Pamela Blackwell, et al., v. Wyeth d/b/a Wyeth, Inc. et al., No. 112, September Term 2008.

EXPERT TESTIMONY—MARYLAND RULE 5-702

Pamela and Ernest Blackwell, parents and next friends of Jamarr Blackwell, sued the drug manufacturer Wyeth, Inc., its affiliates, and others, alleging that Jamarr's autism and mental retardation were caused by thimerosal-laden vaccines administered to Jamarr when he was a baby. When the Blackwells proffered the testimony of five experts witnesses to support their theory of causation, Wyeth moved *in limine* to preclude the five experts' testimony, primarily arguing that the causal connection between thimerosal and autism is not generally accepted in the relevant scientific community and that the experts were not qualified to testify to such a causal connection. A 10-day evidentiary hearing was held on the *in limine* motions in the Circuit Court for Baltimore City to address "whether the plaintiffs' [experts] can support their claim of general causation with science that utilized methods and theories that are generally accepted in the relevant disciplines." After hearing the Blackwells' and Wyeths' experts' testimony, the judge concluded that the Blackwells had failed to demonstrate that the bases of their proffered experts' opinions, including the theory of causation and the analytical framework in support thereof, were generally accepted as reliable in the relevant scientific community. The judge also concluded that the Blackwells' experts were not qualified to testify under Maryland Rule 5-702. Summary judgment was entered in favor of Wyeth, and the Blackwells appealed; the Court of Appeals granted certiorari prior to any proceedings in the Court of Special Appeals.

The Court of Appeals affirmed. Addressing the theory of causation, the Court concluded that

although Dr. Geier, the Blackwells' expert in epidemiology, may have used data that was collected in generally accepted ways, the "analytical gap" between the data and the conclusion was too great to justify the results. The Court, moreover, concluded that neither Dr. Geier's methods nor his theory of causation were generally accepted in the relative scientific community. In holding that the Blackwells' experts were not qualified under Maryland Rule 5-702, the Court held that none of their experts had sufficient knowledge, skill, experience, training, or education, primarily in the field of epidemiology, to proffer reliable expert testimony on matters of complex and novel scientific inquiry, such as whether a causal connection exists between the preservative thimerosal and autism.

IN THE COURT OF APPEALS OF

MARYLAND

No. 112

September Term, 2008

PAMELA BLACKWELL et al.
v.

WYETH d/b/a/ WYETH, INC., et al.

Bell, C.J.
Harrell
Battaglia
Greene
Murphy
Adkins
Barbera,

JJ.

Opinion by Battaglia, J.

Filed: May 7, 2009

In this case, we address the boundaries of *Frye-Reed*[1] with respect to a hypothesis proffered, on behalf of Pamela and Ernest Blackwell, Petitioner, by their expert, Dr. Mark Geier, involving whether the presence of the preservative "thimerosal"[2] in childhood vaccines, causes neurological defects, such as autism,[3] as well as his and four other individuals' qualifications to be experts under Maryland Rule 5-702,[4] in a suit against Wyeth,

---

[1] *Frye-Reed* is the test in Maryland for determining whether expert testimony is admissible. The name is derived from two cases, *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), where this standard of general acceptance in the relevant scientific community was first articulated, and *Reed v. State*, 283 Md. 374, 391 A.2d 364 (1978), where we adopted the *Frye* standard.

[2] The trial judge found that "[t]himerosal is an organic mercury based compound . . . [that] has been used as a preservative in various vaccines and other biological and pharmaceutical products since the 1930's."

[3] This Court once before has been presented with the substantive issue of an alleged relationship between thimerosal and autism. In *Aventis Pasteur, Inc. v. Skevofilax*, 396 Md. 405, 914 A.2d 113 (2007), we reviewed whether a circuit court judge abused his discretion when denying a motion to dismiss without prejudice and granting summary judgment in favor of Aventis Pasteur. Skevofilaxes' expert conceded, in a deposition taken in connection with a thimerosal case pending elsewhere, that his claim of causation between thimerosal, genetic susceptibility and autism was not generally accepted in the medical community. Shortly after the expert was scheduled to be deposed in the Maryland case, the Skevofilaxes informed the judge and opposing counsel that the expert refused to participate further in the litigation. The Skevofilaxes filed a Motion for Dismissal of All Claims Without Prejudice, and Aventis Pasteur filed a Motion for Summary Judgment, the latter of which was granted. After the Court of Special Appeals reversed, holding that the unexpected withdrawal of an expert witness could not outweigh the effort and expense incurred by the Skevofilaxes, we reversed the intermediate appellate court and remanded, holding that the trial judge did not abuse his discretion in granting summary judgment because, after failing to produce an expert who could testify to specific causation, the plaintiff's claims failed as a matter of law.

[4] Maryland Rule 5-702, governing testimony by experts, states:

> Expert testimony may be admitted, in the form of an opinion or otherwise, if the court determines that the testimony will assist

(continued...)

Inc., Respondent.

Pamela and Ernest Blackwell, parents and next friends of Jamarr Blackwell, sued the drug manufacturer Wyeth, Inc., its affiliates,[5] and others,[6] alleging that Jamarr's autism and mental retardation were caused by thimerosal-laden vaccines administered to Jamarr, when he was a baby, between the years 1985 and 1986.[7] After Wyeth moved *in limine* to preclude the testimony of the Blackwells' experts on grounds that the causal connection between thimerosal and autism is not generally accepted in the relevant scientific community and that the experts were not qualified to testify to such a causal connection, a 10-day evidentiary

---

[4](...continued)

> the trier of fact to understand the evidence or to determine a 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.

[5] The affiliates included: Wyeth d/b/a Wyeth, Inc., Wyeth Laboratories, Wyeth-Ayerst, Wyeth-Ayerst Laboratories, Wyeth Lederle Vaccines, Lederle Labratories (collectively "Wyeth").

[6] Other than Wyeth and affiliates, the Blackwells' 22-count Complaint named Baltimore Gas and Electric Company, which became Constellation Energy during the course of the proceedings, Merck & Company, Inc., Sigma-Aldrich, Inc., American International Chemical, Spectrum Laboratory Products, and Eli Lilly and Company. Constellation Energy ultimately prevailed on summary judgment; Merck & Company, Inc., American International Chemical and Spectrum Laboratory Products were dismissed by stipulation; and Sigma-Aldrich, Inc., and Eli Lilly and Company were dismissed with prejudice.

[7] Wyeth concedes in its brief that, "[a]s an infant, [Jamarr] received vaccines, approved by the Food and Drug Administration and made by Defendant-Appellee, Wyeth . . . [that] included thimerosal, an ethyl mercury derivative, as a preservative to prevent bacterial and fungal contamination in vaccines."

hearing was held before Judge Stewert R. Berger of the Circuit Court for Baltimore City, in which he addressed the seminal question of "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." After hearing the testimony of numerous experts presented by both sides,[8] Judge Berger issued a 57-page Memorandum Opinion, ultimately concluding that the Blackwells had failed to demonstrate that the bases of their proffered experts' opinions, including the theory of causation and the analytical framework in support thereof, were generally accepted as reliable in the relevant scientific community. Judge Berger also concluded that the Blackwells' experts were not qualified to testify under Maryland Rule 5-702. Summary judgment was entered in favor of Wyeth, and the Blackwells appealed; we granted certiorari prior to any proceedings in the Court of Special Appeals, *Blackwell v. Wyeth*, 406 Md. 442, 959 A.2d 792 (2008), to address two questions:

> 1. Did the Circuit Court improperly apply the *Reed-Frye* general acceptance standard to the Blackwells' experts' conclusions, rather than the bases upon which they reached their causation opinions, and impermissibly conduct a trial on the merits by using a heightened scientific certainty standard to determine the admissibility of their expert testimony?
>
> 2. Did the Circuit Court apply an erroneous legal standard and abuse its discretion in concluding that the Blackwells' experts' testimony is inadmissible because it does not meet the

[8] During the *Frye-Reed* hearing, the Blackwells presented the testimony of Drs. Mark Geier, M.D., Ph.D; Stephen Siebert, M.D., M.P.H; Elisabeth Mumper, M.D.; Richard Carlton Deth, Ph.D.; and Boyd Haley, Ph.D. Wyeth presented experts Peter M. Layde, M.D., M.Sc., Paul Kostyniak, Ph.D., Joseph Buxbaum, Ph.D, Kwame Anane-Yeboa, M.D., and Bryna Siegel, Ph.D.

requirements of Md. Rule 5-702?

We shall affirm and conclude that Judge Berger appropriately precluded the Blackwells' experts' testimony under *Frye-Reed*[9] and did not abuse his discretion in the application of Maryland Rule 5-702.

I. Background

---

[9] In *Wilson v. State*, 370 Md. 191, 201 n.5, 803 A.2d 1034, 1040 n.5 (2002), Judge Irma S. Raker, writing on behalf of the Court, noted:

> Appellate review of a trial court's decision regarding admissibility under *Frye-Reed* is *de novo*, as both petitioner and the State concede. . . . [In] *Jones v. United States*, 548 A.2d 35 (D.C. 1988) . . . . [t]he court found:
>
> > General acceptance means just that; the answer cannot vary from case to case. For this reason, when the . . . *Frye* test . . . is at issue, it becomes the 'threshold question' of admissibility, to be resolved as a matter of law before the court exercises its discretion in applying all the criteria to a particular proffered expert: The question of the reliability of a scientific technique or process is unlike the question, for example, of the helpfulness of particular expert testimony to the trier of facts in a specific case. The answer to the question about the reliability of a scientific technique or process does not vary according to the circumstances of each case. It is therefore inappropriate to view this threshold question of reliability as a matter within each trial judge's individual discretion.
>
> But more succinctly courts should not subsume the question of qualifying the [scientific] process . . . under the question of qualifying the expert. It follows that, in evaluating whether a scientific technique has gained general acceptance, appellate courts review the trial court's analysis de novo.

(Internal citations and quotations omitted).

In this case we must address the application of *Frye-Reed* to theories proffered as scientific and alleged to have been premised on scientifically accepted methodologies. To place this quandary within the appropriate context, we shall begin by discussing the purpose of scientific inquiry and the scientific method, as well as our framework for the admission of expert testimony.

The quest for truth in the courtroom and the quest for knowledge in science are not necessarily intersecting endeavors. A trial, on the one hand, may be quick and determinative; it is a process by which "advocates for each side present evidence in the light most favorable to their case, and the finder of fact sifts through it and assesses whether it establishes guilt or liability to the required degree of proof." *See* Susan Haack, *Of Truth, in Science and in Law*, 73 Brook. L. Rev. 985, 985-86 (2008). The search for knowledge in science, on the other hand, is rarely quick or final; rather, it represents an ongoing cycle, in which each inquiry into an observable phenomenon is but one aspect of an ongoing quest.[10]

At the heart of this search for knowledge is the use of scientific method—or the analytical process by which a hypothesis is tested and analyzed and conclusions or theories are developed. This process has also been described as empirical study, that being study, "[f]ounded on practical experience, rather than on reasoning alone, but not established scientifically . . . [or] testing a hypothesis by careful observation, hence rationally based on

---

[10] The word *science*, itself, is defined as "[t]he branch of knowledge that produces theoretic explanations of natural phenomena based on experiments and observations." Stedman's Medical Dictionary 1731 (28th ed. 2006).

experience." Stedman's Medical Dictionary 632 (28th ed. 2006) ("empiric").[11] In basic terms, the development of a theory, using the scientific method or empirical testing, follows characteristic steps:

> 1. Observations of some phenomenon are made. For example, the movements of planets (which move in more complex orbits than the stars).
> 2. Possible explanations (theories) are proposed for what is observed. (For the movement of planets, one such theory, radical at the time of its first suggestion, was that the movements of planets could be explained by a theory that placed the Sun and not the Earth at the center of our solar system.)
> 3. Hypotheses are logically derived from the theories. (If the Sun is the center of the solar system, then certain other observations should be true. If the Earth is the center of the solar system, that would lead to different predictions.)
> 4. Studies are designed to test the hypotheses. In essence, the study makes new observations that might disconfirm the hypothesis and thereby falsify the theory. Different theories have different implications and lead to different hypotheses. (Ideally, a study can be devised whose outcome will disconfirm one theory's hypotheses and not the other's. This is called a "critical experiment" because it permits a head-to-head test of two or more theories, and helps to determine which has done the best job of accounting for the relevant phenomena. Sometimes scientific controversies persist for a very long time because no commonly agreed upon critical experiment can be conducted.)
> 5. The results of such empirical tests lead to revision or abandonment of older theories or the creation of still newer and hopefully better theories.
> 6. The process repeats itself as more empirical tests are conducted and theories undergo continued re-evaluation.

David L. Faigman, Michael J. Saks, Joseph Sanders & Edward K. Cheng, 1 Modern

---

[11] An experiment is defined as, "[a] study in which the investigator intentionally alters one or more factors under controlled conditions to study the effects of doing so." Stedman's, *supra*, at 685.

Scientific Evidence: The Law and Science of Expert Testimony, at 263-64 (2008). Specifically, once a theory is conceived based on an observable phenomenon, a hypothesis, which is "[a] conjecture advanced for heuristic purposes, cast in a form that is amenable to confirmation or refutation by conducting of definable experiments and the critical assembly of empiric data," Stedman's, *supra*, at 938, is developed, which defines the scope of an experiment. Studies then are designed to test the hypothesis and gather data:

> To real scientists a finding of fact is only as good as the methods used to find it. Scientific method is the logic by which the observations are made. Well designed methods permit observations that lead to valid, useful, informative answers to the questions that had been framed by the researcher. For scientists, the key word in the phrase "scientific method" is *method*. Methodology—the logic of research design, measures, and procedures—is the engine that generates knowledge that is scientific. While for lawyers and judges credibility is the key to figuring out which witnesses are speaking truth and which are not, for scientists the way to figure out which one of several contradictory studies is most likely correct is to scrutinize the methodology.

Faigman, *supra*, at 260 (emphasis in original). Once data is complied, analysis occurs, from which conclusions are drawn; the hypothesis either remains viable or is disproven:

> Note that a hypothesis or a theory is never proven or confirmed to be true. Testing is capable only of disconfirming. But theories that withstand such attempts at falsification better and longer become accepted, at least until something better comes along. The opposite approach can readily be seen in non-scientific activities of numerous kinds, where investigators engage in a search for evidence that confirms their suspicions. This confirmatory bias is based on the erroneous assumption that a theory is confirmed by the accumulation of facts consistent with the theory. . . . It is the diligent search for inconsistencies, for falsification, that really puts a theory to the

> test. A theory that can withstand such scrutiny is one that deserves credence.

Id. at 264.

"At any time there is a whole continuum of scientific ideas, claims, and theories: some [are] so well-warranted by such strong evidence that it is most unlikely they will have to be revised; some not quite so well-warranted but still pretty solidly established; some promising but as yet far from certain; some new and exciting but highly speculative and as yet untested; and some so wild that few mainstream scientists are willing even to listen." Haack, *supra*, at 996. The strength, therefore, of a scientific theory is measured, in part, by its validity, which is "the extent to which something measures what it purports to measure." Faigman, *supra*, at 269. *See also* Samuel R. Gross & Jennifer L. Mnookin, *Expert Information and Expert Evidence: A Preliminary Taxonomy*, 34 Seton Hall L. Rev. 141, 146-47 (2003) (discussing the distinction between field validity, which is whether a given "field of knowledge . . . has credible tools to produce valid answers," and method validity, which is whether "the methods that were used in this instance [were] capable of producing valid answers"). *See generally* Faigman, *supra*, Ch. 5, "Scientific Method: The Logic of Drawing Inferences from Empirical Evidence," (discussing numerous research designs, methods of measurement, sampling, relationships among variables and threats to validity). The second variable affecting the strength of a scientific theory is its reliability, which has been defined as,

> [*R*]*eliability* refers to the ability of a measure to produce the same result each time it is applied to the same thing. Reliability

> refers to consistency, or reproducibility. If each time a person steps on to a bathroom scale it gives a different reading (while the person's weight has not changed), then the scale is said to lack reliability.

Faigman, *supra*, at 269 (italics in original). Both validity and reliability, then, affect whether a scientific theory is accepted in the field in which it is offered.

General acceptance by other members of the relevant scientific field became the standard for acceptance of a theory, as a result of the opinion of the United States Court of Appeals for the District of Columbia Circuit in *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923):

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a *well-recognized* scientific principle or discovery, the thing from which the deduction is made must be *sufficiently established to have gained general acceptance in the particular field in which it belongs*.

(Emphasis added). The *Frye* "general acceptance" standard was adopted by this Court in *Reed v. State*, 283 Md. 374, 391 A.2d 364 (1978), in which we recognized that the standard did reflect assessment of a theory's validity and reliability. In *Reed*, we were confronted with whether voiceprint recognition, consisting of the use of a spectrograph machine to match patterns in an individual's voice, was admissible, for identification purposes, in a rape case. We concluded that the trial judge erred in admitting the evidence. *Id.* at 399-400, 391 A.2d at 377. In so doing, Judge John C. Eldridge, writing for this Court, recognized that scientific

methodologies or techniques must be generally accepted prior to the admission into evidence of the conclusions reached:

> On occasion, the validity and reliability of a scientific technique may be so broadly and generally accepted in the scientific community that a trial court may take judicial notice of its reliability. Such is commonly the case today with regard to ballistics tests, fingerprint identification, blood tests, and the like. Similarly, a trial court might take judicial notice of the invalidity or unreliability of procedures widely recognized in the scientific community as bogus or experimental. However, if the reliability of a particular technique cannot be judicially noticed, it is necessary that the reliability be demonstrated before testimony based on the technique can be introduced into evidence. Although this demonstration will normally include testimony by witnesses, a court can and should also take notice of law journal articles, articles from reliable sources that appear in scientific journals, and other publications which bear on the degree of acceptance by recognized experts that a particular process has achieved.

Id. at 380, 391 A.2d at 367 (internal citations removed). In adopting the *Frye* test of general acceptance, Judge Eldridge gave guidance regarding its application:

> That is to say, before a scientific opinion will be received as evidence at trial, the basis of that opinion must be shown to be generally accepted as reliable within the expert's particular scientific field. Thus, according to the *Frye* standard, 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.
>
> The identity of the relevant scientific community is, of course, a matter which depends upon the particular technique in question. In general, members of the relevant scientific community will include those whose scientific background and training are sufficient to allow them to comprehend and understand the process and form a judgment about it. In unusual circumstances, a few courts have held that the experts thus

qualified might properly be from a somewhat narrower field.

Id. at 381-82, 391 A.2d at 368 (internal citations omitted).

We recognized in *Reed* that seminal scientific technologies may be rejected, because the "*Frye* standard retards somewhat the admission of proof based on new methods of scientific investigation by requiring that they attain sufficient currency and status to gain the general acceptance of the relevant scientific community," *id.* at 385, 391 A.2d at 370, quoting *United States v. Addison*, 498 F.2d 741, 743-44 (D.C. Cir. 1974), in that "[f]airness to a litigant would seem to require that before the results of a *scientific* process can be used against him, he is entitled to a *scientific* judgment on the reliability of that process." *Id.* at 385, 391 A.2d at 369-70 (emphasis in original). We further recognized that, "*Frye* was deliberately intended to interpose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles" because "[l]ay jurors tend to give considerable weight to 'scientific' evidence when presented by 'experts' with impressive credentials." *Id.* at 386, 391 A.2d at 370, quoting *People v. Kelly*, 549 P.2d 1240, 1245 (Cal. 1976). Accordingly, we concluded that, "[a]s long as the scientific community remains significantly divided, results of controversial techniques will not be admitted, and all [litigants] will face the same burdens. If, on the other hand, a novel scientific process does achieve general acceptance in the scientific community, there will likely be as little dispute over its reliability as there is now concerning other areas of forensic science which have been deemed admissible under the *Frye* standard, such as blood tests, ballistics tests, etc." *Id.* at 388, 391 A.2d at 371.

Since 1978, we have had occasion to elaborate on the application of *Frye-Reed* to various aspects of the scientific method as well as specific methodologies. In *Wilson v. State*, 370 Md. 191, 803 A.2d 1034 (2002), we addressed whether a trial judge erred in rejecting expert opinion testimony, based upon a generally-accepted statistical calculus—the product rule.[12] Wilson had been accused of murder after a second child of his, with a different mother, had died during a night when Wilson was the caretaker. Wilson interposed a SIDS, or Sudden Infant Death Syndrome, defense. At trial, the State proffered the testimony of two experts, who, using the product rule, would have testified that the probability of a child dying with SIDS with cerebral swelling was 1 and 100,000—arrived at by multiplying the statistic that 1 child per 1,000 live births die of SIDS by the statistic that 1 in 10 SIDS deaths involve cerebral swelling—and that the chance of two SIDS deaths occurring in the same family was 1 in 4,000,000—arrived at by squaring the rate of 1 child per 2,000 live births to reach the chance of two children dying from SIDS in the same family. Wilson moved *in limine* to exclude the testimony of the State's experts, but the trial judge denied the motion. At trial, the experts testified, and in closing argument, the State specifically referred to the experts' statistics, stating, "[i]f you multiply his numbers, instead of 1 in 4 million, you get 1 in 10 million that the man sitting here is innocent." *Id.* at 200, 803 A.2d at 1039. The Court of Special Appeals affirmed the conviction, and we granted certiorari to consider whether the

---

[12] The product rule states: "the probability of the joint occurrence of a number of *mutually independent* events is equal to the product of the individual probabilities that each of the events will occur." *Wilson v. State*, 370 Md. 191, 198 n.2, 803 A.2d 1034, 1038 n.2 (2002) (emphasis in original).

Frye-Reed standard applies to the application of statistical methods, which we answered in the affirmative. *Id.* at 196, 202-03, 803 A.2d at 1036, 1040-41, citing *Armstead v. State*, 342 Md. 38, 673 A.2d 221 (1996).

After reiterating the bases of *Frye-Reed* that, "before a scientific expert opinion may be received in evidence, the basis of that opinion must be shown to be generally accepted as reliable within the expert's particular scientific field," *id.* at 203, 803 A.2d at 1041, we addressed whether the use of a generally accepted technique required acceptance of conclusions derived from its use. We concluded that it was not mandated, because one of the necessary predicates to the application of the product rule—mutual independence of events—was not considered; genetics may have been the link between the two infants' deaths:

> We hold that the trial court erred in admitting expert testimony based on the product rule because a condition necessary to the proper application of the product rule was lacking: there was inadequate proof of the independence of Brandi and Garrett's deaths. As evidenced by the authorities above cited, there is not general agreement in the scientific community as to the relationship between SIDS deaths within a single family. Stated another way, there is not general agreement in the medical community that multiple SIDS deaths in a single family are genetically unrelated. The literature continues to reflect a lively debate concerning the role of genetics in SIDS.
>
> * * *
>
> In light of the widespread disagreement as to the causes of SIDS, we are unable to find general acceptance of the notion that there is no genetic component to SIDS. Unanimity is not required for general acceptance, but it is clear to us that a genuine controversy exists within the relevant scientific community. In sum, there was inadequate proof of the statistical

> independence of SIDS deaths within a single family. Therefore, based on the current state of medical opinion, the product rule should not be employed in calculating the likelihood of multiple SIDS deaths within a single family.

Id. at 209, 210-11, 803 A.2d 1044-45 (citations omitted). Accepted methodology, then, does not mandate acceptance of conclusions ostensibly developed therefrom.

We also have had the opportunity to apply *Frye-Reed* when considering whether a theory, which had been accepted in the scientific and legal communities, continues to meet the standard. Comparative Bullet Lead Analysis (CBLA), by which two bullets are compared to see if they originate from the same original molten source, had gained currency as admissible scientific evidence prior to *Clemons v. State*, 392 Md. 339, 896 A.2d 1059 (2006). In *Clemons*, the State presented an FBI CBLA expert, who testified that a bullet found at a crime scene and bullets found in a gun possessed by Clemons, seized two days after the crime, originated from the same original source. Clemons moved *in limine* to exclude the expert's testimony, arguing that an essential premise of CLBA theory was no longer generally accepted in the relevant scientific community—that bullets originating from a given ingot or vat of lead were uniquely homogenous. The trial judge admitted the evidence, and the Court of Special Appeals affirmed the conviction. We reversed, holding that the trial judge erred in admitting the CBLA testimony, because it was no longer generally accepted in the field of metallurgy that the elemental composition of the molten source for the creation of bullets was uniform, homogenous or unique. In so holding, we engaged in an in-depth review of the CBLA technique, observing,

> Recently the assumptions regarding that uniformity or homogeneity of the molten source and the uniqueness of each molten source that provide the foundation for CBLA have come under attack by the relevant scientific community of analytical chemists and metallurgists[,]

Id. at 368, 896 A.2d 1059, 1076, and concluded:

> We conclude that CBLA does not satisfy the requirement under the *Frye-Reed* test for the admissibility of scientific expert testimony because several fundamental assumptions underlying the process are not generally accepted by the scientific community. Therefore, we reverse the judgment of the Court of Special Appeals and remand the case to the Circuit Court for Prince George's County for a new trial.

Id. at 372, 896 A.2d at 1079 (emphasis added).

More recently, in *Montgomery Mutual Insurance Company v. Chesson*, 399 Md. 314, 923 A.2d 939 (2007), we considered whether a trial judge erred in denying a defendant's *in limine* motion for a *Frye-Reed* hearing to determine the admissibility of expert testimony that exposure to mold caused certain physical ailments, described as either sick building syndrome or bio-toxic illness, "a combination of ailments associated with exposure to modern buildings that lack proper ventilation." *Chesson*, 399 Md. at 317 n.1, 923 A.2d at 940-41 n.1. Montgomery Mutual, a workers' compensation insurer, alleged that the claimant's expert's theory, regarding a causal connection between mold exposure and certain human health effects, had not been generally accepted within the relevant scientific community, nor had the tests used in developing the theory. The trial judge denied the motion without holding a hearing, and the Court of Special Appeals affirmed, stating, *inter alia*, that the experts utilized medical tests that were generally accepted in the scientific

community. *Montgomery Mutual Ins. Co. v. Chesson*, 170 Md. App. 551, 570-71, 907 A.2d 873, 885 (2006). We reversed and remanded, recognizing that the tests utilized, as well as the results and theory, must be subjected to *Frye-Reed* scrutiny:

> In the case *sub judice*, the Court of Special Appeals held that it was unnecessary for the Circuit Court to hold a *Frye-Reed* hearing, reasoning (1) that [the expert's] medical diagnosis was not a proper subject for *Frye-Reed* analysis, and (2) that the tests [the expert] used in reaching his medical diagnoses are generally accepted in the medical community, and are therefore not subject to *Frye-Reed* analysis. We disagree and hold that, based on this record, the Circuit Court should have held a *Frye-Reed* hearing to determine whether the medical community generally accepts the theory that mold exposure causes the illnesses that respondents claimed to have suffered, and the propriety of the tests [the expert] employed to reach his medical conclusions.

Chesson, 399 Md. at 328, 923 A.2d at 947 (citations omitted) (emphasis added). *See also State v. Smullen*, 380 Md. 233, 266, 268, 844 A.2d 429, 448, 449-50 (2004) (noting that the battered-spouse syndrome is a novel scientific theory that would have been subjected to *Frye* had not the Maryland General Assembly expressly made it admissible, in a case addressing whether battered-spouse syndrome could be used as a self-defense).

From even a limited review of our *Frye-Reed* history, it can be seen that our jurisprudence engages trial judges in a serious gate-keeping function, to differentiate serious science from "junk science." Commentators on the *Frye* standard have recognized the importance of this role:

> Courts therefore have a duty to ensure that experts are presenting reliable testimony.
> This obligation is especially acute because unlike ordinary fact witnesses, who typically come from a very limited pool of

witness[es], there is usually an almost unlimited pool of experts. For example, many qualified experts could testify in a typical medical malpractice case. While attorneys are stuck with the testimonial limitations of the available fact witnesses, an attorney who needs an expert can "shop" for an expert with a pleasing courtroom manner who will agree with the attorney's theory of the case.

* * *

Some of these potential expert witnesses will be venal "hired guns." As Judge Jack Weinstein has noted, "[a]n expert can be found to testify to the truth of almost any factual theory, no matter how frivolous." Ordinary fact witnesses may also have their biases, but attorneys can only take advantage of these biases if the witnesses already exist; they cannot normally shop for an ordinary fact witness. By contrast, attorneys can seek expert witnesses who will parrot the attorneys' line, and, indeed, implicitly "bribe" them to do so.

Moreover, ordinary biases, such as a familial or friendly relationship to one of the parties, can typically be brought out on cross-examination. Some authorities have argued that cross-examination will also reveal an expert witness' bias to the jury. However, it [is] not at all clear how opposing counsel can discredit a "hired gun" expert for taking money for his testimony, given that opposing counsel will have his own expert—who may be scrupulously honest—on his payroll.

In any event, even if the biases of hired guns can be revealed through cross-examination, that does not resolve the problems caused by expert-shopping. Not all, and perhaps not even most experts who testify to opinions outside the mainstream of their field are venal hired guns. Our system assumes, perhaps optimistically, that the jury can determine if an expert is lying. But what if the expert is simply shading the truth? Or, even more likely, what if the expert is simply eccentric or outside the mainstream? Parties have every incentive to hire "outlier" experts with sincere but extreme views so long as they can conceal the outlier status. There is no reason to hire an expert, for example, who will tell the jury that a client's losses are worth $150,000 if an attorney can find an equally credible expert willing to testify that the true figure is $300,000. Moreover, there is no ethical obligation on attorneys to hire

> mainstream experts. Indeed, their duty to zealously advocate for their clients may *require* them to hire outliers if it would help their client's case.

David E. Bernstein, *Frye, Frye Again: The Past, Present, and Future of the General Acceptance Test*, 2 Bureau of National Affairs Expert Evidence Report (Feb. 18, 2002) (footnotes omitted) (emphasis in original), *available at* http://litigationcenter.bna.com /pic2/lit.nsf/id/BNAP- 57HQ4Q?OpenDocument (last visited May 5, 2009).

II. Procedural History

On June 9, 2004, the Blackwells filed a 22-count complaint against various thimerosal manufacturers, numerous manufacturers of thimerosal-laden products, and BG&E, alleging that mercury contained in their products or emissions caused their son Jamarr's autism. Wyeth, as the manufacturer of a thimerosal-laden product, was sued for defective design, breach of warranty of fitness for a specific purpose, failure to warn, strict liability, negligence, defect in manufacturing, common law fraud, negligent misrepresentation, fraudulent misrepresentation, fraudulent misrepresentation through another, deceptive trade practices under the Maryland Consumer Protection Act, breach of implied warranties, intentional infliction of emotional distress, and civil battery.

Wyeth moved to preclude the testimony of five experts offered by the Blackwells under *Frye-Reed*, arguing that the experts' theory, that thimerosal caused Jamarr's autism, and the various methodologies employed in reaching that conclusion, were not generally accepted in the relevant scientific community. Wyeth also alleged that the Blackwells' experts were not qualified to testify under Maryland Rule 5-702. The Blackwells filed

reciprocal motions regarding a number of Wyeth's experts.

Between August 18-29, 2007, Judge Stuart R. Berger of the Circuit Court for Baltimore City conducted a *Frye-Reed* hearing on these motions,[13] wherein testimony was

---

[13] In *Clemons v. State*, 392 Md. 339, 896 A.2d 1059 (2006), we discussed the procedural parameters of *Frye-Reed* and our preference that a trial judge hold a hearing prior to trial and outside the presence of the jury, to determine the admissibility of expert testimony:

> Judges have discretion to defer a pre-trial ruling on a motion *in limine* and ordinarily do so where the issue can be better developed or achieve a better context based on what occurs at trial. Where evidence is subject to challenge under *Frye-Reed*, however, the issue should, whenever possible, be dealt with prior to trial. The evidence bearing on whether the challenged evidence is actually the product of a novel scientific technique and, if so, whether that technique is generally accepted in the relevant scientific community will usually be collateral to the substantive issues at trial and may, itself, be inadmissible with respect to those substantive issues. That alone justifies resolving the issue prior to trial. Dealing with the issue pre-trial also avoids delays and diversions at trial that may inconvenience both witnesses and the jury. *See* Maryland Rule 5-104(c) ("Hearings on preliminary matters shall be conducted out of the hearing of the jury when required by rule or the interests of justice.").
>
> * * *
>
> Maryland Rule 5-103(c) also provides support for our conclusion that *Frye-Reed* examinations are better conducted in pre-trial hearings in its admonition that "[p]roceedings shall be conducted, to the extent practicable, so as to prevent inadmissible evidence from being suggested to a jury by any means, such as making statements or offers of proof or asking questions within the hearing of the jury." Conducting the hearing outside the presence of the jury would preclude its members from improperly considering evidence that is

(continued...)

adduced from each of the Blackwells' experts—Mark Geier, M.D., Ph.D; Stephen Siebert, M.D., M.P.H; Elisabeth Mumper, M.D.; Richard Carlton Deth, Ph.D.; and Boyd Haley, Ph.D—and from Wyeth's five proposed experts—Peter M. Layde, M.D., M.Sc., Paul Kostyniak, Ph.D., Joseph Buxbaum, Ph.D, Kwame Anane-Yeboa, M.D., and Bryna Siegel, Ph.D. (of whom only Drs. Yeboa and Buxbaum were challenged by the Blackwells). In an order supported by an extensive memorandum opinion, Judge Berger granted Wyeth's Motion to Preclude Testimony of Plaintiff's Expert Witnesses, pursuant to *Frye-Reed* and Maryland Rule 5-702, and denied the Blackwells' Motion to Exclude Certain Defense Experts and Certain Expert Testimony. Thereafter, Judge Berger granted Wyeth's motion for summary judgment, finding "no genuine dispute as to any material fact." The Blackwells noted an appeal to the Court of Special Appeals, and this Court granted certiorari prior to any

---

[13](...continued)

> irrelevant to the task at hand and ensure that the verdict is derived from evidence properly before it.
>
> If the issue is to be dealt with at trial, it should be addressed, in its entirety, as a preliminary matter prior to admission of the challenged evidence, not, as here, by having the challenge made only to Peters's status as an expert during the State's case and then receiving most of the evidence bearing on whether the inferences sought to be drawn from CBLA are generally accepted in the relevant scientific community during the defense case, after the challenged inferences have already been admitted.
>
> If a party raises a *Frye-Reed* objection, all evidence bearing on admissibility of the challenged evidence should be presented and considered *before* a ruling is made on the challenge.

Id. at 347-48 n.6, 896 A.2d at 1064 n.6 (internal quotations and citations omitted) (emphasis in original).

proceedings in the intermediate appellate court, to address the exclusion of the Blackwells' experts' testimony.[14]

III. Discussion

Before us, the Blackwells argue that the Judge erred in his *Frye-Reed* analysis, because he denied the admissibility of their experts' theory, that thimerosal in the vaccines produced by Wyeth and administered to their son, Jamarr, caused his autism, because it was not generally accepted in the relevant scientific community,[15] and because their experts were not qualified to testify about a causal relationship between thimerosal and autism, under Maryland Rule 5-702. The Blackwells argue, in essence, that the trial judge impermissibly determined the element of causation on summary judgment and precluded the jury from

---

[14] After oral argument before this Court, Wyeth filed a Motion for Judicial Notice on March 8, 2009, asking this Court to take judicial notice of various scientific articles pulled from Internet websites; the motion was opposed by the Blackwells. We need not rule on this motion, however, because we are satisfied that the record before us is sufficient, without our having to take judicial notice of any other materials.

[15] Specifically, in oral argument, the Blackwells asserted that the following six propositions are generally accepted in the scientific community, supporting their experts' theory that thimerosal caused or exacerbated Jamarr's autism:

> 1. mercury is a potent neurotoxin;
> 2. ethyl, the inorganic material found in thimerosal, the preservative in vaccines, is also a potent neurotoxin;
> 3. thimerosal could cause mental retardation;
> 4. there is a genetic susceptibility to mercury toxicity;
> 5. mercury can cause behavioral abnormalities that define autism; and
> 6. it is biologically plausible that thimerosol containing vaccines can cause more developmental injury and autism.

appropriate fact-finding.

Wyeth argues that the trial judge properly precluded the testimony of the Blackwells' experts, because they were not qualified under Rule 5-702 and because their conclusions and analyses were not accepted in the relevant scientific community.

A. *Frye-Reed* Analysis

The essence of the instant case is the application of the *Frye-Reed* test to the analysis undertaken by an expert where the underlying data and methods for gathering this data are generally accepted in the scientific community but applied to support a novel theory. In reaching his ultimate conclusion that "the plaintiffs . . . failed in their burden of proving that the bases of the expert witnesses' testimony are generally accepted as reliable within the relevant scientific field," Judge Berger discussed the importance of the threshold determination with which he was vested. He noted that "[u]nder 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." He also observed that the *Frye-Reed* test "'was deliberately intended to interpose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles,'" quoting *Chesson*, 399 Md. at 328, 923 A.2d at 946, in turn quoting *Reed*, 283 Md. at 386, 391 A.2d at 370, that the test posed a minimum threshold for the admissibility of scientific evidence in Maryland, and that trial courts continued to retain discretion to exclude such testimony on other grounds—such as lack of helpfulness or expert qualification.

In discerning the factual predicates developed during the hearing, which have not been

challenged for clear error,[16] Judge Berger found that "[t]himerosal is an organic mercury-based compound," that has been used in "various vaccines and other biological and pharmaceutical products since the 1930's," and that it was undisputed that Jamarr had received a diphtheria tetanus and whole-cell pertussis vaccine ("DTP"), at 2 months, 4 months, 6 months and 18 months, pursuant to the Centers for Disease Control and Prevention's published recommended schedule, as well as a hemophilia influenza type b ("Hib") vaccine. According to Judge Beger, "[b]oth the DTP vaccine and the Hib vaccine contained 50 micrograms of thimerosal, which results in approximately 25 micrograms of mercury in each vaccination." Judge Berger also found that "[i]n July of 1999, the Public Health Service and the American Academy of Pediatrics issued a joint statement recommending the removal of thimerosal from vaccines" as a precautionary measure, and that "[b]y March of 2001, all vaccines on the recommended childhood immunization schedule were available without thimerosal."

Turning to the issue of Jamarr's developmental challenges, Judge Berger found that, "autism or autism spectrum disorder ("ASD") 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 or interests," and that "[u]nder the American Psychiatric Association's Diagnostic and Statistical Manual . . . the onset of autistic disorder is prior to three years of age." His

---

[16] At oral argument, counsel for the Blackwells pointed to findings of fact with which he took umbrage. We shall discuss these factual findings *infra*.

review of the scientific literature regarding autism's causes, and in particular, the findings of the National Academy of Sciences' Institute of Medicine's (hereinafter "IOM") 2001 and 2004 Committees,[17] led him to note that the 2001 IOM Committee, which was tasked with evaluating "the alleged connection between thimerosal-containing vaccines and a broad range of neurodevelopmental disorders including autism, ADHD, and speech or language delay," concluded:

> The hypothesis that thimerosal exposure through the recommended childhood immunization schedule has caused neurodevelopmental disorders is not supported by clinical or experimental evidence.
>
> * * *
>
> [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.

These conclusions were founded upon the following bases:

> (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

[17] Judge Berger noted that, "[t]he 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."

> 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.

The 2001 IOM Committee Report was succeeded in 2004 by another IOM Committee, which, Judge Berger found, again attempted to assess whether a causal link between the administration of thimerosal and autism had been proven in the scientific community. To assess 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 relationship," according to Judge Berger's review. In that context, he continued, the 2004 Committee reviewed a vast body of literature on the subject and considered extensive presentations and submissions made by scientists during an open scientific meeting, ultimately concluding, "that the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." This rejection, Judge Berger found, was in large part, based on "[e]pidemiological studies examining [thimerosal] 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)," all of which, "consistently provided evidence of no association between [thimerosal] 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)."

As Judge Berger found, the 2004 IOM Committee ultimately determined that the link between thimerosal and autism was largely speculative:

> In 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.
>
> * * *
>
> Given the lack of direct evidence for a biological mechanism and the fact that all well-designed epidemiological studies provide evidence of no association between thimerosal and autism, the committee recommends that cost-benefit assessments regarding the use of thimerosal-containing versus thimerosal-free vaccines and other biological or pharmaceutical products, whether in the United States or other countries, should not include autism as a potential risk.

Judge Berger also acknowledged that a "plethora of venerable publications reject[] the plaintiffs' theoretical link between thimerosal-containing vaccines and autism," including the Global Advisory Committee on Vaccine Safety, which advises the World Health Organization on health related issues, the Centers for Disease Control and Prevention, the American Academy of Pediatrics, and the National Institutes of Health, all of which have taken the position that thimerosal vaccines do not cause or contribute to autism. He stated that epidemiology, or "the science that studies the distribution of diseases within populations," was 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," and recognized that none of the Blackwells' experts was qualified as an expert in epidemiology.

Turning to the opinions rendered by the Blackwells' primary expert,[18] Dr. Mark Geier, Judge Berger looked first at Dr. Geier's analytical framework, whereby he purported to have completed an epidemiological analysis on scientifically accepted data compiled in various third-party databases: the Vaccine Adverse Effect Reporting System (VAERS), the Vaccine Safety Datalink, the Department of Education database, and the California Department of Social Services database. He then subjected Dr. Geier's conclusion, that thimerosal in vaccines causes autism in a small number of genetically susceptible individuals, to *Frye-Reed* scrutiny.

Judge Berger began by observing that the only published epidemiological studies purporting to show a causal link between thimerosal-containing vaccines and autism were the studies undertaken by Dr. Mark Geier and his son, Dr. David Geier, which suggested that the VAERS database could be extrapolated to show a causal connection between thimerosal and autism. He recognized the distinction between the use of data that is scientifically accepted and analysis purportedly based on that data, when the analysis employed is inappropriate to the data produced, which is dependent on the context in which it was produced and the hypothesis under scrutiny:

> It is significant to this Court that the IOM Committee criticized

---

[18] Judge Berger's *Frye-Reed* analysis focused primarily on Dr. Geier, because he was the only expert proffered by the Blackwells as an expert in the field of epidemiology.

the technique utilized in [one of the Geier studies] . . . expressly noting 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.

Admittedly, Dr. Geier acknowledged that [this study] is controversial. Indeed, the American Academy of Pediatrics ("AAP"), in a May, 2003 posting to their website, stongly denounced the Geier and Geier publication . . . stating:

> This paper uses data from the [VAERS] inappropriately and contains numerous conceptual and scientific flaws, omissions of fact, inaccuracies, and misstatements. . . . fail[ing] to acknowledge the inherent limitations of the VAERS database when drawing conclusions of adverse event associations . . . [and] [c]omparing 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.

Dr Geier presented several additional publications 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 exposive 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. Critically, with regard to the pre-2004 published Geier and Geier VAERS database studies, the [IOM] opined:

> (1) [t]he three studies have <u>serious methodological limitations</u> that make their results uninterpretable;
>
> (2) [t]he results of their studies are likewise

> improbable;
> (3) [t]he articles also lack a complete and transparent description of their methods and underlying data, making it difficult to confirm or evaluate their findings.
>
> 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.
>
> 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."
>
> 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."

Judge Berger concluded that, as a result of flawed analysis of acceptable data, Dr. Geier's epidemiological studies did not pass scrutiny under *Frye-Reed*:

> 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."

* * *

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.

* * *

For the purposes of the *Frye-Reed* test, the "relevant scientific community" includes the full community of scientists with sufficient training and expertise 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. Moreover, other organizations have issued statements that comport with the comprehensive analysis supplied in the 2004 IOM Committee Report.

* * *

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. IOM

> Reports are highly regarded in the relevant scientific community, and their reliability has been recognized by numerous courts. . . . 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.

(Emphasis added).

Although we have not in the past had occasion to scrutinize the analytical phase of a scientific process underlying a novel scientific opinion, where the underlying data may otherwise be generally accepted in the scientific community, various federal courts have had occasion to scrutinize the reliability of the analytical framework utilized by an expert in formulating a novel theory of science, and to them we turn, recognizing that they utilized the *Daubert* standard rather than *Frye*.[19] We explore what they have opined, nevertheless, when

---

[19] In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589, 113 S. Ct. 2786, 2794, 125 L. Ed. 2d 469, 480 (1993), the Supreme Court held that Federal Rules of Evidence superseded the common law and that *Frye* is an "austere standard, absent from, and incompatible with, the Federal Rules of Evidence" that "should not be applied in federal trials." Currently under Federal Rules of Evidence, Rule 702, expert opinion testimony is admissible if the subject matter is one where "scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, . . . the witness qualified as an expert by knowledge, skill, experience, training, or (continued...)

they are speaking about reliability.

The Supreme Court in *General Electric Company v. Joiner*, 522 U.S. 136, 118 S.Ct. 512, 139 L. Ed. 2d 508 (1997), recognized that the analysis employed by an expert must be reliable. In *Joiner*, an electrician, alleging that his small cell lung cancer was caused by exposure to polychlorinated biphenyls (PCBs) and to furans and dioxins (PCB derivatives), sued the manufacturers of the products and attempted to introduce expert testimony linking his exposure to the chemicals to his small cell lung cancer. The trial judge excluded the testimony, reasoning that the expert's conclusions did not rise above "subjective belief or unsupported speculation," *Joiner v. General Electric Co.*, 864 F. Supp. 1310, 1326 (N.D. Ga. 1994), and then granted summary judgment in favor of the manufacturer. The Court of Appeals for the Eleventh Circuit reversed, *Joiner v. General Electric Co.*, 78 F.3d 524, 533 (11th Cir. 1996), holding that the District Court should not have excluded expert testimony that merely "drew different conclusions from the research than did each of the experts," and that the court should have permitted the "jury to decide the correctness of competing expert opinions."

The Supreme Court reversed the Eleventh Circuit and excluded the expert's testimony. The Court recognized that the analysis of data or extrapolation requires more than

---

[19](...continued)
education . . . [and] (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702. *See generally Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 119 S. Ct. 1167; 143 L. Ed. 2d 238 (1999); *Daubert*, 509 U.S. at 579, 113 S. Ct. at 2786, 125 L. Ed. 2d at 469.

mere conjecture to pass reliability scrutiny:

> [Joiner] claims that because the District Court's disagreement was with the conclusion that the experts drew from the studies, the District Court committed legal error and was properly reversed by the Court of Appeals. But conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

Joiner, 522 U.S. at 146, 118 S. Ct. at 519, 139 L. Ed. 2d at 518-19, citing *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360-61 (6th Cir. 1992) (When "[t]he analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide. . . . a jury should not be asked to speculate on the issue of causation."). In calling attention to the "analytical gap" between existing data and the opinion proffered by an expert, the Court admonished against reliance solely on an expert's word that his conclusion is appropriate to the underlying data and methods. *Id.* This concept of "analytical gap" had been employed by federal courts before *Joiner*, *see Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 598 (9th Cir. 1996) ("When a scientist claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist, the [trial] court should be wary that the method has not been faithfully applied."), and even before *Daubert*. *See Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1115 (5th Cir. 1991) (en banc) ("When analyzing the validity of an expert's methodology, we seek to determine whether it connects the facts to the conclusion in a

scientifically valid way. We answer this question by applying the *Frye* test: whether the methodology or reasoning that the expert uses to connect the facts to his conclusion is generally accepted within the relevant scientific community.").

Since *Joiner*, the concept of the "analytical gap" also has been applied by numerous federal appellate courts. *See, e.g., Bland v. Verizon Wireless, L.L.C.*, 538 F.3d 893, 898 (8th Cir. 2008) (affirming a trial judge's exclusion of expert testimony from plaintiff's treating physician, who linked plaintiff's exercised-induced asthma to her inhalation and ingestion of freon that was allegedly sprayed into her water bottle by a Verizon employee, and holding that there was "simply too great an analytical gap" between "the data identified and [the expert's] proffered opinion" because the expert "lacked knowledge regarding what level of exposure to freon constitutes an appreciable risk of causing asthma and the specific concentration and degree of [plaintiff's] exposure to the freon"); *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254-255 (2d Cir. 2005) (excluding expert testimony that medication was capable of causing or exacerbating cirrhosis because the expert's failure to consider other causes when employing differential diagnosis created "too great an analytical gap between the data and the opinion proffered"); *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir. 2003) (discussing the "analytical gap" when holding, "[t]he problem with the proposed testimony in this case does not lie in the quality of [the experts'] research. . . . [but in] the absence of an empirical link between that research and the opinion that [defendant] likely gave a false confession").

The "analytical gap" concept also has been employed by some of our sister states in

a *Frye* analysis. In *Goeb v. Tharaldson*, 615 N.W.2d 800, 816 (Minn. 2000), for example, the Minnesota Supreme Court upheld the exclusion of expert testimony because the methodology was unreliable and the conclusions proffered exhibited "too great a leap" from the data gathered. The Goebs had sued a pesticide applicator, Tharaldson, and Dow Chemical, the manufacturer, alleging that exposure to the insecticide Dursaban, after it was sprayed in the house into which they were moving, caused injury to them and their child. The Goebs offered the testimony of two experts, both of whom would have testified, based on the Goebs' medical records referring to adverse health affects, as well as on the toxic levels of the chemical chlorpyifos in their bodies,[20] that the Goebs were suffering from organophosphate[21] poisoning caused by their exposure to Dursaban. *Id.* at 806-08. Dow had argued that the experts' conclusion should be excluded under *Frye* because the Goebs' level of exposure was not factored into their analysis. After the expert testimony was excluded, the Goebs sought review, arguing that the experts' testimony had been based upon generally accepted methodologies. The court affirmed, accepting the contention that the experts had used generally accepted methods in completing their tests, but rejecting the experts' analysis when affirming the trial judge's conclusion "that [the expert] made too great a leap to get from 'mere exposure of an unquantified amount of Dursban' to his conclusions about

---

[20] Chlorpyifos is a chemical that is commonly used in pesticides.

[21] Organophosphates are "[a] series of phosphorus-containing organic compounds . . . . [that are] [u]sed as insecticides [and] have also been used as gases in warfare." Stedman's, *supra*, at 1380.

appellants' illnesses." *Id.* at 816. *See also Kane v. Motorola, Inc.*, 335 Ill. App. 3d 214, 221-22 (2002) (discussing *Joiner* and the "analytical gap" concept when applying a *Frye* analysis).

Generally accepted methodology, therefore, must be coupled with generally accepted analysis in order to avoid the pitfalls of an "analytical gap." Dr. Geier's faulty extrapolation from VAERS data, a potentially reliable source, manifests the *ipsa dixit* identified in the *Joiner* opinion because his conclusion is ethereal. The conclusion is ethereal because the bases of the expert's opinion, including the theory of causation, and the methodologies, are not "generally accepted as reliable within the expert's particular scientific field," *see Chesson*, 399 Md. at 327, 923 A.2d at 947, and the data he relies upon was not tested nor gathered for the purpose of testing the hypothesis that thimerosal in vaccines causes autism. None of Dr. Geier's research aimed at establishing a link between thimerosal and autism, moreover, is based upon sound methodology. *See, e.g.*, Mark R. Geier & David A. Geier, *Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief Communication*, 228 Experimental Biology and Med. 660, 660-64 (2003) (relying on VAERS data); Mark R. Geier & David A. Geier, *Thimerosal in Childhood Vaccines, Neurodevelopment Disorders, and Heart Disease in the United States*, 8 J. Am. Physicians and Surgeons, Spring 2003, at 6-11 (relying on VAERS data); David A. Geier & Mark R. Geier, *An Assessment of the Impact of Thimerosal on Childhood Neurodevelopmental Disorders*, 6 Pediatric Rehabilitation, Apr.-June 2003, at 97-102 (relying on VAERS data); David A. Geier & Mark R. Geier, *A Comparative Evaluation of the Effects of MMR*

Immunization and Mercury Doses from Thimerosal-Containing Childhood Vaccines on the Population Prevalence of Autism, 10 Med. Sci. Monitor, Mar. 2004, at Pl33-39 (relying on Department of Education data); David A. Geier & Mark R. Geier, *Neurodevelopmental Disorders Following Thimerosal-Containing Childhood Immunizations: A Follow-Up Analysis*, 23 Int'l J. of Toxicology 369, 369-376 (2004) (relying on VAERS data); Mark R. Geier & David A. Geier, *The Potential Importance of Steroids in the Treatment of Autism Spectrum Disorders and Other Disorders Involving Mercury Toxicity*, 64 Med. Hypotheses 946, 946-954 (2005) (merely suggesting a series of experiments that need to be conducted to potentially develop steroid treatments to reduce the affects of mercury poisoning); David A. Geier & Mark R. Geier, *A Two Phased Population Epidemiological Study of the Safety of Thimerosal-Containing Vaccines: A Follow-Up Analysis*, 11 Med. Sci. Monitor, Apr. 2005, at CR160-70 (relying on VAERS data); David A. Geier & Mark R. Geier, *An Assessment of Downward Trends in Neurodevelopmental Disorders in the United States Following Removal of Thimerosal from Childhood Vaccines*, 12 Med. Sci. Monitor, June 2006, at CR231-39 (relying on VAERS data); David A. Geier & Mark R. Geier, *An Evaluation of the Effects of Thimerosal on Neurodevelopmental Disorders Reported Following DTP and Hib Vaccines in Comparison to DTPH Vaccine in the United States*, 69 J. Toxicology and Envtl. Health 1481, 1481-95 (2006) (relying on VAERS data); David A. Geier & Mark R. Geier, *A Meta Analysis Epidemiological Assessment of Neurodevelopmental Disorders Following Vaccines Administered from 1994 through 2000 in the United States*, 27 Neuroendocrinology Letters, May 2006, at 401-13 (relying on

VAERS data); David A. Geier & Mark R. Geier, *A Clinical and Laboratory Evaluation of Methionine Cycle-Transsulfuration and Androgen Pathway Markers in Children with Autistic Disorders*, 66 Hormone Research 182, 182-188 (2006) (studying 16 pre-pubertal children, 11 and under, with previously diagnosed autism and suggesting a possible interaction between a particular alpha-amino acid cycle, the methionine cycle-transsulfuration, and androgen pathways in some children with autism); David A. Geier & Mark R. Geier, *A Prospective Assessment of Porphyrins in Autistic Disorders: A Potential Marker for Heavy Metal Exposure*, 10 Neurotoxicity Research, Aug. 2006, at 57, 62 (studying urine samples of 37 children age-7 and under and concluding, "[t]his study provides the first clinical evidence from Americans with [autism] that associates them with specific urinary porphyrin markers known to be associated with heavy metals. . . . The results . . . provide insights into the apparent dose-response effect mercury exposure may have in some children with [autism], *and suggest that additional research should be conducted to evaluate mercury exposure in [autism]*") (emphasis added); David A. Geier & Mark R. Geier, *A Clinical Trial of Combined Anti-Androgen and Anti-Heavy Metal Therapy in Autistic Disorders*, 27 Neuroendocrinology Letters, Oct. 2006, at 833-38 (administering the drugs LUPRON and CHEMET to 11 children to lower their androgen levels or heavy-metal levels respectively, and observing amelioration of autistic symptoms in some of those children obtaining reduced androgen levels).

In attempting to avoid the pitfalls of postulating a direct causal link between thimerosal and autism, which would require accountability for those children who had been

vaccinated without becoming autistic, Dr. Geier postulated an alternative hypothesis—that thimerosal in vaccines cause autism in certain genetically susceptible individuals. According to Judge Berger's findings, this hypothesis was apparently inspired by statements made in the 2001 and 2004 IOM Report—that a link is "biologically plausible," and that it is well settled that even a large well-designed epidemiological study might fail to detect "the possibility that vaccines contribute to autism in some small subset of cases or very unusual circumstances." Two predicates of Dr. Geier's alternative theory are that (1) autism is associated with certain genes—the A1298C polymorphism in the MTHFR gene, the null polymorphism of the GSTMI gene, the I105Vpolymorphism of the GSTPI gene, the I114T, R197Q, and K268R polymorphisms in the NATZ gene, and an unspecified variant in the CYP3A4 gene; and (2) based on a differential diagnoses analysis,[22] Jamarr's neurological disorders were caused or exacerbated by his exposure to thimerosal because of his genetic susceptibility. We shall first address Judge Berger's factual findings with respect to these predicates, as well as the Blackwells' challenges thereto, under the clear error standard,[23] and

---

[22] Differential diagnosis, which essentially is a process of elimination, has been defined as, "[t]he process of weighing the probability of one disease versus that of other diseases possibly accounting for a patient's illness. The differential diagnosis of rhinitis (a runny nose) includes allergic rhinitis (hayfever), the abuse of nasal decongestants and, of course, the common cold." MedicineNet.com, Differential Diagnosis Definition, http://www.medterms.com /script/main/art.asp?articlekey=2991 (last visited May 5, 2009).

[23] We review a challenge to the factual findings of trial judge for "clear error," considering "the evidence in the light most favorable to the prevailing party and decide not whether the trial judge's conclusions of fact were correct, but only whether they were supported by a preponderance of the evidence." *City of Bowie v. MIE, Props., Inc.*, 398 Md.

(continued...)

then shall evaluate de novo Judge Berger's ultimate conclusion—that neither the genetic susceptibility theory nor the tests used to determine if Jamarr's autism was due to genetic susceptibility were generally accepted in the relevant scientific field. *See Wilson*, 370 Md. at 201-02 n.5, 803 A.2d at 1040 n.5.

In rejecting the association of autism with certain gene polymorphisms identified by Dr. Geier, Judge Berger found that, although "[t]he 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," it, nevertheless, "'found no corroborating data in the laboratory, in animals, or in humans, linking vaccines or vaccine components for autism based on genetic susceptibility." He also found that "there is no evidence that the presence of these polymorphisms impairs the body's ability to excrete mercury."

During oral argument before us, the Blackwells' attorney specifically challenged Judge Berger's generalized factual finding, "that there is no evidence that any of the polymophisms identified by Dr. Geier are associated with autism," arguing that the Blackwells submitted three studies that provided such evidence: Steven Buyske, et al., *Analysis of Case-Parent Trios at a Locus with a Deletion Allele: Association of GSTM1 with Autism*, 7 BMC Genetics, Feb. 2006, at 1-16; G.A. Westphal, et al., *Homozygous Gene Deletions of the Glutathione* S-*Transferases M1 and T1 Are Associated with Thimerosal*

---

[23](...continued)
657, 676, 922 A.2d 509, 521 (2007).

Sensitization, 73 Inter. Archives of Occupational Health, 384, 384-88 (2000); and S. Jill James, et al., *Metabolic Endophenotype and Related Genotypes Are Associated with Oxidative Stress in Children With Autism*, 26 Am. J. of Med. Genetics 947, May 2006, at 947-56. Judge Berger made the contested statement in the following paragraph where he discussed his general findings with respect to Dr. Geier's identified polymorphisms:

> Autism is likely to involve multiple genes. 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.

Judge Berger subsequently supported these general findings with specific findings: first, he found that "there is no evidence that the A1298C polymorphism in the MTHFR gene is associated with autism," based on "[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." *See* Marvin Boris et al., *Association of MTHFR Gene Variants with Autism*, 9 J. of Am. Physicians and Surgeons, Winter 2004, at 106, 107; James, *supra* at 951. Judge Berger next found that "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 among ethnic groups," observing that the MTHFR 1298A/C polymorphism exhibited this variance according to a Single Nucleotide Polymorphism Cluster Report database.[24] Judge Berger then addressed Dr. Geier's identification of the null polymorphism, finding:

> 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. 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.

He based this determination primarily on studies by James, *supra*, at 947-56, and Buyske, *supra*, at 1-16.

The existence of articles from Buyske, Westphal and James, proffered by the Blackwells, do not contradict, with any significance, Judge Berger's specific factual findings: Buyske's article, *Analysis of Case-Parent Trios at a Locus with a Deletion Allele: Association of GSTM1 with Autism*, defines what he considers to be the appropriate methodology to test for a possible association of a specific genotype with autism. Buyske, *supra*, at 1. Westphal's article, *Homozygous Gene Deletions of the Glutathione* S-*Transferases M1 and T1 are Associated with Thimerosal Sensitization*, discusses a study that

---

[24] The NCBI, or Single Nucleotide Polymorphism database, is provided by the National Institutes of Health and is available at http://www.ncbi.nlm.nih.gov. The specific Cluster Report relied upon by Judge Berger is available at http://www.ncbi.nlm.nih.gov/SNP/snp_ref.cgi?rs=1695.

he conducted, in which he tested allergic reactions to thimerosal in men and women over the age of 38, none of whom was identified as autistic; autism was not being studied. Westphal, *supra*, at 385. The James article, *Metabolic Endophenotype and Related Genotypes are Associated with Oxidative Stress in Children With Autism*, recognized its own limitation, "[g]iven the relatively small number of cases and controls in the present study," and suggested that "abnormal metabolic profile observed in a significant proportion of autistic children suggests the provocative possibility that some autistic behaviors could be a neurologic manifestation of a genetically based *systemic* metabolic derangement." James, *supra*, at 954 (italics in original). Clearly, this article suggests a hypothesis for further testing—a hypothesis which does not bear on any purported relationship between thimerosal and autism. Judge Berger supported his general finding that there was, "no evidence that any of the polymorphisms identified by Dr. Geier are associated with autism," with articles specifically addressing polymorphisms identified by Geier; he did not err in his finding.

In rejecting the methodology utilized by Dr. Geier of differential diagnosis to arrive at a genetic susceptibility thesis, Judge Berger recognized that "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." According to Judge Berger, Dr. Geier had performed urinary porphyrin,[25] mercury toxicity, testosterone and

---

[25] A porphyrin urine analysis depends on testing urine for the existence of porphyrins, the excessive excretion of which may indicate the condition of porphyria. *See* Stedman's, *supra*, at 1542. Porphyrins are "[p]igments widely distributed throughout nature (continued...)

genetic polymorphism[26] tests, but that none of them is "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." Noting as well that Dr. Geier's differential diagnosis methodology "fail[ed] to even consider the single most important alleged cause of autism"—unknown genetics—Judge Berger concluded that "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

---

[25](...continued)
(e.g. heme, bile pigments, cytochromes) . . . ." *Id.* at 1543. Porphyria is,

> A diverse group of diseases in which the production of heme is disrupted. Porphyria is derived from the Greek word "porphyra", which means purple. When heme production is faulty, porphyrins are overproduced and lend a reddish-purple color to urine. All forms of porphyrias are inherited. The key clinical features are skin sensitivity to sunlight and/or by intermittent acute attacks of abdominal and nerve pain. . . . Affected individuals are unable to complete heme synthesis, and intermediate products, porphyrin or its precursors, accumulate. . . .

MedicineNet.com, Porphyria Definition, http://www.medterms.com/script/main/art.asp ?articlekey=10360 (last visited May 5, 2009).

[26] A polymorphism is "[a] variation in the DNA that is too common to be due merely to new mutation. A polymorphism must have a frequency of at least 1% in the population. Examples of polymorphisms include the genes for sickle cell disease, thalassemia and G6PD deficiency." MedicineNet.com, Polymorphism Definition, http://www.medterms.com /script/main/art.asp?articlekey=4992 (last visited May 5, 2009). *See also* Stedman's, *supra*, at 1536.

thimerosal-containing vaccines and autism":

> 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 [by] 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.

(Emphasis added).

The Blackwells contest Judge Berger's finding of fact that "Dr. Geier failed even to consider the single most important alleged cause of autism—[unknown genetics]"—when conducting differential diagnosis, arguing that Dr. Geier addressed genetics as a possible cause and that it is not generally accepted in the relevant scientific community that unknown genetics is "the single most important alleged cause" of this disorder. The Blackwells assert that Dr. Geier considered genetics and genetic interactions, but that, according to Dr. Geier,

unknown genetics account for less than 5% of autism cases, and he need not discount all possible causes. Conversely, Wyeth's expert, Dr. Yeboa, opined that unknown genetics "constitutes the most cases of autism," a premise supported by the 2004 IOM Report ("Autism is a very complex disorder. A strong genetic component clearly exists. . . . As yet a biological marker specific for autism has not been defined. It is possible that Autism encompasses a spectrum of disease subtypes that have different etiologies."), as well as other articles proffered to Judge Berger by both the Blackwells and Wyeth. *See, e.g.*, Boris, *supra*, at 106-07 ("Autism is a complex neurodevelopment disorder with numerous possible genetic and environmental influences. . . . A search for additional genomic and environmental risk factors should be undertaken. . . . It is unlikely that any single polymorphism accounts for the majority of autistic risk factors."); Fatema J. Serajee et al., *Polymorphisms in Xenobiotic Metabolism Genes and Autism*, 19 J. of Child Neurology, June 2004, at 413, 413 (2004) ("Although there is an underlying genetic predisposition, the etiology of autism is currently unknown."); A. Bailey, et al., *Autism as a Strongly Genetic Disorder: Evidence from a British Twin Study*, 25 Psychological Med. 63, 63 (1995); Lorna Wing & David Potter, *The Epidimiology of Autistic Spectrum Disorders: Is the Prevalence Rising?*, 8 Mental Retardation and Developmental Disabilities Res. Rev. 151, 152 (2002) ("As a result of the ever growing list of studies, autism is now seen as a disorder of the developing brain, mainly genetic in origin and part of a wider spectrum of disorders."). Judge Berger did not err in finding that "a gene or series of interacting genes that have not yet been identified" is the "most prevalent alleged cause of autism," based upon our review of the record. We agree

that Dr. Geier did not sufficiently consider genetics in his differential diagnosis equation. This conclusion is similar to that reached in *Wilson*, in which we recognized that the State's expert, in applying the product rule, did not account for a genetic linkage between siblings, who may have died of SIDS, rather than been murdered by their father.

Based on Judge Berger's rejection of Dr. Geier's underlying hypothesis and methodology, i.e. the identification of specific genes and differential diagnosis, we hold that Judge Berger's ultimate determination—that Dr. Geier's genetic susceptibility theory is no more than hypothesis and conjecture, devoid of a generally accepted methodology to support it—should not be disturbed by us.

B. Certification of Experts under Maryland Rule 5-702

We also address whether Judge Berger properly precluded the testimony of the Blackwells' experts based on their lack of proper qualifications under Maryland Rule 5-702, which governs the admissibility of expert testimony:

> 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 a 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.

In the context of Rule 5-702, we have previously stated that, "the admissibility of expert testimony is within the sound discretion of the trial judge and will not be disturbed on appeal unless clearly erroneous." *Wilson*, 370 Md. at 200, 803 A.2d at 1039; *Deese v. State*, 367

Md. 293, 302-03,786 A.2d 751, 756 (2001). Put another way, "it is well settled . . . that the trial court's determination [regarding the qualification of experts] . . . may be reversed if it is founded on an error of law or some serious mistake, or if the trial court clearly abused its discretion" and "will seldom constitute a ground for reversal." *Radman v. Harold*, 279 Md. 167, 173, 367 A.2d 472, 476 (1977).

In *Radman*, we articulated the standard for evaluating the qualifications of an expert witness:

> [A] witness may be competent to express an expert opinion if he is reasonably familiar with the subject under investigation, regardless of whether this special knowledge is based upon professional training, observation, actual experience, or any combination of these factors. The classic formulation of this Court's views on the subject of the qualification of experts appears in *Casualty Ins. Co. v. Messenger*, wherein it is stated:
>
> > It is a familiar rule of evidence that a witness, in order to qualify as an expert, should have such special knowledge of the subject on which he is to testify that he can give the jury assistance in solving a problem for which their equipment of average knowledge is inadequate. It is sufficient if the court is satisfied that the expert has in some way gained such experience in the matter as would entitle his evidence to credit. It is not a ground for excluding the testimony of an expert that he bases his statements in whole or in part upon what he has read, provided that his reading can be assumed to constitute part of his general knowledge adequate to enable him to form a reasonable opinion of his own. A witness is qualified to testify as an expert when he exhibits such a degree of knowledge as to make it appear that his opinion is of some value, whether such knowledge has been gained from observation or experience, standard books, maps of recognized

> authority, or any other reliable sources. The knowledge of an expert in any science or art would be extremely limited if it extended no further than inferences from happenings within his own experience. His testimony is admitted because it is based on his special knowledge derived not only from his own experience, but also from the experiments and reasoning of others, communicated by personal association or through books or other sources.

Id. at 169-70, 367 A.2d at 474 (emphasis added) (internal citations omitted). Because *Radman* was a medical malpractice case, we also opined regarding specialized qualifications of medical experts:

> In light of the fact that we have never treated expert medical testimony any differently than other types of expert testimony, *see Crews v. Director*, 245 Md. 174, 179, 225 A. 2d 436, 439 (1967); *Ager v. Baltimore Transit Co.*, 213 Md. 414, 420, 132 A. 2d 469, 472 (1957); *cf. Shilkret v. Annapolis Emergency Hosp.*, 276 Md. 187, 190, 349 A. 2d 245, 247 (1975), we perceive no reason why a person who has acquired sufficient knowledge in an area should be disqualified as a medical expert *merely* because he is not a specialist or *merely* because he has never personally performed a particular procedure. Consequently, we are in substantial agreement with the reasoning of the Supreme Court of Connecticut as expressed in the following succinct statement from the recent case of *Fitzmaurice v. Flynn*, 167 Conn. 609, 356 A. 2d 887, 892 (1975):
>
> > Recognizing the complexity of knowledge required in the various medical specialties, more than a casual familiarity with the specialty of the defendant physician is required. The witness must demonstrate a knowledge acquired from experience or study of the standards of the specialty of the defendant physician sufficient to enable him to give an expert opinion as to the conformity of the defendant's conduct to those

> particular standards, and not to the standards of the witness' particular specialty if it differs from that of the defendant. It is the scope of the witness' knowledge and not the artificial classification by title that should govern the threshold question of admissibility.

Id. at 171-72, 367 A.2d at 475 (emphasis added) (footnote omitted). *See also Ungar v. Handelsman*, 325 Md 135, 146, 599 A.2d 1159, 1164 (1992) (citing *Radman*); *Consol. Mech. Contractors, Inc. v. Ball*, 263 Md. 328, 338-39, 283 A.2d 154, 159 (1971) (permitting expert to testify as to why that it was difficult for him to find a job for plaintiff because of plaintiffs' injuries); *Wolfinger v. Frey*, 223 Md. 184, 189-90, 162 A.2d 745, 748 (1960) (permitting general practitioner to testify as to cause of plaintiff's injury).

Before us, the Blackwells urge that Judge Berger abused his discretion by disqualifying their witnesses from testifying. Wyeth, having addressed the experts' credentials during *voir dire*, reasserts that the Blackwells' experts lack the necessary knowledge, expertise, training or education to offer an opinion about a causal relationship between thimerosal and autism. Although we agree with the Blackwells that generally there is "no reason why a person who has acquired sufficient knowledge in an area should be disqualified as a medical expert merely because he is not a specialist or merely because he has never personally performed a particular procedure," we cannot say, in this case, that Judge Berger abused his discretion by adhering to "artificial classifications" of a specialty's title, without concern for "the witness' knowledge" and ability to convey valuable information to jurors. *See Radman* 279 Md. at 172, 367 A.2d at 475.

Deese v. State, 367 Md. at 302, 786 A.2d at 756, upon which the Blackwells rely, was a child abuse/felony murder case, in which a father was convicted of murdering his child, as a result of "shaken baby syndrome." There, we considered whether a doctor, who had been the director of pediatric emergency at Johns Hopkins Hospital with expertise in the areas of pediatrics and pediatric emergency medicine, could testify as to the cause of the child's death, despite admitting that he was neither a specialist nor board certified in the areas of pathology or forensic pathology.[27] *Id.* at 301-04, 786 A.2d at 755-56. Quoting *Sippio v. State*, 350 Md. 633, 649, 714 A.2d 864, 872 (1998), we iterated that "[i]n order to determine whether a proposed witness is qualified to testify as an expert, the trial court must examine whether the witness has sufficient knowledge, skill, experience, training, or education pertinent to the subject of the testimony." We ultimately concluded that the trial judge did not abuse his discretion in admitting the testimony because, although forensic pathology might have been the most relevant field of expertise, "[the State's expert's] training in pediatrics and pediatric emergency medicine, combined with his experience in dealing with victims of child abuse," sufficiently qualified him to testify as to the cause of the child's death. *Deese*, 367 Md. at 304, 786 A.2d at 757.

In *Massie v. State*, 349 Md. 834, 709 A.2d 1316 (1998), another case relied upon by

---

[27] "Pathology" is, "[t]he form of medical science and specialty practice concerned with all aspects of disease, but with special reference to the essential nature, causes, and development of abnormal conditions, as well as the structural and functional changes that result from the disease processes. Stedman's, *supra*, at 1442. The modifier *forensic*, moreover, as in forensic pathology, denotes "[use] in or suitable to courts of law or public debate." Black's Law Dictionary, at 676 (8th ed. 2004).

the Blackwells, we addressed an expert's qualification in the area of forensics. Massie had been convicted of murder and argued that the trial judge abused his discretion in permitting a forensics police investigator, who was not a doctor of medicine, to testify that the victim had been dead for as long as five hours, or "from 11:15 a.m. at the earliest." *Id.* at 838, 709 A.2d at 1317. The trial judge admitted the testimony, finding that although the investigator was not a pathologist, he had substantial experience in the area of forensic science, taught courses in the area, and was present at the scene to collect evidence and examine the victim's body. We affirmed, noting that "[t]ime of death is a subject which courts have long recognized as an appropriate one for expert testimony," and that "[i]n the instant matter [the expert's] examination of the deceased's body gave him a sufficient factual basis to support opinion testimony," so that the expert, "by virtue of his experience, training, and education, had special knowledge on the subject beyond the experience of the jurors and that [the] opinion would assist the jury." *Id.* at 851, 709 A.2d at 1324.

Further, in *In re: Yve S.*, 373 Md. 551, 819 A.2d 1030 (2003), we addressed when a witness is not qualified. In that case, a mother had challenged a determination by the Montgomery County Department of Health and Human Services—changing her 12-year-old daughter's permanency plan from reunification with the mother to permanent foster care—presenting a judge of the Circuit Court for Montgomery County with the question of whether "the mother's mental illness had stabilized to the point where she could take care of her daughter properly . . . [and whether] neglect [would] be repeated." *Id.* at 613-14, 819 A.2d at 1067. During the review hearing, the judge permitted, over the mother's objection, the

testimony of a social worker, who opined that the mother appeared to relapse into another manic episode during trial and that although the mother had done "an amazing job in the last two years" of stabilizing herself, the pressure of caring for Yve S., who had special needs, would cause her to relapse, such that a placement with the mother would not last. *Id.* at 615, 819 A.2d at 1068. The trial judge, thereafter, entered an order establishing permanent foster care as the goal of the permanency plan, and the Court of Special Appeals affirmed; we granted certiorari, in part, to address whether the admission of the social worker's opinion was prejudicial error. In reversing and remanding, we held that the circuit court judge erred by admitting the social worker's testimony, because she was not qualified to make a "complex" medical diagnosis of mental illness nor to speculate as to the mother's future ability to control her illness:

> These statements [by the social worker] are not only speculative, but amount to a lay diagnosis or prognosis regarding a complex medical issue. [The social worker] is not qualified to do that, as she was not qualified as a psychiatrist, psychologist, or licensed clinical social worker. The testimony was improper and should have been stricken.

Id. at 615-16, 819 A.2d at 1068. Hence, when"complex medical issue[s]" or diagnoses are in question, we have required a specificity of knowledge, skill, experience, training, or education for qualification.

With this in mind, we turn to Judge Berger's findings and determinations regarding the Blackwells' experts. Judge Berger initially found that the field of epidemiology was 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," and also found that, "[a]fter reviewing the testimony and evidence, this Court finds that the fields of epidemiology, toxicology and genetics are central to many of the issues in this cause, including the causation issues that have been presented in this proceeding,"[28] on the following basis:

> 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. The 2004 IOM Report specifically notes that "[e]pidemiologic studies carry the most weight in a causality assessment." 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.

When specifically addressing the credentials of the Blackwells' five experts, Judge Berger also made the following findings regarding the experts' lack of qualification to conduct epidemiological, toxicological and genetic empirical research:

Dr. Mark Geier

---

[28] The Blackwells do not contest the finding that epidemiology is the relevant field, but rather dispute that their experts are not qualified under Rule 5-702 to offer an opinion based upon epidemiological principles.

With respect to Dr. Geier, Judge Berger found that, in addition to being a board-certified genetic counselor, he had been proffered as an expert in genetics, "vaccine injuries," "differential etiology of autism," "mercury toxicity," medicine, "urinary porphyrin analysis" and epidemiology; that he "is not an epidemiologist or toxicologist," with no degree or board certification in either field, and that nothing regarding "his knowledge, skill, training, experience, or education" made him qualified to testify under Maryland Rule 5-702: "Dr. Geier's credentials as a medical doctor and a genetic counselor are not a foundation sufficient for him to offer an opinion that thimerosal-containing vaccines cause autism." Judge Berger also noted that, in at least one federal case, Dr. Geier had been deemed unqualified to testify as an expert regarding the impact of the administration of thimerosal. *See, e.g.*, *Redfoot v. B.F. Ascher & Co.*, 2007 U.S. Dist. LEXIS 40002, *36-37 (N.D. Cal. 2007) (excluding the testimony of Dr. Geier under Federal Rule 702 in a case where he was proffered to testify that the Ayr Saline Nasal Mist was defective in design because it contained thimerosal, which may have caused the plaintiffs' child's autism).

Dr. Boyd Haley

Judge Berger found that Dr. Haley is a Professor of Chemistry at the University of Kentucky at Lexington, that he was offered by the Blackwells as an expert in the fields of mercury toxicity, biochemistry and physiology, and that he was qualified in the areas of biochemistry and physiology by virtue of his knowledge, skill, experience, training and education. Judge Berger acknowledged, based in part on Dr. Haley's approximately 130 articles on neuro-degeneration caused by mercury, that Dr. Haley was well-qualified to

testify as to the general toxicity of mercury in human brain cells, but that he was not qualified to testify whether the administration of a vaccine containing thimerosal results in the exposure of a child's brain to mercury, whether autistic children metabolize and excrete mercury the way other children are able to, or whether thimerosal in childhood vaccines causes neurological damage in genetically susceptible children.

Dr. Richard Deth

Judge Berger found that "Dr. Deth teaches pharmacology at Northeastern University," that "he was offered by the [Blackwells] as an expert in the areas of physiology, neuropharmacology and the effects of thimerosal in the human brain," and that Dr. Deth was "clearly qualified to testify as an expert witness in the areas of physiology and neuropharmacology." Judge Berger, however, excluded Dr. Deth's testimony, because although he was qualified in these fields, his opinion "that exposure to mercury for thimerosal-containing vaccines causes autism," would have required him to delve into fields of toxicology, epidemiology, neurology and genetics—all fields with which he had little or no expertise.

Dr. Elizabeth Mumper

With respect to Dr. Mumper, Judge Berger found that she is a general pediatrician in private practice in Virginia, that the Blackwells proffered her "as an expert in the fields 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." Although Dr. Mumper was qualified to testify regarding the diagnosis and treatment of children with neurodevelopmental disorders, Judge Berger determined that her experience was not relevant to the ability to assess the underlying cause of these conditions. Specifically, Judge Berger iterated, as he did when discussing Dr. Deth, that qualification to testify to causation would involve some expertise, knowledge or skill in the areas of epidemiology, toxicology or genetics.

Dr. Stephen Siebert

Judge Berger found that Dr. Seibert, who has a master's degree in public health and is board certified in the field of psychiatry, was qualified to testify in the fields of psychiatry and forensic psychiatry. As with the other experts of the Blackwells, however, Judge Berger found that Dr. Seibert's board certifications bore no relevance to the "appropriate basis for opinion testimony on the issue of whether thimerosal-containing vaccines can cause autism." Further, Judge Berger noted that, although Dr. Siebert was well-qualified to testify to his diagnosis of Jamarr Blackwell as mentally retarded and autistic, he did not possess the expertise to testify regarding the causes of Jamarr's autism by nature of his knowledge and experience.

In this case, Judge Berger did not receive Dr. Geier, as well as the other of the Blackwells' experts, as qualified to testify regarding causation because they were not qualified in the field of epidemiology, which he determined to be central to the Blackwells' claims. Although we recognize that Judge Berger excluded Dr. Geier's testimony under the third prong of Maryland Rule 5-702, which requires "a sufficient factual basis [to] exist[] to

support the expert testimony," and the *Frye-Reed* analysis, we, nevertheless, address Dr. Geier's credentials along with the four other experts, because *voir dire* of an expert is normally the threshold issue.

We have not had occasion to review the exclusion of witnesses based on *voir dire* of their credentials in a case where a complex and novel theory of science has been postulated. In *Massie* and *Deese*, we addressed expert specialization in the context of an expert's ability to execute a previously acceptable technique for determining the time or manner of death. In *Radman*, we held that an expert need not be specialized in a precise field where negligence had been alleged in order to opine about deviation from the standard of care. In each instance, we rebuffed challenges based on specialization in a relevant field, when we were presented with the expert's ability to perform an accepted technique.

When a novel theory of science is presented, however, its reliability and validity are dependent not only on the application of generally acceptable methodology and analyses, but also upon the knowledge, skill, experience, training or education of the scientist who purports to utilize them, because the expert must embody expertise in the *relevant* scientific field to be able to give an opinion regarding the results of the process of scientific discovery. One of our sister states, when confronted with this conundrum under a similar rule governing experts,[29] identified three factors as relevant in defining the minimal level of qualification

---

[29] In *Rodgers v. State*, 205 S.W.3d 525, 527 (Tex. Crim. App. 2006), the Texas Court of Criminal Appeals addressed the qualification of experts under Texas Rule 702, which is similar to Maryland Rule 5-702, and stated:

(continued...)

necessary:

> Appellate courts may consider several criteria in assessing whether a trial court has clearly abused its discretion in ruling on an expert's qualifications. First, is the field of expertise complex? The degree of education, training, or experience that a witness should have before he can qualify as an expert is directly related to the complexity of the field about which he proposes to testify. If the expert evidence is close to the jury's common understanding, the witness's qualifications are less important than when the evidence is well outside the jury's own experience. For example, DNA profiling is scientifically complex; latent-print comparison (whether of fingerprints, tires, or shoes) is not.
>
> Second, how conclusive is the expert's opinion? The more conclusive the expert's opinion, the more important is his degree of expertise. Testimony that "a given profile occurred one time in 2.578 sextillion (2.578 followed by 21 zeroes), a number larger than the number of known stars in the universe (estimated at one sextillion)" requires a much higher degree of scientific expertise than testimony "that the defendant's tennis shoe could have made the bloody shoe print found on a piece of paper in the victim's apartment."
>
> And third, how central is the area of expertise to the resolution of the lawsuit? The more dispositive it is of the disputed issues, the more important the expert's qualifications are. If DNA is the only thing tying the defendant to the crime, the reliability of the expertise and the witness's qualifications to give his opinion are more crucial than if eyewitnesses and a confession also connect the defendant to the crime.

Rodgers v. State, 205 S.W.3d 525, 528 (Tex. Crim. App. 2006) (footnotes omitted). *See*

---

[29](...continued)

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.

Radman v. Harold, 279 Md. 167, 171 n.2, 367 A.2d 472, 475 n.2 (1977), quoting *Baltimore Refrigerating & Heating Co. of Baltimore v. Kreiner*, 109 Md. 361, 370, 71 A. 1066, 1070 (1909) ("[E]xpert capacity is a matter wholly relative to the subject of the particular inquiry."); *See also* Faigman, *supra*, at 41, ("[J]ust as with [federal] Rule 702 validity assessments, the judge's gatekeeping obligation should extend not merely to qualifications in the abstract, but qualifications to testify about the subject that is relevant to the issues in dispute.").

Although we do not apply the second prong, regarding the conclusiveness of the expert's opinion, because it would necessitate going to the merits of the expert's opinion prior to a review of credentials, we do believe that two of the factors are relevant in our analysis—those being whether the field of expertise is complex and whether the area of expertise is central to the resolution of the lawsuit. In the present case, clearly the level of complexity regarding the establishment of a causal relationship between the administration of a vaccine containing thimerosal and the onset of autism is complex; to the extent that "establishing" such a conclusion is even possible, it involves the extrapolation from, and scientific review of, numerous studies spanning a gamut of fields and methodologies, and most particularly, available epidemiological studies. As Blackwells' counsel stated during oral argument before this Court, their experts' causal conclusions are based on: (1) peer reviewed published epidemiological studies; (2) in vitro studies; (3) toxicological studies;

(4) pharmacokinetic[30] studies that discuss the distribution of mercury throughout the body; (5) diagnostic tests of blood "to determine the level of gluthionine in the body, which is a molecule necessary to eliminate mercury"; (6) porphyrin urine analysis to determine mercury toxicity; (7) differential diagnosis; and (8) "extrapolation from animal studies and from other in vitro studies." It is noteworthy also, as the IOM Committee recognized in its 2004 Report, that any conclusion regarding the cause of autism is complicated by the fact that "autism," itself, is not a single disorder but a "set of developmental disorders characterized by sustained impairments in social interaction [and] communication," and that "autism," and "autistic spectrum disorders" refer to a "broad[] group of pervasive developmental disorders." IOM Report, at 3-4 (2004) (emphasis added).

That the complex field of epidemiology is central to the resolution of the lawsuit, moreover, is not disputed. The Blackwells have never challenged Judge Berger's finding that epidemiology, primarily, is the relevant field for establishing a causal relationship, nor do they dispute that the establishment of a causal relationship is dispositive to the outcome of the lawsuit. Their contention, rather, is that their experts were qualified to offer conclusions based on epidemiological principles.

Judge Berger, therefore, did not abuse his discretion when he required a specificity of knowledge, skill, experience, training or education related to the resolution of the lawsuit,

---

[30] Pharmacokinetics is a branch of pharmacology, "[r]elating to the disposition of drugs in the body (i.e., their absorption, distribution, metabolism, and elimination)." Stedman's, *supra*, at 1473.

and concluded that Drs. Geier's, Haley's, Deth's, Mumper's and Siebert's fields of expertise were not relevant to the specific bodies of science that purport to maintain generally acceptable scientific methods and analyses related to autism and its causes. Based upon all of the forgoing analysis, we agree with the well-reasoned and cogent opinion of Judge Berger.

JUDGMENT OF THE CIRCUIT COURT FOR BALTIMORE CITY AFFIRMED. COSTS IN THIS COURT TO BE PAID BY APPELLANTS.