autism, the diagnosis of Jamarr Blackwell as autistic is not in dispute in this proceeding. The issues that are contested, including the etiology of autism and its alleged relationship to thimerosal-containing vaccines, are way outside of Dr. Siebert's field of expertise, namely psychiatry and forensic psychiatry.

Inasmuch as Dr. Siebert clearly does not possess sufficient qualifications to testify about the asserted connection between thimerosal-containing vaccines and autism, it would be inappropriate to allow Dr. Siebert to present his unqualified opinions on specific causation to be presented to the finder of fact in this proceeding.

V. PLAINTIFFS' MOTION TO PRECLUDE WYETH'S EXPERT WITNESSES PURSUANT TO MARYLAND RULE 5-702

1. Dr. Peter M. Layde

Wyeth offered the testimony of its epidemiologist, Dr. Peter M. Layde, M.Sc., who is currently a Professor and Interim Chair of the Department of Population Health Studies at the Medical College of Wisconsin. He is also an Adjunct Professor in the University's Medical School, teaching epidemiology to both graduate and medical students. Dr. Layde has published over 150 peer-

²²Understandably, Dr. Siebert was unable to answer questions concerning the distinctions among forms of mercury, the signs and symptoms of mercury poisoning, and the pharmacokinetics of ethyl mercury.

reviewed publications in epidemiology, and has conducted epidemiological research funded by numerous organizations, including the NIH and CDC.

Dr. Layde testified before an IOM panel looking at the safety of DTP vaccinations, and has provided testimony on vaccine safety to the World Health Organization and the CDC. On the specific issue of thimerosal in vaccines, Dr. Layde was one of the consultants chosen by the CDC to address a set of initial results from the Vaccine Safety Datalink Study. The plaintiffs have not challenged Dr. Layde's expertise in the area of epidemiology.

2. Dr. Joseph D. Buxbaum

Wyeth presented expert testimony in the area of genetics from Dr. Joseph D. Buxbaum. Dr. Buxbaum is a Professor in the Departments of Psychiatry, Neuroscience, Genetics and Genetic Sciences at the Mount Sinai School of Medicine in New York. Dr. Buxbaum serves as a member of the Genetics of Health and Disease section of the NIH Center for Scientific Review, and serves on the Advisory Board of the Autism Research Consortium.

Dr. Buxbaum's research focuses on the molecular genetic basics of neuropsychiatric illnesses, with specific focus on autism. He has been offered as an expert in genetics, and is clearly qualified to render opinions regarding genetics, including but not limited to testimony regarding the polymorphisms that plaintiffs claim are associated with the alleged vaccine-induced autism.

3. Dr. Kwame Anyane-Yeboah

Dr. Kwame Anyane-Yeboah is a clinical geneticist, and a Professor of Pediatrics at Columbia University. For a period of twenty years (until 2003), Dr. Yeboah served as the director of the Division of Clinical Genetics at New York Presbyterian Hospital. As part of his clinical practice, Dr. Yeboah routinely sees children with autism and other genetic conditions. He has authored or collaborated on approximately 45 articles published in peer-reviewed journals. On August 31, 2007, this Court qualified Dr. Kwame Anyane-Yeboah as an expert in clinical genetics.

4. Dr. Paul J. Kostyniak

Dr. Paul J. Kostyniak was offered by Wyeth as an expert in toxicology. He has a Ph.D. in toxicology and is board certified in the field of toxicology. Dr. Kostyniak is a professor of pharmacology and toxicology at the University of Buffalo School of Medicine and Biomedical Sciences. He also runs the toxicology research center at the University of Buffalo. He is the author of over 50 peer-reviewed publications and numerous other book chapters, reviews and proceedings in the field of toxicology. He has been involved in the area of mercury toxicology since approximately 1973. He was qualified by this Court as an expert in toxicology.

5. Dr. Bryna Siegel

Dr. Bryna Siegel was offered by Wyeth as an expert in the fields of autism and child development. She has a Ph.D. in childhood development. She performed three years of post-doctoral

training focusing on the research methods and clinical presentation of neurodevelopmental disorders in children. Dr. Siegel is a member of the Autism Society of America and has been invited by the American Academy of Pediatrics to present on topics related to autism, including the topic of diagnosing autism.

Dr. Siegel has published in excess of 75 peer-reviewed articles and three books on the subject of autism. She runs a clinical practice in San Francisco, California. In that context, she has seen approximately 3,700 children with autism in connection with offering diagnostic assessment and treatment planning. On August 29, 2007, Dr. Siegel was offered and received as an expert in the fields of autism and child development.

6. Dr. Paul H. Lipkin

Wyeth presented the testimony of several proposed expert witnesses at the hearing in this proceeding. One of those witnesses, Dr. Paul H. Lipkin, did not testify before this Court. Dr. Paul H. Lipkin is a pediatrician with a subspecialty in neurodevelopmental disabilities. Dr. Lipkin is the Director of the Center for Development and Learning at the Kennedy Krieger Institute, which treats autistic patients, and heads the American Academy of Pediatrics' Council on Children with Disabilities. He is board certified in neurodevelopmental disabilities and has authored a number of peer-reviewed journal articles and chapters in textbooks in the field of neurodevelopmental disabilities.

In their post-hearing filings, plaintiffs maintain that Dr. Lipkin cannot offer testimony on the etiology of autism, because he cannot identify the specific gene or set of genes that causes autism. This Court has not located any legal requirement that Dr. Lipkin be able to identify the specific genetic cause of autism in order to offer any testimony concerning autism etiology. Dr. Lipkin's qualifications satisfy the requirements in Md. Rule 5-702, and the plaintiff's motion to exclude his testimony is denied.

As identified previously, the plaintiffs have not challenged the qualifications or the expertise of Dr. Layde, Dr. Kostyniak or Dr. Siegel. Indeed, the Court qualified these witnesses as expert witnesses at the hearing. However, the plaintiffs have challenged the qualifications of Dr. Buxbaum, Dr. Yeboa and Dr. Lipkin. For the reasons stated supra at pp. 48-50, this Court overrules these challenges and will qualify these witnesses for the purposes of the hearing in this case. Accordingly, plaintiffs' motion to preclude testimony of defendants' expert witnesses pursuant to Md. Rule 5-702 is denied.

Lastly, the plaintiffs attempt to exclude Wyeth's witnesses from the relevant scientific community. It is well settled that the proponent of an expert witness bears the burden of proving that the bases of the witness' opinion are generally accepted as reliable within the relevant scientific community. See Reed v. United States, supra, 283 Md. at 381. The "relevant scientific community" for purposes of the Frye-Reed test, includes the full

"community of scientists with sufficient training and experience to permit them to comprehend novel scientific methods, and may not properly be restricted to those who practice or otherwise adhere to the methods at issue." Reed, supra, 283 Md. at 444.

The plaintiffs argue that Dr. Kostyniak, a toxicologist with specialized expertise in mercury toxicology (whose testimony the plaintiffs have not sought to exclude from the case), is outside of the relevant scientific community, because he testified that toxicologists do not diagnose mercury intoxication. This Court finds plaintiffs' argument without merit. Dr. Kostyniak's testimony falls within the scientific community relevant to the issues of causation presented in this proceeding because, as a toxicologist, he is qualified to assess the methodologies used and to reach conclusions concerning the toxicity of substances such as mercury.

Dr. Yeboa, whom plaintiffs also attack, is also within the relevant scientific community in this proceeding. He is a board-certified clinical geneticist who routinely evaluates autistic patients. His expertise includes assessing the diagnostic methodologies that Dr. Geier uses as a clinical geneticist. He testified that those diagnostic methodologies--including Dr. Geier's overall method of "differential diagnosis" and other diagnostic testing methods for the purpose of diagnosing vaccine-induced autism--are not generally accepted to be reliable among clinical geneticists.

Based on his review of Jamarr Blackwell's medical records, Dr. Yeboa determined that Jamarr Blackwell had certain features that were in the spectrum of Sotos syndrome. Sotos syndrome is associated with autism. The plaintiffs have challenged Dr. Yeboa's findings under the Frye-Reed test for admissibility. Inasmuch as the Court has granted Wyeth's Frye-Reed motion and denied plaintiffs' motion to exclude Wyeth's experts' testimony under Md. Rule 5-702, this Court need not reach the issue over whether to preclude this testimony under the Frye-Reed test for admissibility.

CONCLUSION

Based on the evidence received at the Frye-Reed hearing, the expert opinion evidence plaintiffs propose to offer through Dr. Boyd Haley, Dr. Richard Deth, Dr. Elizabeth Mumper, Dr. Mark Geier and Dr. Stephen Siebert is inadmissible under Frye-Reed. In sum, the plaintiffs, the proponents of the above-identified expert witnesses, have failed in their burden of proving that the bases of the expert witnesses' testimony are generally accepted as reliable within the relevant scientific field. See Reed v. United States, supra, 283 Md. at 381; Keene Corp. v. Hall, 96 Md. App. 644, 656 (1993).

For the purposes of the Frye-Reed test, the "relevant scientific community" includes the full community of scientists with sufficient training and experience to permit them to comprehend novel scientific methods, and may not properly be restricted to those who practice or otherwise adhere to the methods

at issue. Reed v. United States, *supra*, 283 Md. at 444. For the reasons stated in this Memorandum Opinion, the plaintiffs have failed to satisfy their burden of proof under Frye-Reed, because they have failed to show that the methodologies underlying their expert witness' opinions are generally accepted to be reliable in the relevant scientific community.

The consensus of the scientific community with expertise relevant to the issue of general causation in this case is reflected by the comprehensive and venerable report published by the Institute of Medicine in 2004. PX 10. Moreover, other organizations have issued statements that comport with the comprehensive analysis supplied in the 2004 IOM Committee Report. Those entities include, but are not limited to: The American Academy of Pediatrics ("AAP"), the Centers for Disease Control and Prevention ("CDC"), the National Institutes of Health ("NIH"), the World Health Organization ("WHO"), the European Agency for the Evaluation of Medicinal Products ("EMEA") and the Public Health Agency of Canada ("PHAC").

It is well established that where an expert witness offers a novel medical theory of causation, the bases of the expert's opinion, including the theory of causation, and the methodologies, must all be generally accepted or reliable in the relevant scientific community. See Montgomery Mut. Ins. Co. v. Chesson, *supra*, 399 Md. at 327 (2007). This Court finds that it is generally accepted in the relevant scientific community that autism

is genetic in origin except in rare instances of prenatal exposures to certain substances at defined periods during pregnancy. Further, for the reasons explicated in this Memorandum Opinion, this Court notes that it is generally accepted in the relevant scientific community that thimerosal in vaccines does not cause or contribute to neurodevelopmental disorders such as autism.

Critical to this Court's analysis is the 2004 IOM Report. PX 10. IOM Reports are highly regarded in the relevant scientific community, and their reliability has been recognized by numerous courts. See e.g. Falksen v. Sec'y of Dep't of HHS, No. 01-0317V, 2004 WL 985956 at t13 n. 35 (Fed. Cl. Mar. 30, 2004) ("The Court gives great deference to the findings of the [IOM]...a prestigious medical research organization funded by Congress to provide objective, timely, authoritative information and advice concerning health to government, the corporate sector, the professions, and the public...to review the medical literature on the health problems or injuries occurring after vaccination.") After careful consideration by this Court, the 2004 Committee's finding that "the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism" is generally accepted in the relevant scientific community.

After reviewing the testimony and evidence, this Court finds that the fields of epidemiology and toxicology and genetics are central to many of the issues in this case, including the causation issues that have been presented in this proceeding. For the

reasons stated in this Memorandum Opinion, Dr. Geier's epidemiological studies purporting to show an association between thimerosal-containing vaccines and autism were not conducted in accordance with generally accepted epidemiological methods.

Further, Dr. Geier performed a differential diagnosis in this proceeding. It is generally accepted in the relevant scientific community that differential diagnosis is a methodology by which the cause of a medical problem is identified considering and then ruling out the potential causes until the most probable cause remains. It is well settled that "[g]enerally, it is not appropriate to rely on a differential diagnosis to prove general causation." See Doe v. Ortho-Clinical Diagnostics, Inc., 440 F.Supp.2d 465, 477 (M.D.N.C. 2006), citing, Riggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005).

Indeed, "[a] differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion." Doe v. Ortho-Clinical Diagnostics, Inc., supra, 440 F.Supp.2d at 471, quoting Roche v. Lincoln Property Co., 278 F.Supp.2d 744, 751 (E.D. Va. 2003), aff'd 175 Fed.Appx. 597, 603 (4th Cir. 2006). It is noteworthy that other courts have acknowledged that Dr. Geier's methodology of differential diagnosis is fundamentally flawed, because he improperly "rules in" thimerosal as a potential cause of autism, and he cannot rule out the high likelihood that autism in any given individual was caused purely by genetic factors that do not require

an environmental trigger. See e.g. Doe v. Ortho-Clinical Diagnostics, Inc., supra, 440 F.Supp.2d 405 (M.D.N.C. 2006) (excluding Dr. Geier's differential diagnosis); Redfoot v. Ascher, No. C 05 2045 PJH, 2007 WL 1593239 at 11.

Accordingly, for the foregoing reasons, this Court grants Wyeth's Motion to Preclude Testimony of plaintiffs' expert witnesses pursuant to the Frye-Reed test. Further, this Court denies Plaintiffs' Motion to Exclude Certain Defense Experts and Certain Expert Testimony.

Judge Stuart R. Berger

*The Judge's Signature Appears
On The Original Document Only*

December 21, 2007

Date

Stuart R. Berger
Judge, Circuit Court for Baltimore City