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BLACKWELL v. WYETH: IT'S OUR COURTROOM AND WE'LL FRYE (ONLY) IF WE WANT TO—THE MARYLAND COURT OF APPEALS'S UNSTATED ADOPTION OF DAUBERT

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In Blackwell v. Wyeth, the Court of Appeals of Maryland addressed the admissibility of expert testimony that attempted to establish a causal connection between thimerosal and autism pursuant to the Frye/Reed standard and Maryland Rule of Evidence 5-702.2 The court held the expert testimony inadmissible because the novel methodology, theory, and analytical framework proposed by the plaintiffs' proffered epidemiological expert were not "generally accepted" within the relevant scientific community as required by Frye/Reed.³ The court also found the proffered epidemiologist and the plaintiffs' remaining experts to be unqualified to address disease causation pursuant to Rule 5-702.4 In so holding, the court correctly excluded the expert testimony,⁵ but significantly collapsed the Maryland Frye/Reed standard into the federal Daubert standard by relying on Daubert precedent and considering several Daubert factors.⁶ The Court of Appeals should have acknowledged this collapse and formally adopted Daubert to account for differences in the following: (1) the arguments raised by litigants, (2) the role of judges in making evidentiary determinations, ⁷ and (3) the appellate review standards pursuant to either standard.⁸ Such an acknowledgment would have avoided inconsistencies in the application of expert testimony admissibility standards in Maryland

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- 1. 408 Md. 575, 971 A.2d 235 (2009).
- 2. Id. at 577-78, 971 A.2d at 236-37.
- 3. Id. at 585, 608-09, 617-18, 971 A.2d at 241, 255, 260-61.
- 4. Id. at 618, 630, 971 A.2d at 261, 268.
- 5. See infra Part IV.A.
- 6. See infra Part IV.B.
- 7. See infra Part IV.B, C.1.
- 8. See infra Part IV.C.2.

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courts and promoted true assessment of novel scientific evidence by trial judges.⁹

I. The Case

Between 1985 and 1989, Jamarr Blackwell received several administrations of the diphtheria tetanus and whole-cell pertussis ("DTP") vaccine and haemophilus influenzae type b ("Hib") vaccine. ¹⁰ Both of these vaccines contained fifty micrograms of the organic mercury-based preservative thimerosal. ¹¹ Thimerosal is forty-nine percent mercury by weight and therefore Jamarr received approximately twenty-five micrograms of mercury with each administration of these vaccines. ¹²

On June 11, 2004, Jamarr's parents, Pamela and Ernest Blackwell ("Blackwells"), brought a products liability action alleging that the thimerosal preservative in the DTP and Hib vaccines manufactured by Wyeth and other defendants injured Jamarr.¹³ The Blackwells contended that exposure to thimerosal proximately caused Jamarr to develop autism.¹⁴ To support this allegation, the Blackwells sought to proffer the expert testimony of Professors Boyd Haley¹⁵ and Richard Deth,¹⁶ and Doctors Elizabeth Mumper,¹⁷ Mark Geier,¹⁸ and Stephen Seibert¹⁹ to establish that exposure to thimerosal in the DTP and Hib vaccines generally causes autism in genetically susceptible individu-

^{9.} See infra Part IV.C.

^{10.} Blackwell v. Sigma Aldrich, Inc., No. 24-C-04-004829, slip op. at 10–11 (Md. Cir. Ct. Dec. 21, 2007), available at http://www.baltocts.state.md.us/about/publications/opinions/blackwell_memorandum_opinion.pdf. The name provided for the Hib vaccine reflects that used by the Center for Disease Control and Prevention. Ctr. for Disease Control & Prevention, Haemophilus Influenzae Type B (Hib) Vaccine: What You Need to Know 1 (1998), http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hib.pdf.

^{11.} Blackwell, No. 24-C-04-004829, slip op. at 10-11.

^{12.} Id.

^{13.} See id. at 1, 11. Although Jamarr had reached the age of majority by the time of the lawsuit, he remained unable to manage his own legal and business affairs. Id. at 1. Therefore, Pamela and Ernest Blackwell brought this action both as his parents and next friends. Id.

^{14.} Id. at 1, 7.

^{15.} *Id.* at 20–21. Dr. Haley was a professor of chemistry at the University of Kentucky and studied mercury's adverse effects on the brain. *Id.* at 20.

^{16.} *Id.* at 21. Dr. Deth was a professor of pharmacology at Northeastern University and sought to testify on thimerosal's effects on the brain. *Id.*

^{17.} *Id.* at 21–22. Dr. Mumper was a general pediatrician and testified, based on her clinical experience, as to the neurological effects of mercury on children. *Id.*

^{18.} *Id.* at 22–23. Dr. Geier was a genetic counselor and an obstetrician and testified, based on eleven epidemiological studies he conducted, that thimerosal-containing vaccines cause autism. *Id.* at 22, 24.

^{19.} Id. at 23. Dr. Siebert was a psychiatrist with a master's degree in public health. Id.

als.²⁰ Wyeth subsequently sought to preclude the testimony of these expert witnesses pursuant to the Frye/Reed standard²¹ and Maryland Rule of Evidence 5-702.²²

The Circuit Court for Baltimore City conducted a ten day, pretrial evidentiary hearing to determine the admissibility of the Blackwells' proffered expert witness testimony.²³ According to the circuit court, *Frye/Reed* sets forth the minimum threshold standard for the admissibility of novel scientific theories, which is that the theories must be generally accepted within the relevant scientific community.²⁴ In addition, the expert must be qualified.²⁵ The circuit court found epidemiology to be the most relevant scientific field to the general causation issue,²⁶ and noted that Dr. Geier was the only witness proffered by the Blackwells as an epidemiological expert.²⁷ Therefore, the circuit court assessed only the admissibility of Dr. Geier's testimony pursuant to the *Frye/Reed* standard.²⁸

Several of Dr. Geier's epidemiological studies utilized the Vaccine Adverse Event Reporting System,²⁹ and he testified that in all eleven of his epidemiological studies there was evidence of a causal link be-

^{20.} Id. at 20-23, 30.

^{21.} *Id.* at 1. The *Frye/Reed* standard provides that novel scientific theories must be generally accepted by the relevant scientific community in order to be admissible. Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923); Reed v. State, 283 Md. 374, 381, 391 A.2d 364, 368 (1978); *see infra* Part II.A.1.

^{22.} *Blackwell*, No. 24-C-04-004829, slip op. at 1. Rule 5-702 provides the following: 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.

Md. R. 5-702.

^{23.} Blackwell, No. 24-C-04-004829, slip op. at 2.

^{24.} Id. at 2-3.

^{25.} *Id.* at 3; see Mp. R. 5-702 (noting that "the court shall determine (1) whether the witness is qualified as an expert by knowledge, skill, experience, training, or education").

^{26.} *Blackwell*, No. 24-C-04-004829, slip op. at 23–24. Epidemiology is the study of the distribution of diseases within a population, and medical causality is central to that study. *Id.*

^{27.} Id. at 24.

^{28.} *Id.* The court separately addressed the admissibility of the testimony of Dr. Geier and the testimony of the Blackwells' other experts pursuant to Rule 5-702. *Id.* at 33–41.

^{29.} *Id.* at 25. The Vaccine Adverse Event Reporting System is a post-marketing safety surveillance program conducted by the Center for Disease Control and the Food and Drug Administration where post-vaccination adverse side effects are reported, analyzed, and disseminated to the public. United States Department of Health and Human Services, Vaccine Adverse Event Reporting System, http://www.vaers.hhs.gov (last visited Mar. 28, 2010). Dr. Geier also utilized the Vaccine Safety Datalink, the Department of Education

tween exposure to thimerosal-containing vaccines and autism.³⁰ Dr. Geier performed a differential diagnosis³¹ analytical framework to support the theory that exposure to thimerosal caused autism in genetically susceptible individuals.³² The circuit court found that the Blackwells failed to demonstrate that Dr. Geier's novel methodology, theory, and analytical framework were generally accepted as reliable within the relevant scientific community, and therefore held his testimony inadmissible pursuant to the *Frye/Reed* standard.³³

The circuit court then considered Wyeth's motion to exclude the Blackwells' expert testimony pursuant to Rule 5-702.³⁴ The circuit court noted that its inadmissibility determination under *Frye/Reed* regarding Dr. Geier's testimony was arguably dispositive.³⁵ Nevertheless, the circuit court went on to consider Dr. Geier's qualifications, as well as the remaining experts' qualifications, pursuant to Rule 5-702.³⁶ The circuit court found the experts proffered by the Blackwells to be unqualified because they were not experts in the field of epidemiology,³⁷ which the court reasoned was necessary to establish that thimerosal-containing vaccines cause autism.³⁸ Wyeth subsequently moved for summary judgment and the circuit court granted the motion.³⁹

The Court of Appeals of Maryland granted certiorari prior to any proceedings in the Maryland Court of Special Appeals to determine whether the circuit court improperly applied the *Frye/Reed* standard to

database, and the California Department of Social Services database in one or more of his epidemiological studies. *Blackwell*, No. 24-C-04-004829, slip op. at 25.

^{30.} Blackwell, No. 24-C-04-004829, slip op. at 24.

^{31.} *Id.* at 33. A differential diagnosis is a methodology that determines the cause of a medical problem by ruling out other possible causes until the most probable cause remains. *Id.*

^{32.} *Id.* at 30. Specifically, Dr. Geier associated "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" to contribute to a child's genetic susceptibility. *Id.* at 31.

^{33.} Id. at 30, 48-49.

^{34.} Id. at 33-34.

^{35.} Id. at 34.

^{36.} Id. at 34, 37-41.

^{37.} *Id.* at 36–41. While the circuit court addressed Dr. Geier's testimony pursuant to the *Frye/Reed* standard because he was proffered as an expert in the field of epidemiology by the Blackwells, the circuit court ultimately concluded he was unqualified because his credentials as a medical doctor and genetic counselor did not provide the adequate foundation for him to testify as to whether thimerosal caused autism. *Id.* at 24, 36–37.

^{38.} Id. at 23-24.

^{39.} Blackwell v. Sigma Aldrich, Inc., No. 24-C-04-004829, slip op. at 1 (Md. Cir. Ct. Feb. 8, 2008).

Dr. Geier's conclusions, rather than to the bases upon which he reached those conclusions, and whether the circuit court abused its discretion in finding the Blackwell experts' testimony inadmissible for failing to meet the requirements of Rule 5-702.⁴⁰

II. LEGAL BACKGROUND

Maryland courts admit expert testimony pursuant to two separate channels—the Frye/Reed standard and Maryland Rule of Evidence 5-702.41 Expert testimony discussing novel scientific theories must meet the minimum threshold Frye/Reed standard ⁴² in addition to the Rule 5-702 requirements to be admissible.⁴³ Expert testimony addressing non-novel scientific evidence, however, must only meet the requirements of Rule 5-702.44 In contrast, a unanimous United States Supreme Court rejected the *Frye* standard's applicability to federal courts in Daubert v. Merrell Dow Pharmaceuticals, Inc. 45 and held that federal courts shall admit all expert testimony pursuant to Federal Rule of Evidence ("FRE") 702.46 The Frye/Reed and Daubert standards, as well as Rule 5-702 and FRE 702, all developed concurrently and in response to each other, and their development can be divided into three eras: (1) the supremacy of Frye from 1923 to $1993;^{47}$ (2) the Supreme Court's announcement of the federal *Daubert* standard and Maryland's promulgation of Rule 5-702 from 1993 to 1994;⁴⁸ and (3) Frye/Reed's collapse into Daubert from 1994 to the present.⁴⁹

^{40.} Blackwell v. Wyeth, 408 Md. 575, 579–80, 971 A.2d 235, 238 (2009).

^{41.} See United States v. Horn, 185 F. Supp. 2d 530, 547–48 n.29 (D. Md. 2002) ("Under Maryland evidence law, the *Frye/Reed* test applies only to introduction of [novel] scientific evidence, and Rule 5-702 alone covers all other types of expert opinion testimony."); Reed v. State, 283 Md. 374, 389, 391 A.2d 364, 372 (1978) ("Testimony based on a technique which is found to have gained 'general acceptance in the scientific community' *may* be admitted into evidence, but only if a trial judge also determines in the exercise of his discretion . . . that the expert is properly qualified").

^{42.} See infra Part II.A.1.

^{43.} See infra text accompanying notes 97-101.

^{44.} See supra note 41.

^{45. 509} U.S. 579 (1993).

^{46.} See infra Part II.B-C.

^{47.} See infra Part II.A.

^{48.} See infra Part II.B.

^{49.} See infra Part II.C.

A. Following Frye, Federal and Maryland Courts Evaluated Novel Scientific Theories Similarly

In the era in which *Frye v. United States*⁵⁰ reigned supreme, state and federal courts followed *Frye*'s holding that trial courts may admit expert testimony discussing novel scientific theories only if those theories are generally accepted within the relevant scientific community.⁵¹ Following its announcement, many federal and state courts adopted the *Frye* standard.⁵² The Court of Appeals of Maryland adopted *Frye* in *Reed v. State*,⁵³ and despite the promulgation of FRE 702 in 1975,⁵⁴ many federal courts continued to apply *Frye*'s general acceptance standard.⁵⁵

1. Frye v. United States Set Forth the "General Acceptance" Standard that Was Subsequently Adopted by the Maryland Court of Appeals in Reed v. State

In *Frye*, a brief opinion devoid of supporting case precedent, the Court of Appeals of the District of Columbia set forth the original admissibility standard governing expert testimony as to novel scientific theories. The court refused to admit the defendant's expert testimony interpreting a systolic blood pressure deception test to prove the defendant's truthfulness. The *Frye* court observed the following:

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.⁵⁸

^{50. 293} F. 1013 (D.C. Cir. 1923).

^{51.} See infra Part II.A.1.

^{52.} See infra Part II.A.1-2.

^{53. 283} Md. 374, 391 A.2d 364 (1978); see infra Part II.A.1.

^{54.} Act of Jan. 2, 1975, Pub. L. No. 93-595, 88 Stat. 1926, 1937.

^{55.} See infra Part II.A.2.

^{56.} See Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923) (finding that in order to be admissible, the scientific principle or discovery must "have gained general acceptance in the particular field in which it belongs").

^{57.} *Id.* at 1013–14. The systolic blood pressure deception test measured changes in systolic blood pressure, and the proffered expert asserted that rises in systolic blood pressure were brought about by "nervous impulses sent to the sympathetic branch of the autonomic nervous system" indicative of "conscious deception or falsehood." *Id.* at 1013.

^{58.} Id. at 1014 (emphasis added).

The *Frye* court held the testimony to be inadmissible because the defendant failed to show the systolic blood pressure deception test had gained such standing.⁵⁹

In Reed v. State, 60 the Maryland Court of Appeals addressed the admissibility of expert testimony interpreting voiceprint spectrograms that compared the defendant's voice to telephone calls made by an alleged rapist.⁶¹ Adopting the Frye "general acceptance" standard,⁶² the court held the testimony to be inadmissible. 63 The court reasoned that the application of novel scientific techniques must be reliable,64 and general acceptance within the relevant scientific community best demonstrates such reliability.⁶⁵ The identity of the relevant scientific community, the court discussed, depends upon the particular technique at issue and generally "includes those whose scientific background and training are sufficient to allow them to comprehend and understand the process and form a judgment about it."66 The court further reasoned that the reliability of new techniques does "not vary according to the circumstances of each case" and is therefore not "a matter within each trial judge's individual discretion."67 The court found the voiceprint spectrograms were not generally accepted within the relevant scientific community and excluded the evidence.⁶⁸

2. FRE 702 Omitted a Reference to "General Acceptance," but Federal Case Law Continued to Rely on the Frye Standard

Despite the absence of *Frye* or its "general acceptance" standard from the language of FRE 702, many federal courts continued to apply *Frye* following the promulgation of FRE 702. Congress first enacted the Federal Rules of Evidence in 1975.⁶⁹ According to the original FRE 702, "[i]f 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."⁷⁰ As the Supreme Court later ac-

^{59.} Id.

^{60. 283} Md. 374, 391 A.2d 364 (1978).

^{61.} *Id.* at 375–76, 391 A.2d at 364–65.

^{62.} Id. at 389, 391 A.2d at 372.

^{63.} Id. at 399, 391 A.2d at 377.

^{64.} Id. at 380, 391 A.2d at 367.

^{65.} Id. at 381, 391 A.2d at 368.

^{66.} Id. at 382, 391 A.2d at 368.

^{67.} Id. at 381, 391 A.2d at 367-68.

^{68.} Id. at 399, 391 A.2d at 377.

^{69.} Act of Jan. 2, 1975, Pub. L. No. 93-595, 88 Stat. 1926.

^{70. 28} U.S.C. app. R. 702 (1976) (amended 2000).

knowledged in *Daubert*, there is no reference to *Frye* or its "general acceptance" standard within FRE 702 or its drafting history.⁷¹ Regardless of this omission, many federal courts continued to apply the *Frye* standard.

In United States v. Tranowski⁷² and United States v. Shorter,⁷³ the United States Courts of Appeals for the Seventh Circuit and the District of Columbia Circuit referenced FRE 702, but only generally regarding the qualifications of experts⁷⁴ and the relevance of expert testimony,⁷⁵ respectively. The admissibility of the expert testimony in those cases, however, ultimately turned on those courts' application of the Frye standard. In Tranowski, the Seventh Circuit cited Frye in refusing to admit the testimony of the Government's astronomy expert attempting to date a photograph by measuring the lengths of shadows to determine the altitude and azimuth of the sun. ⁷⁶ The court found that an application of this technique had never been performed before and was not "'sufficiently established to have gained general acceptance in the particular field to which it belongs." Similarly, in Shorter, the D.C. Circuit held that novel scientific methods must meet the Frye standard and refused to admit the expert's testimony because the relevant scientific community did not generally accept a link between pathological gambling and the failure to pay taxes.⁷⁸

In *United States v. Brown*⁷⁹ and *United States v. Hendershot*,⁸⁰ the Sixth and Ninth Circuits made little or no reference to FRE 702 in addressing the admissibility of expert testimony. In *Brown*, the Sixth Circuit mentioned FRE 702 in a single citation,⁸¹ but affirmed the fol-

^{71.} Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 588 (1993) ("Nothing in the text of this Rule establishes 'general acceptance' as an absolute prerequisite to admissibility. Nor does respondent present any clear indication that [FRE] 702 or the Rules as a whole were intended to incorporate a 'general acceptance' standard. The drafting history makes no mention of *Frye*").

^{72. 659} F.2d 750 (7th Cir. 1981).

^{73. 809} F.2d 54 (D.C. Cir. 1987).

^{74.} Tranowski, 659 F.2d at 754-55.

^{75.} Shorter, 809 F.2d at 59.

^{76.} Tranowski, 659 F.2d at 755-56.

^{77.} Id. (quoting Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923)).

^{78.} Shorter, 809 F.2d at 59-61.

^{79. 557} F.2d 541 (6th Cir. 1977).

^{80. 614} F.2d 648 (9th Cir. 1980).

^{81.} Brown, 557 F.2d at 556 (citing Fed. R. Evid. 702). After discussing Frye's "general acceptance" standard as a necessary predicate to admission of expert testimony, the court cited FRE 702 to support its contention that "[t]he clear trend in federal court [was] toward the admission of expert testimony whenever it [would] aid the trier of fact." Id. (citing Fed. R. Evid. 702). The court went on to rebut this trend and discussed a four-prong test as necessary to protect the defendant's interest in a fair trial. Id. (quoting United States v. Baller, 519 F.2d 463, 466 (4th Cir. 1975)).

lowing four-prong test to determine the admissibility of expert testimony: "1. qualified expert; 2. proper subject; 3. conformity to a generally accepted explanatory theory; and 4. probative value compared to prejudicial effect." Analyzing the third prong, the court cited Frye and held that the Government failed to demonstrate the "ion microprobic analysis [was] a generally accepted procedure" and failed to show the experiments were reliable and accurate enough "to be said to cross 'the line between the experimental and demonstrable stages.' "83 Similarly, in Hendershot, the Ninth Circuit affirmed the admissibility of expert testimony because the Government demonstrated that the shoeprint technique utilized at the crime scene was generally accepted, but made no reference to FRE 702.84

B. The Great Schism: Daubert Removes Frye from the Federal Courts and Maryland Rule of Evidence 5-702 Retains Frye/Reed in the Wake of Daubert

Eighteen years after Congress enacted the Federal Rules of Evidence, a unanimous United States Supreme Court held that adoption of FRE 702 superseded *Frye.*⁸⁵ In *Daubert*, the Court vacated the Ninth Circuit's judgment to exclude the plaintiff's expert testimony demonstrating a causal link between Bendectin and birth defects after the Ninth Circuit determined the expert's methodology was not generally accepted as reliable in the relevant scientific community.⁸⁶ According to the Court, nothing in the text of FRE 702 established the necessity of "general acceptance," and nothing in the drafting history indicated the incorporation of *Frye.*⁸⁷

A majority of the Court went on to address the trial judge's "gatekeeping role" and the limitations FRE 702 placed on scientific knowledge. The Court distinguished *Frye*'s limited applicability and FRE 702: While *Frye* "focused exclusively on 'novel' scientific techniques, [the Court did] not read the requirements of [FRE] 702 to

^{82.} *Id.* (emphasis added) (quoting United States v. Green, 548 F.2d 1261, 1268 (6th Cir. 1977)).

^{83.} Id. at 557 (quoting Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923)).

^{84.} Hendershot, 614 F.2d at 654.

^{85.} Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589 (1993).

^{86.} Id. at 584, 597-98.

^{87.} Id. at 588.

^{88.} See id. at 589, 597. According to the majority, the trial judge must screen expert testimony to ensure that all scientific testimony and evidence is relevant and reliable. *Id.* at 589.

^{89.} Id. at 589.

apply specifically or exclusively to unconventional evidence."⁹⁰ Therefore, all expert testimony discussing scientific knowledge, and, more specifically, the methodology or technique upon which it was based, must be relevant, reliable, helpful, and "fit."⁹¹ To determine whether the methodology or technique meets those four factors, the Court set forth the following inquiries: (1) whether the theory or technique can, or has been, tested;⁹² (2) whether the theory or technique has been subjected to peer review and publication;⁹³ (3) what the technique's known or potential rate of error was;⁹⁴ (4) whether standards exist and are maintained for the technique's operation;⁹⁵ and (5) whether the theory or technique has "general acceptance" within the relevant scientific community.⁹⁶

One year after *Daubert*, the Maryland Court of Appeals adopted Rule 5-702.⁹⁷ The Rule states the following:

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.⁹⁸

According to the Committee's note, this Rule was not intended to overrule the *Frye/Reed* standard.⁹⁹ Instead, "[t]he required scientific foundation for the admission of novel scientific techniques or principles is left to development through case law."¹⁰⁰ Thus, promulgation of Rule 5-702 created two separate channels for Maryland courts to admit expert testimony—the *Frye/Reed* standard in conjunction with

^{90.} Id. at 592 n.11.

^{91.} Id. at 589-92.

^{92.} Id. at 593.

^{93.} Id. at 593-94.

^{94.} Id. at 594.

^{95.} Id.

^{96.} *Id.* The Court stated "general acceptance" was "an important factor in ruling particular evidence admissible," and could have a *bearing* on the inquiry. *Id.*

^{97.} Md. R. 5-702.

^{98.} Id.

^{99.} Md. R. 5-702 committee's note ("This Rule is not intended to overrule *Reed v. State*, 283 Md. 374 (1978) and other cases adopting the principles enunciated in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).").

^{100.} Id.

Rule 5-702 for novel scientific theories and Rule 5-702 for all other expert testimony.¹⁰¹

C. Despite Subsequent Developments to the Daubert Standard that Further Distinguished Daubert from the Frye/Reed Standard, Maryland Case Law Has Significantly Merged with Daubert Precedent

Despite Maryland courts' stated adherence to the *Frye/Reed* standard, application of *Frye/Reed* has collapsed significantly into the developing federal *Daubert* standard. Since *Daubert*, the United States Supreme Court has had two opportunities to further define *Daubert*'s applicability, ¹⁰² and in 2000, Congress amended FRE 702 to incorporate the principles articulated in the *Daubert* trilogy. ¹⁰³ In light of the *Daubert* trilogy and the 2000 amendment to FRE 702, many federal courts were forced to reconsider past *Frye* holdings. ¹⁰⁴ The Maryland courts also were not outside *Daubert*'s influence, and subsequent to the Rule 5-702 Committee's note's "wait and see" approach, Maryland's *Frye/Reed* standard collapsed into the *Daubert* trilogy. ¹⁰⁵

1. The Daubert Trilogy: The United States Supreme Court Adopted an Abuse of Discretion Standard of Review and Applied Daubert to All Expert Testimony, Leading to an Amendment to the Federal Evidence Rules in 2000

The Daubert trilogy consists of three cases—Daubert, ¹⁰⁶ General Electric Co. v. Joiner, ¹⁰⁷ and Kumho Tire Co. v. Carmichael ¹⁰⁸—and demonstrates the Supreme Court's attempt to further refine its expert admissibility standard. In Joiner, the Court set forth an abuse of discretion appellate standard of review consistent with trial judges' "gatekeeper" role articulated in Daubert. ¹⁰⁹ In Kumho, the Court held

^{101.} See supra note 41 and accompanying text.

^{102.} See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999) (extending Daubert's holding to include testimony based on "technical" or "other specialized" knowledge, in addition to "scientific knowledge"); Gen. Elec. Co. v. Joiner, 522 U.S. 136, 141–43 (1997) (confirming an abuse of discretion standard of review for evidentiary rulings). Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), General Electric Co. v. Joiner, 522 U.S. 136, and Kumho Tire Co. v. Carmichael, 526 U.S. 137, are commonly referred to as the Daubert trilogy.

^{103.} See infra Part II.C.1.

^{104.} See infra Part II.C.2.

^{105.} See infra Part II.C.3.

^{106. 509} U.S. 579.

^{107. 522} U.S. 136.

^{108. 526} U.S. 137 (1999).

^{109.} See infra text accompanying notes 113-18.

that *Daubert* was applicable to all expert testimony and not simply scientific expert testimony,¹¹⁰ and further articulated that the *Daubert* factors were relevant to, but not dispositive of, admissibility of an expert's testimony.¹¹¹ In 2000, Congress incorporated the *Daubert* trilogy into FRE 702.¹¹²

In Joiner, the respondent alleged his small-cell lung cancer resulted from exposure to polychlorinated biphenyls in electrical transformers manufactured by General Electric and other defendants. 113 In response to the Eleventh Circuit's "'particularly stringent standard of review to the trial judge's exclusion of expert testimony,'"114 petitioners appealed and argued for a traditional "abuse of discretion" review. 115 A unanimous Court agreed with the petitioners and held that appellate courts should review a trial judge's admissibility determination pursuant to Daubert and FRE 702 under an abuse of discretion standard. 116 A majority of the Court further explained that while Daubert suggested that a trial judge's focus must be on the principles and methodology employed by the expert and not on his conclusions, there may not be "too great an analytical gap between the data and the opinion proffered." Therefore, the Court held that the district court did not abuse its discretion because "[n]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse* dixit of the expert."118

In *Kumho*, the Court addressed the admissibility of an engineer's expert testimony regarding potential defects in a tire's manufacturing. A unanimous Court extended *Daubert*'s general "gatekeeping" holding to apply not only to testimony based on "scientific knowledge," but also to testimony based on "technical" or "other specialized" knowledge as articulated in FRE 702. To further clarify

^{110.} See infra text accompanying notes 119-22.

^{111.} See Kumho, 526 U.S. at 159 (Scalia, J., concurring) ("[As] the Court makes clear today, the Daubert factors are not holy writ").

^{112.} See infra notes 123-26 and accompanying text.

^{113.} Gen. Elec. Co. v. Joiner, 522 U.S. 136, 139-40 (1997).

^{114.} Id. at 140 (quoting Joiner v. Gen. Elec. Co., 78 F.3d 524, 529 (11th Cir. 1996)).

^{115.} Id. at 140-41.

^{116.} *Id.* at 141–43. The Court based its conclusion on cases dating back to 1879, specifically *Spring Co. v. Edgar*, 99 U.S. 645 (1879), stating that "'[c]ases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous.'" *Joiner*, 522 U.S. at 141–42 (quoting *Edgar*, 99 U.S. at 658).

^{117.} Joiner, 522 U.S. at 146.

^{118.} Id.

^{119.} Kumho Tire Co. v. Carmichael, 526 U.S. 137, 142-43 (1999).

^{120.} Id. at 141.

Daubert's applicability to all forms of expert testimony, the Court reasoned that a trial judge *may* consider one or more *Daubert* factors to assess the testimony's reliability, ¹²¹ noting that the list of specific factors do not necessarily apply to every expert. ¹²²

Following the Court's decisions in *Daubert, Joiner*, and *Kumho*, Congress amended FRE 702 in 2000:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case. 123

According to the Advisory Committee's note, the Court adopted these changes in response to *Daubert* and cases applying *Daubert*, including *Kumho* and *Joiner*.¹²⁴ FRE 702's broad language sought to account for the *Daubert* factors, while not requiring any single factor and permitting trial judges to consider other relevant factors articulated both before and after *Daubert*.¹²⁵ This approach provided the trial judge with significant discretion to determine the admissibility of expert testimony.¹²⁶

2. Subsequent to Daubert and the 2000 Amendment to FRE 702, Many Federal Courts Were Forced to Reconsider Previous Holdings Under Frye

The *Daubert* trilogy prompted many federal courts to reconsider previous holdings pursuant to *Frye* and address the differences between the *Frye* and *Daubert* standards. Despite *Daubert*'s inclusion of "general acceptance" as one potentially relevant factor, *Frye* and

^{121.} Id. at 149-50.

^{122.} Id.

^{123.} Fed. R. Evid. 702 (emphasis added).

^{124.} FED. R. EVID. 702 advisory committee's note.

^{125.} *Id.* The Advisory Committee's note also mentioned several additional factors, including (1) "[w]hether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion," and (2) "[w]hether the expert has adequately accounted for obvious alternative explanations." *Id.*

^{126.} Id.

 $\it Daubert$ are different standards that call for different analyses by trial judges. 127

In *United States v. Prince-Oyibo*, ¹²⁸ the Fourth Circuit considered *Daubert*'s impact on the court's per se bar on admission of polygraph evidence established pursuant to *Frye*, and whether an en banc proceeding was necessary to overrule the court's per se bar. ¹²⁹ In *Prince-Oyibo*, the defendant sought to use a polygraph test to prove his lack of intent to obtain a fraudulent visa. ¹³⁰ Distinguishing *Daubert* from *Frye*, the court emphasized that a "'trial judge must ensure that any and all scientific testimony or evidence admitted is . . . reliable,'" and that "[t]he analysis must be a 'flexible one.'" While the court ultimately held that only the en banc court had the authority to overrule the per se bar, it noted its "inclin[ation] to hold that *Daubert* requires a more nuanced evaluation of polygraph evidence than that dictated by the per se rule." The court in *Prince-Oyibo* therefore acknowledged that *Daubert* and *Frye* were different standards that articulated different roles for trial judges.

In *United States v. Horn*, ¹³³ the United States District Court for the District of Maryland considered whether standard field sobriety tests ("SFSTs") were admissible to provide either circumstantial evidence of intoxication or impairment, or direct evidence of specific blood alcohol content. ¹³⁴ Because the majority of case law on the admissibility of SFSTs came from state courts applying *Frye*, ¹³⁵ Judge Grimm addressed several differences between the *Frye* and *Daubert* standards. ¹³⁶ First, "[u]nder *Daubert*... the trial court [is] forced to reckon with the factors that really do determine whether the evidence is reliable, rele-

^{127.} See, e.g., Ruffin v. Shaw Indus., Inc., 149 F.3d 294, 296 (4th Cir. 1998) ("[T]he primary significance of the Supreme Court's decision in *Daubert* was to make the 'general acceptance' standard merely one factor in a multi-factor analysis, not the determinative test for admitting scientific evidence.").

^{128. 320} F.3d 494 (4th Cir. 2003).

^{129.} Id. at 497-98.

^{130.} Id. at 496.

 $^{131.\ \}textit{Id.}$ at 498 (quoting Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589, 594 (1994)).

^{132.} *Id.* at 501. The court also acknowledged that the Fifth and Ninth Circuits "held that *Daubert* effectively overturned their respective per se bars . . . leav[ing] the admission or exclusion of such evidence to the discretion of the district courts." *Id.* at 499 (citing United States v. Cordoba, 104 F.3d 225, 227–28 (9th Cir. 1997); United States v. Posado, 57 F.3d 428, 433–34 (5th Cir. 1995)).

^{133. 185} F. Supp. 2d 530 (D. Md. 2002).

^{134.} Id. at 534.

^{135.} Id. at 535.

^{136.} Id. at 553-54.

vant and 'fits' the case at issue." Conversely, under *Frye*, "all that is needed to admit the evidence is the testimony of one or more experts in the field that the evidence at issue derives from methods or procedures that have become generally accepted." As a result, *Frye* courts never had to *understand* the evidence at issue. Further, once a court concluded a methodology attained general acceptance under *Frye*, the doctrine of stare decisis allowed "for subsequent courts simply to follow suit" and "without there ever having been a contested, detailed examination of the underpinnings of that methodology." Finally, *Daubert* did not merely apply to novel scientific theories, but applied consistently to any expert testimony discussing scientific, technical, or other specialized knowledge. As evident in *Horn*, the *Daubert* and *Frye* standards require different applications by trial judges.

3. Despite the Differences Between Daubert and Frye/Reed, Maryland Case Law Has Mirrored Federal Changes to Daubert and FRE 702

Maryland courts consistently state adherence to the *Frye/Reed* standard, ¹⁴² but inconsistently permit *Daubert* to influence the admissibility of expert testimony addressing novel scientific theories. Application of the *Frye/Reed* standard has included references to the trial judge's "wide latitude" in admissibility determinations, ¹⁴³ *Daubert* precedent, ¹⁴⁴ and the language of FRE 702, ¹⁴⁵ thus allowing Maryland *Frye/Reed* case law to collapse into the *Daubert* standard.

In *Reed*, the Maryland Court of Appeals stated that the reliability of novel scientific techniques was not a "matter within each trial judge's individual discretion." Generally, "the admissibility of expert testimony *is* within the sound discretion of the trial judge," and

^{137.} Id.

^{138.} Id.

^{139.} Id. at 554.

^{140.} Id.

^{141.} *Id*.

^{142.} See Clemons v. State, 392 Md. 339, 349 n.7, 896 A.2d 1059, 1065 n.7 (2006) ("Both parties erroneously claimed that Maryland follow[ed] the Supreme Court's reasoning in Daubert . . . Maryland has continued to adhere to the Frye test rather than the Daubert standard."); Burral v. State, 352 Md. 707, 738, 724 A.2d 65, 80 (1999) ("[W]e have not abandoned Frye or Reed."); Schultz v. State, 106 Md. App. 145, 153 n.3, 664 A.2d 60, 64 n.3 (1995) ("[T]he Frye/Reed standard is still the standard utilized in Maryland to determine the admissibility of scientific evidence.").

^{143.} See infra notes 150-55 and accompanying text.

^{144.} See infra text accompanying notes 156-62.

^{145.} See infra text accompanying notes 163-67.

^{146.} Reed v. State, 283 Md. 374, 381, 391 A.2d 364, 367 (1978).

^{147.} Wilson v. State, 370 Md. 191, 200, 803 A.2d 1034, 1039 (2001) (emphasis added).

therefore comes under an abuse of discretion standard of review. ¹⁴⁸ In contrast, appellate review regarding the reliability, and therefore admissibility, of a novel scientific technique pursuant to the *Frye/Reed* standard is de novo. ¹⁴⁹ On two recent occasions the Maryland Court of Appeals referenced the trial judge's "wide latitude in determining whether expert testimony is sufficiently reliable to be admissible." ¹⁵⁰ In *Wilson v. State*, ¹⁵¹ the court accurately made this statement in reference to whether an expert was qualified pursuant to Rule 5-702. ¹⁵² In *Montgomery Mutual Insurance Co. v. Chesson*, ¹⁵³ the court referenced the trial judge's "wide latitude" in assessing the reliability of expert testimony, but then further articulated that the *Frye/Reed* standard determined the reliability of novel scientific methods. ¹⁵⁴ Further, the *Chesson* court made no reference to a de novo appellate review standard. ¹⁵⁵

The Maryland Court of Appeals and the Court of Special Appeals also considered *Daubert* precedent to support a *Frye/Reed* analysis on

^{148.} See id. at 216–17, 803 A.2d at 1048–49 (discussing the trial judge's wide latitude in determining the qualification of an expert and whether such a determination was an abuse of discretion).

^{149.} Id. at 201 & n.5, 803 A.2d at 1039-40 & n.5.

^{150.} *Id.* at 200, 803 A.2d at 1039; *accord* Montgomery Mutual Insurance Co. v. Chesson, 399 Md. 314, 327, 923 A.2d 939, 946 (2007). *But see* CSX Transp., Inc v. Miller, 159 Md. App. 123, 183, 858 A.2d 1025, 1059 (2004) (criticizing *Kumho* "as a tediously fact-specific 'tempest in a teapot,' in large measure over whether the term '*gatekeeper*' [could] be applied to characterize a judge ruling on the admissibility of expert opinion testimony" (emphasis added)), *cert. granted*, 384 Md. 581, 865 A.2d 589 (2005), *cert. dismissed*, 387 Md. 351, 875 A.2d 702 (2005).

^{151. 370} Md. 191, 803 A.2d 1034. In *Wilson*, the Court of Appeals addressed expert testimony that applied a product rule computation to determine the statistical improbability that two siblings would die of Sudden Infant Death Syndrome ("SIDS"). *Id.* at 195, 803 A.2d at 1036. The court found that the *Frye/Reed* standard applied because administration of the product rule required two mutually independent events, and the court needed to determine whether it was generally accepted that genetics played no role in SIDS, therefore making application of the product rule appropriate. *Id.* at 203, 206–09, 803 A.2d at 1041–44. The court found it was not generally accepted that the deaths of two siblings by SIDS were mutually independent events, and therefore held the trial judge erred in admitting the testimony. *Id.* at 209, 803 A.2d at 1044.

^{152.} Id. at 200, 803 A.2d at 1039.

^{153. 399} Md. 314, 923 A.2d 939. In *Chesson*, the Court of Appeals addressed whether the Circuit Court for Howard County abused its discretion by failing to hold a *Frye/Reed* hearing upon petitioner's challenge to respondent's expert, who purported to establish a causal connection between mold exposure and certain health effects. *Id.* at 317–18, 923 A.2d at 940–41. The court held that the circuit court abused its discretion. *Id.* at 333, 923 A.2d at 950. A court must conduct a *Frye/Reed* analysis when a medical expert's opinion evidence is based on an underlying scientific principle, "not presented as a scientific test the results of which were controlled by inexorable, physical laws." *Id.* at 330–32, 923 A.2d at 948–49 (citations and internal quotation marks omitted).

^{154.} Id. at 327, 923 A.2d at 946.

^{155.} See id.

several occasions. In *Wood v. Toyota Motor Corp.*, ¹⁵⁶ appellant sought to admit expert testimony concluding that the chemical burns she sustained when her airbag deployed were caused by a design defect. ¹⁵⁷ Applying Rule 5-702, the Court of Special Appeals affirmed the trial judge's exclusion of the expert testimony because the expert had not provided a rational explanation for how the data he relied upon led to his conclusions. ¹⁵⁸ In support of this holding, the court referenced the 2000 amendment to FRE 702 and opined that "[Maryland] case law is consistent with the amendments to [FRE] 702." ¹⁵⁹

Further, in *Chesson*, the Court of Appeals supported its application of the *Frye/Reed* standard to expert medical testimony that attempted to establish that mold exposure causes illness by reviewing other *Daubert* and *Frye* jurisdictions that had evaluated the same issue. Similarly, in *Conaway v. Deane*, the Court of Appeals assessed whether homosexuality was an immutable characteristic and found that no scientific or sociological study attempting to prove this fact had "withstood analysis for evidentiary admissibility" in either *Frye* or *Daubert* jurisdictions. The foregoing cases demonstrate Maryland courts' reliance on precedent from other jurisdictions in assessing the reliability of novel scientific theories.

Finally, in *Giant Food, Inc. v. Booker*, ¹⁶³ the Court of Special Appeals incorporated the language of FRE 702 into its *Frye/Reed* analysis. In *Giant Food, Inc.*, the court addressed whether the trial court accurately admitted appellee's expert testimony that found that exposure to Freon caused appellee's adult onset asthma. ¹⁶⁴ In reversing the trial court's admissibility determination, the court held that "the expert's testimony lacked a sufficient factual basis, and the opinion was not the product of reliable principles and methods." ¹⁶⁵ The court acknowledged that the latter phrase was taken from FRE 702, but explicitly reaffirmed its adherence to the *Frye/Reed* standard. ¹⁶⁶ The court noted the similarities between Rule 5-702 and FRE 702 and reasoned

^{156. 134} Md. App. 512, 760 A.2d 315 (2000), cert. denied, 362 Md. 189, 763 A.2d 735 (2000).

^{157.} Id. at 515, 760 A.2d at 317.

^{158.} Id. at 523-24, 760 A.2d at 321-22.

^{159.} Id. at 523 n.13, 760 A.2d at 322 n.13.

^{160. 399} Md. at 330-31, 923 A.2d at 948.

^{161. 401} Md. 219, 932 A.2d 571 (2007).

^{162.} Id. at 292 & n.57, 932 A.2d at 615 & n.57.

^{163. 152} Md. App. 166, 831 A.2d 481 (2003), cert. denied, 378 Md. 614, 837 A.2d 926 (2003).

^{164.} Id. at 178, 831 A.2d at 487-88.

^{165.} Id. at 171, 190, 831 A.2d at 483, 494-95.

^{166.} Id. at 183-84 & n.11, 831 A.2d at 491 & n.11.

that Maryland case law pursuant to Rule 5-702 required such a foundation, despite the language's absence from the rule. 167

III. THE COURT'S REASONING

In Blackwell v. Wyeth, 168 the Court of Appeals of Maryland found the Blackwells' proffered expert testimony inadmissible because the epidemiology expert's methodology, theory, and analytical framework were not generally accepted within the relevant scientific community, 169 and further found that the experts were unqualified to testify as to disease causation pursuant to Maryland Rule of Evidence 5-702.¹⁷⁰ Writing for a unanimous court, Judge Battaglia began by addressing the application of the Frye/Reed standard¹⁷¹ to novel scientific theories. 172 Novel scientific theories must be valid and reliable prior to a trial court admitting expert testimony discussing those theories.¹⁷³ The court explained that *Frye/Reed*'s "general acceptance" within the relevant scientific community standard "reflect[ed an] assessment of a theory's validity and reliability, 174 and required "trial judges [to engage] in a serious gate-keeping function, to differentiate serious science from 'junk science.' "175 The court noted that application of the Frye/Reed standard retarded the admission of novel scientific theories, but suggested a litigant was entitled to reliable and accepted scientific judgment prior to scientific testimony being used against him.176

The court did not assess all of the Blackwells' experts pursuant to the *Frye/Reed* standard. Rather, the court only performed a *Frye/Reed* analysis for the Blackwells' proffered epidemiological expert, Dr. Mark Geier.¹⁷⁷ Dr. Geier's studies involved generally accepted "underlying data and methods for gathering this data . . . to support a novel theory"¹⁷⁸ that exposure to thimerosal-containing vaccines

^{167.} *Id.* (citing Wood v. Toyota Motor Corp., 134 Md. App. 512, 523–24 & n.13, 760 A.2d 315, 321–22 & n.13 (2000), *cert. denied*, 362 Md. 189, 763 A.2d 735 (2000)).

^{168. 408} Md. 575, 971 A.2d 235 (2009).

^{169.} Id. at 617-18, 971 A.2d at 261.

^{170.} Id. at 630, 971 A.2d at 268.

^{171.} See supra note 21 and accompanying text.

^{172.} Blackwell, 408 Md. at 580-81, 971 A.2d at 238.

^{173.} Id. at 584, 971 A.2d at 240-41.

^{174.} Id. at 585, 971 A.2d at 241.

^{175.} Id. at 591, 971 A.2d at 245.

^{176.} Id. at 586-87, 971 A.2d at 242.

^{177.} Id. at 600 & n.18, 971 A.2d at 250 & n.18.

^{178.} Id. at 596, 971 A.2d at 247-48.

causes autism.¹⁷⁹ The court reasoned, however, that it needed to scrutinize the methodology and analysis employed in *interpreting* the data, even if the underlying data is generally accepted.¹⁸⁰

Turning first to Dr. Geier's methodologies, the court stated that the relevant scientific community believed Dr. Geier's studies inappropriately interpreted data produced by adverse events reporting databases. 181 Specifically, the relevant scientific community found Dr. Geier's studies arbitrarily linked acute vaccine reactions like fever, pain, and vomiting to the occurrence of autism, 182 and erroneously assigned those reporting patients who received thimerosal-containing vaccines a higher cumulative thimerosal total than patients who received non-thimerosal-containing vaccines. 183 Further, Dr. Geier's studies lacked transparency regarding his methods and data, making it difficult to evaluate the findings.¹⁸⁴ Accordingly, the 2001 National Academy of Sciences' Institute of Medicine Committee Report concluded Dr. Geier's hypothesis was not supported by clinical or experimental evidence. 185 The court also found that after considering relevant studies and publications, the 2004 Committee readdressed the issue and concluded that the evidence favored a rejection of the hypothesis. 186 Various other members of the relevant scientific community, the American Academy of Pediatrics, the Center for Disease Control and Prevention, the Global Advisory Committee on Vaccine

^{179.} *Id.* at 600, 971 A.2d at 250. Dr. Geier's studies utilized the following third-party databases: Vaccine Adverse Event Reporting System, the Vaccine Safety Datalink, the Department of Education database, and the California Department of Social Services database. *Id.*

^{180.} *Id.* at 604–05, 608, 971 A.2d at 253, 255. This court had not previously addressed the application of the *Frye/Reed* standard to this situation. *Id.* at 604, 971 A.2d at 253. The court, however, found support in persuasive precedent of other federal and state courts. *Id.* at 604–08, 971 A.2d at 253–55 (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136 (1997); Goeb v. Tharaldson, 615 N.W.2d 800 (Minn. 2000)).

^{181.} *Id.* at 601, 971 A.2d at 250–51 (quoting Inst. of Med. of the Nat'l Acads., Immunization Safety Review: Vaccines and Autism 59 n.18 (2004), *available at* http://www.nap.edu/catalog.php?record_id=10997 [hereinafter 2004 IOM Committee Report]).

^{182.} *Id.*, 971 A.2d at 251 (quoting American Academy of Pediatrics, Study Fails to Show a Connection Between Thimerosal and Autism (May 16, 2003), http://www.aap.org/profed/thimaut-may03.htm [hereinafter AAP May 2003 Posting]).

^{183.} Id. at 601-02, 971 A.2d at 251.

 $^{184.\ \}textit{Id.}$ at $602,\,971$ A.2d at 251 (quoting 2004 IOM Committee Report, supra note 181, at 62).

^{185.} *Id.* at 597–98, 971 A.2d at 248–49 (quoting Inst. of Med. of the Nat'l Acads., Immunization Safety Review: Thimerosal-Containing Vaccines and Neurological Disorders 3–4 (2001), *available at* http://books.nap.edu/openbook.php?record_id=10208).

^{186.} Id . at 598–99, 971 A.2d at 249 (citing 2004 IOM Committee Report, supra note 181, at 1).

Safety, and the National Institutes of Health also rejected the hypothesis proffered by Dr. Geier. 187

The relevant scientific community also rejected Dr. Geier's novel theory, that thimerosal-containing vaccines cause autism in genetically susceptible individuals, and analytical framework. 188 According to the court, a generally accepted methodology must be coupled with a generally accepted analysis to avoid "analytical gap" concerns. 189 Dr. Geier's analytical framework was predicated on his unreliable theory that autism was associated with certain genetic polymorphisms that made an individual genetically susceptible to autism. 190 Dr. Geier sought to prove this theory through a differential diagnoses analysis. 191 Differential diagnosis is an analytical tool that determines causation by ruling out other probable causes. 192 Finding support from federal courts, the court claimed that generally, differential diagnoses cannot prove general causation. 193 Before conducting a differential diagnosis, a scientist must have reason to "rule in" a particular cause that is, a scientist must have previously proven general causation—and Dr. Geier improperly "rule[d] in" thimerosal. 194 According to the court, the tests performed by Dr. Geier within the differential diagnosis were not generally accepted methods for diagnosing or determin-

^{187.} *Id.* at 600, 971 A.2d at 250. The court noted that the only publications supporting Dr. Geier's studies and his hypothesis were those written by himself and his son. *Id.* at 600–01, 971 A.2d at 250.

^{188.} *Id.* at 611–12, 971 A.2d at 256–57.

^{189.} Id . at 608, 971 A.2d at 255. The court relied on $\mathit{General\,Electric\,Co.\,v.\,Joiner}$, 522 U.S. 136 (1997):

[[]C]onclusions and methodology are not entirely distinct from one another. . . . [N]othing 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.

Blackwell, 408 Md. at 606, 971 A.2d at 253–54 (emphasis omitted) (quoting Joiner, 522 U.S. at 146).

^{190.} Blackwell, 408 Md. at 608, 611–14, 971 A.2d at 255–59. Genetic polymorphisms are variations in the DNA too common to be new mutations. *Id.* at 615 n.26, 971 A.2d at 259 n.26. Specifically, Dr. Geier considered "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." *Id.* at 611, 971 A.2d at 256–57.

^{191.} Id. at 614-15, 971 A.2d at 259.

¹⁹⁹ Id.

^{193.} *Id.* at 616, 971 A.2d at 259–60 (citing Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005); Doe v. Ortho-Clinical Diagnostics, Inc., 440 F. Supp. 2d 465, 477 (M.D.N.C. 2006)).

^{194.} Id.

ing the causes of autism, 195 and Dr. Geier also failed to consider the most prevalent alleged cause of autism, an unknown genetic etiology. 196

Finally, the court addressed the qualifications of the experts proffered by the Blackwells pursuant to Rule 5-702.¹⁹⁷ The court considered two factors in its analysis: (1) whether the field of expertise was complex; and (2) how central this field was to the resolution of the lawsuit.¹⁹⁸ The court agreed with the conclusion of the Circuit Court for Baltimore City, issued by Judge Berger, that epidemiology was the most relevant scientific field relating to disease causation.¹⁹⁹ The court found the field of epidemiology to be complex²⁰⁰ and that the existence of a causal relationship between thimerosal-containing vaccines and autism was dispositive of the lawsuit.²⁰¹ None of the Blackwells' proffered experts were epidemiologists.²⁰² The experts were qualified to discuss the adverse effects of mercury²⁰³ and thimerosal on the human brain,²⁰⁴ and autism diagnoses in general,²⁰⁵ but these experts lacked the necessary experiences or education needed to determine whether thimerosal exposure causes autism.²⁰⁶

IV. Analysis

In *Blackwell v. Wyeth*, the Court of Appeals of Maryland held the Blackwells' proffered expert testimony inadmissible because the epidemiological expert's novel methodology, theory, and analytical framework were not "generally accepted" within the relevant scientific community as required by *Frye/Reed*,²⁰⁷ and the remaining experts were unqualified to address disease causation under Maryland Rule of Evidence 5-702.²⁰⁸ In so holding, the court correctly excluded the expert testimony,²⁰⁹ but significantly collapsed its analysis of Maryland's

^{195.} *Id.* at 615, 971 A.2d at 259. Dr. Geier performed urinary porphyrin, mercury toxicity, testosterone, and genetic polymorphism tests. *Id.*

^{196.} Id.

^{197.} Id. at 618, 971 A.2d at 261.

^{198.} *Id.* at 629, 971 A.2d at 267.

^{199.} *Id.* at 623–24, 971 A.2d at 264. The court also found support for this conclusion in the 2004 IOM Committee Report. *Id.* at 624, 971 A.2d at 264.

^{200.} Id. at 629, 971 A.2d at 267.

^{201.} Id. at 630, 971 A.2d at 268.

^{202.} Id. at 624, 630, 971 A.2d at 264-65, 268.

^{203.} Id. at 625, 971 A.2d at 265.

^{204.} Id. at 625-26, 971 A.2d at 265.

^{205.} Id. at 626, 971 A.2d at 265-66.

^{206.} Id. at 630, 971 A.2d at 268.

^{207.} Id. at 585, 608-09, 617-18, 971 A.2d at 241, 255, 260-61.

^{208.} Id. at 618, 630, 971 A.2d at 261, 268.

^{209.} See infra Part IV.A.

Frye/Reed standard into the federal Daubert standard.²¹⁰ In particular, the court considered several Daubert factors and supported its reasoning with Daubert precedent.²¹¹ The court should have expressly adopted the Daubert standard to account for differences in the following: (1) potential arguments raised by litigants, (2) the role of judges in determining the admissibility of expert testimony, and (3) the appellate review standards pursuant to either standard. Such an acknowledgement would avoid inconsistent applications of the expert testimony admissibility standard in Maryland courts²¹² and allow trial judges to truly consider the scientific evidence at issue.²¹³

A. The Court of Appeals Correctly Excluded the Blackwells' Expert Testimony Pursuant to Frye/Reed and Rule 5-702

In addition to the requirements of Rule 5-702, which govern all expert testimony, expert testimony discussing novel scientific theories must meet the minimum threshold *Frye/Reed* standard to be admissible.²¹⁴ Therefore, a court may exclude expert testimony because the novel scientific theory was not generally accepted within the relevant scientific community *or* because the expert was not qualified to testify as to that particular subject. The court correctly excluded the Blackwells' epidemiological expert pursuant to the *Frye/Reed* standard and the remaining experts pursuant to Rule 5-702.²¹⁵

 The Court Properly Held that Dr. Geier's Methodology, Theory, and Analytical Framework Were Not "Generally Accepted" Within the Relevant Scientific Community

The court correctly excluded Dr. Geier's expert testimony because the relevant scientific community did not generally accept his

^{210.} See infra Part IV.B.

^{211.} See infra text accompanying notes 244-69.

^{212.} See infra Part IV.C.1-2.

^{213.} See infra Part IV.C.3.

^{214.} See Reed v. State, 283 Md. 374, 389, 391 A.2d 364, 372 (1978) (stating that testimony based on a generally accepted technique will still only be admitted "if a trial judge also determines in the exercise of his discretion . . . that the proposed testimony will be helpful to the jury, that the expert is properly qualified, etc."); Joseph F. Murphy & Paul W. Grimm, Murphy & Grimm's Comparative Guide to the Maryland & Federal Rules of Evidence 238 (2007) ("[I]n [Maryland] state court, there is a dual track that is followed. For all expert testimony involving matters that do not implicate novel scientific issues, Rule 5-702, as interpreted by the courts of appeals governs. For novel scientific evidence, the Reed case applies."). When the Court of Appeals adopted the Rule 5-702, it expressly stated "[t]his Rule is not intended to overrule Reed v. State." Md. R. 5-702 committee's note; see also Lynn McLain, Maryland Rules of Evidence 160 (2007) ("The Committee note makes clear that the Court of Appeals' adoption of Rule 5-702 did not overrule Reed v. State"). 215. See infra Part IV.A.1-2.

methodology, theory, or analytical framework. The identity of the relevant scientific community depends upon the particular technique at issue and generally "include[s] those whose scientific background and training are sufficient to allow them to comprehend and understand the process and form a judgment about it."216 The court found that the National Academy of Sciences' Institute of Medicine ("IOM"), the Center for Disease Control and Prevention ("CDC"), the Global Advisory Committee on Vaccine Safety, the American Academy of Pediatrics, and the National Institutes of Health all refuted the existence of a causal connection between thimerosal-containing vaccines and autism. 217 The court correctly concluded that these government institutions and private groups represented the relevant scientific community for its Frye/Reed analysis. The IOM is an independent, nonprofit organization that "asks and answers the nation's most pressing questions about health and health care . . . to help those in government and the private sector make informed health decisions by providing evidence upon which they can rely."218 The CDC sets forth recommended immunization schedules²¹⁹ and analyzes the Vaccine Adverse Event Reporting System ("VAERS") data in conjunction with the Food and Drug Administration for the reporting of adverse events subsequent to vaccine administration.²²⁰ The World Health Organization established the Global Advisory Committee on Vaccine Safety in 1999 to "respond promptly, efficiently, and with scientific rigour to vaccine safety issues of potential global importance."221 The American Academy of Pediatrics is "an organization of 60,000 pediatricians committed to the attainment of optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults."222 Finally, the National Institutes of Health, "the steward of medical and behavioral research for the Nation," pursues "fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the

^{216.} Reed, 283 Md. at 382, 391 A.2d at 368.

^{217.} Blackwell v. Wyeth, 408 Md. 575, 599-600, 971 A.2d 235, 249-50 (2009).

^{218.} Institute of Medicine of the National Academies, About the IOM, http://www.iom.edu/About-IOM.aspx (last visited Mar. 28, 2010).

^{219.} Center for Disease Control and Prevention, Immunization Schedules, http://www.cdc.gov/vaccines/recs/schedules/default.htm (last visited Mar. 28, 2010).

^{220.} Center for Disease Control and Prevention, Vaccine Safety and Adverse Events, http://www.cdc.gov/vaccines/vac-gen/safety/default.htm (last visited Mar. 28, 2010).

^{221.} World Health Organization, Global Advisory Committee on Vaccine Safety, http://www.who.int/vaccine_safety/en (last visited Mar. 28, 2010).

^{222.} American Academy of Pediatrics, About AAP, http://www.aap.org/about.html (last visited Mar. 28, 2010).

burdens of illness and disability."²²³ Based on the purposes and experiences of the foregoing government institutions and private groups, the court accurately considered them to be the relevant scientific community.

The court correctly concluded that the relevant scientific community did not "generally accept" Dr. Geier's methodology, theory, and analytical framework. Regarding Dr. Geier's methodology, the 2004 IOM Committee Report reviewed "the extant published and unpublished epidemiological studies regarding causality and studies of potential biologic mechanisms by which these immunizations might cause autism,"224 and criticized Dr. Geier's use of the VAERS database because it lacked "complete reporting of all adverse events and because many report events lack[ed] a confirmed diagnosis or confirmed attribution to vaccine."225 As to Dr. Geier's genetic susceptibility theory, the 2001 and 2004 IOM Committee Reports accepted that a biological correlation between genetics and autism was possible, but the court found that none of the specific polymorphisms cited by Dr. Geier was accepted by the relevant scientific community.²²⁶ Finally, Dr. Geier's differential diagnosis omitted an unknown genetic etiology from the list of possible causes of autism,²²⁷ and the 2004 IOM Committee Report specifically opined that "[a] strong genetic component clearly exists," even though "a biological marker specific for autism has not been defined."228 Dr. Geier's failure to consider this possibility rendered his analytical framework unacceptable by the relevant scientific community.²²⁹ Thus, the court correctly excluded Dr. Geier's expert testimony because his methodology, theory, and analytical framework were not generally accepted within the relevant scientific community.

^{223.} National Institutes of Health, About NIH, http://nih.gov/about/#mission (last visited Mar. 28, 2010).

^{224. 2004} IOM COMMITTEE REPORT, supra note 181, at 1.

^{225.} Id. at 59 n.18.

^{226.} Blackwell v. Wyeth, 408 Md. 575, 611–14, 971 A.2d 235, 256–59 (2009); see also 2004 IOM Committee Report, supra note 181, at 139 (finding "no corroborating data . . . linking vaccines or vaccine components to autism based on genetic susceptibility").

^{227.} Blackwell, 408 Md. at 615, 971 A.2d at 259.

^{228. 2004} IOM COMMITTEE REPORT, supra note 181, at 8.

^{229.} Blackwell, 408 Md. at 616-17, 971 A.2d at 260.

2. The Court Properly Found that Dr. Geier and the Blackwells' Remaining Experts Were Unqualified to Testify as to Disease Causation Pursuant to Rule 5-702

The court also correctly excluded the Blackwells' remaining experts, as well as Dr. Geier's testimony, because they were unqualified to testify as to disease causation pursuant to Rule 5-702. According to Rule 5-702(1), the court must determine "whether the witness is qualified as an expert by knowledge, skill, experience, training, or education."230 In mass tort cases, plaintiffs must prove general and specific causation—exposure to the substance can cause harm to an individual and in fact did cause the plaintiff's particular injury.²³¹ Epidemiological studies can provide proof of general causation by "compar[ing] the incidence of defects among groups of persons exposed to a drug to groups of persons not exposed" or by "match[ing] those who have injury with others who are uninjured and compar[ing] the two groups' frequency of exposure to the drug."232 Therefore, the court correctly concluded that epidemiology was the necessary qualification to assess medical and disease causation.²³³ While the court considered Dr. Geier's testimony pursuant to the Frye/Reed standard because he was proffered as an epidemiological expert, it ultimately concluded he was not qualified because he lacked training in both epidemiology and toxicology.²³⁴ The remaining experts were excluded for similar reasons.235

^{230.} Md. R. 5-702(1).

^{231.} Joseph Sanders, From Science to Evidence: The Testimony on Causation in the Bendectin Cases, 46 Stan. L. Rev. 1, 14 (1993).

^{232.} Id. at 14, 22.

^{233.} Other courts have also concluded that epidemiology is the critical field to assess medical causation. *See, e.g.,* Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 830 (D.C. Cir. 1988) ("When [epidemiological] studies are available and relevant, and particularly when they are numerous and span a significant period of time, they assume a very important role in determinations of questions of causation."), *cert. denied,* 493 U.S. 882 (1989); *In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985) (finding epidemiological studies to be "the only useful studies having any bearing on causation"), *aff'd,* 818 F.2d 187 (2d Cir. 1987), *cert. denied,* 487 U.S. 1234 (1988); *In re* Swine Flu Immunization Prods. Liab. Litig., 508 F. Supp. 897, 907 (D. Colo. 1981) ("[W]here... the exact organic cause of a disease cannot be scientifically isolated, epidemiologic data becomes highly persuasive."), *aff'd sub nom.* Lima v. United States, 708 F.2d 502 (10th Cir. 1983).

^{234.} Blackwell, 408 Md. at 624-25, 630, 971 A.2d at 265, 268.

^{235.} Id. at 630, 971 A.2d at 268.

B. The Court of Appeals Collapsed the Frye/Reed Standard into the Daubert Standard by Relying on Daubert Precedent and Considering Several "Daubert Factors" to Exclude Dr. Geier's Testimony

The Court of Appeals's assessment of Dr. Geier's testimony did not simply rely on the absence of general acceptance in the relevant scientific community regarding his theory that thimerosal-containing vaccines can cause autism. Instead, the court articulated a *Daubert* "gatekeeping" role for trial judges, and significantly collapsed Maryland's *Frye/Reed* standard into the federal *Daubert* standard by considering several *Daubert* factors and relying upon *Daubert* precedent. Since "general acceptance" is a *Daubert* factor, the Court of Appeals arguably completed a *Frye/Reed* analysis in name only and assessed Dr. Geier's expert testimony pursuant to the *Daubert* standard. This collapse changes both the arguments litigants ought to raise in support of or against admissibility of expert testimony discussing novel scientific theories, and the role of trial judges in evaluating such evidence.

According to the *Blackwell* court's articulation of *Frye/Reed* jurisprudence, "trial judges [engage] in a serious gate-keeping function, to differentiate serious science from 'junk science.' "236 The court further asserted that "[c]ommentators on the *Frye* standard have recognized the importance of this [gatekeeping] role: 'Courts therefore have a duty to ensure that experts are presenting reliable testimony.' "237 This latter statement was taken out of context by the court. In the article from which the court was quoting, author David E. Bernstein argued for the rejection of *Frye* and adoption of *Daubert*. Bernstein criticized the reasoning behind *Frye*'s limited applicability to scientific evidence only, specifically the risk that juries will consider scientific evidence infallible. Instead, Bernstein argued the risk was present with *any* expert witness, therefore necessitating the trial judge's gatekeeping role for non-scientific expert testimony as well. In *Daubert*, the Supreme Court first articulated

^{236.} Id. at 591, 971 A.2d at 245.

^{237.} *Id.* at 591–93, 971 A.2d at 245–46 (citing and quoting David E. Bernstein, Frye, Frye, *Again: The Past, Present, and Future of the General Acceptance Test*, 41 JURIMETRICS J. 385, 402–03 (2001)).

^{238.} Bernstein, *supra* note 237, at 404 ("A better solution would be for *Frye* jurisdictions to adopt amended Federal Rule of Evidence 702, which incorporates the holding of the Supreme Court's expert evidence trilogy.").

^{239.} *Id.* at 401–02.

^{240.} See id. at 403 (stating that the Supreme Court has likewise recognized that all expert testimony should "be subjected to a reliability test" (citing Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999))).

the trial judge's gatekeeping role: The trial judge must screen expert testimony to ensure all scientific testimony and evidence is relevant and reliable. For the Maryland Court of Appeals to include a reference to the trial judge "gatekeeper" role is an unstated affirmation of *Daubert*²⁴² and rejection of *Reed*. In *Reed*, the court specifically stated that "it [was] . . . *inappropriate* to view" the reliability of new scientific techniques "as a matter within each trial judge's individual discretion." By deeming the trial judge a "gatekeeper," the *Blackwell* court changed the role of the trial judge in determining the admissibility of novel scientific expert testimony in Maryland courts.

Further, the court directly considered the science to specifically explain why the relevant scientific community rejected Dr. Geier's studies. By addressing the reasoning behind the relevant scientific community's rejection of Dr. Geier's methodology, theory, and analytical framework, the Blackwell court considered several Daubert and FRE 702 factors. First, the court considered whether Dr. Geier's epidemiological studies could be "tested." The court cited the 2004 IOM Committee's finding that "[Dr. Geier's] articles [lacked] a complete and transparent description of their methods and underlying data, making it difficult to confirm or evaluate their findings," and the finding that the "the results [were] uninterpretable, primarily due to the lack of a complete description of their methods."245 In other words, Dr. Geier's method was not "testable" given the lack of transparency. The court also considered the "potential rate of error" 246 of Dr. Geier's studies.²⁴⁷ The American Academy of Pediatrics did not accept Dr. Geier's studies because his faulty comparison of "late onset, chronic conditions like autism [with] acute vaccine reactions like fe-

^{241.} Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589, 597 (1993); see also United States v. Prince-Oyibo, 320 F.3d 494, 498 (4th Cir. 2003) ("In Daubert, the Supreme Court made clear that it is the duty of the trial court to perform the gatekeeping function with respect to expert testimony").

^{242.} See 4 Jack B. Weinstein & Margaret A Berger, Weinstein's Federal Evidence § 702.05[1][b] (Joseph M. McLaughlin ed., 2d ed. 2009) (noting that "the 2000 amendments to [FRE] 702 codify the principle that trial courts must perform their gatekeeping role for all proffered expert testimony").

^{243.} Reed v. State, 283 Md. 374, 381, 391 A.2d 364, 367 (1978) (emphasis added).

^{244.} Blackwell v. Wyeth, 408 Md. 575, 601, 602, 971 A.2d 235, 251 (2009); see also Daubert, 509 U.S. at 593 (setting forth "testability" as one of the inquiries to determine admissibility of scientific evidence).

^{245.} Blackwell, 408 Md. at 602, 971 A.2d at 251 (citation and internal quotation marks omitted).

^{246.} See Daubert, 509 U.S. at 594 (setting forth "potential rate of error" as one of the inquiries to determine admissibility of scientific evidence).

^{247.} See Blackwell, 408 Md. at 602, 971 A.2d at 251 (discussing the 2004 IOM Committee Report's findings and noting the improbability of the results of Dr. Geier's studies).

ver, pain, and vomiting" was a serious methodological flaw; there was no indication one corresponded to the other.²⁴⁸ Further, in Dr. Geier's studies comparing thimerosal-containing and thimerosal-free vaccines, he assigned a higher cumulative mercury exposure total for the former vaccines without actual knowledge of exposure data.²⁴⁹ The court's articulation of serious methodological flaws is indicative of a serious "potential rate of error."²⁵⁰

The court also arguably considered two factors discussed in the FRE 702 Advisory Committee's note: (1) "[w]hether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion"; and (2) "[w]hether the expert has adequately accounted for obvious alternative explanations."251 According to the court, Dr. Geier's genetic susceptibility theory "was apparently inspired by statements made in the 2001 and 2004 IOM Report," suggesting that a genetic cause for autism might exist. 252 From this premise, Dr. Geier posited that the A1298C polymorphism in the MTHFR gene was associated with autism. 253 At the Frye/Reed hearing, however, Judge Berger found that this polymorphism, unlike autism, varied across ethnic groups, and therefore *could not* be a genetic cause of the disease.²⁵⁴ Thus, it appears that the *Blackwell* court was troubled by the fact that Dr. Geier "unjustifiably extrapolated" from the accepted premise that a genetic cause for autism might exist to his unfounded conclusion that thimerosal-containing vaccines caused autism in genetically susceptible individuals, specifically those with the A1298C polymorphism in the MTHFR gene.

The court also found that Dr. Geier's differential diagnosis, performed to prove causation for his genetic susceptibility theory, failed to consider an obvious alternative conclusion. The court agreed with Judge Berger's finding that an unknown genetic etiology was the "'single most important alleged cause of autism' "255 and also agreed with his conclusion that Dr. Geier's differential diagnosis neglected to consider this cause. Again, the court moved beyond whether the rele-

^{248.} AAP May 2003 Posting, supra note 182.

^{249.} Blackwell, 408 Md. at 601-02, 971 A.2d at 251.

^{250.} See supra note 246.

^{251.} FED. R. EVID. 702 advisory committee's note.

^{252.} Blackwell, 408 Md. at 611, 971 A.2d at 256.

^{253.} Id. at 611, 971 A.2d at 256-57.

^{254.} Id. at 613, 971 A.2d at 258.

^{255.} See id. at 615–17, 971 A.2d at 259–60 (quoting Blackwell v. Sigma Aldrich, Inc., No. 24-C-04-004829, slip op. at 33 (Md. Cir. Ct. Dec. 21, 2007), available at http://www.baltocts.state.md.us/about/publications/opinions/blackwell_memorandum_opinion.pdf).

^{256.} Id. at 617, 971 A.2d at 260.

vant scientific community accepted Dr. Geier's theory, and specifically considered *Daubert* and FRE 702 factors to support its inadmissibility holding.²⁵⁷

Interestingly, Judge Berger's circuit court opinion also considered two other *Daubert* factors: (1) "whether the theory or technique has been subjected to peer review and publication";²⁵⁸ and (2) "the existence and maintenance of standards controlling the technique's operation."²⁵⁹ Judge Berger addressed defendant Wyeth's contention that the journals publishing Dr. Geier's articles were "relatively obscure or unknown journals that are not typically used to report significant epidemiological studies."²⁶⁰ Judge Berger also noted that Dr. Geier purported to follow the CDC's methodology interpreting VAERS data in his studies, but in actuality, "there [were] significant and material distinctions between the CDC studies and the Geier . . . publications."²⁶¹ While these considerations were well-reasoned, and the court was certainly correct in its holding, these findings significantly depart from what is required pursuant to the *Frye/Reed* standard.

In addition to considering several Daubert factors in its analysis of Dr. Geier's expert testimony, the Court of Appeals also relied on Daubert precedent in two critical points in its reasoning. First, in analyzing Dr. Geier's differential diagnosis, the court noted the following: "[W]e 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 "262" To rationalize extending Frye/Reed to include assessment of an expert's analytical framework, the court relied on General Electric Co. v. Joiner. 263 In Joiner, the United States Supreme Court explained that a trial judge's focus ought to be on the expert's principles and methodology and not his conclusions; however, there also cannot be "too great an analytical gap between the data and the opinion proffered."264 Therefore, the Blackwell court proceeded to scrutinize Dr. Geier's analytical framework surrounding the "generally accepted" VAERS data because "generally accepted

^{257.} See supra text accompanying notes 244-56.

^{258.} See supra text accompanying note 93.

^{259.} See supra text accompanying note 95.

^{260.} Blackwell, No. 24-C-04-004829, slip op. at 24.

^{261.} Id. at 25.

^{262.} Blackwell v. Wyeth, 408 Md. 575, 604-05, 971 A.2d 235, 253 (2009).

^{263.} *Id.* at 605–06, 971 A.2d at 253–54 (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136 (1997)).

^{264.} Joiner, 522 U.S. at 146.

methodology . . . must be coupled with generally accepted analysis in order to avoid the pitfalls of an 'analytical gap.'"²⁶⁵ The court then cited two *Daubert* cases, originally cited by Judge Berger, that lent support to Judge Berger's ultimate rejection of Dr. Geier's utilization of differential diagnoses.²⁶⁶ According to *Ruggiero v. Warner-Lambert Co.*²⁶⁷ and *Doe v. Ortho-Clinical Diagnostics, Inc.*,²⁶⁸ both *Daubert* cases, differential diagnosis should not be used to prove general causation.²⁶⁹

While the above findings were all relevant pursuant to a Daubert analysis, they are unnecessary pursuant to a strict Frye/Reed analysis. On the one hand, Frye/Reed permits judges to rely upon the assertions of the relevant scientific community.²⁷⁰ Daubert, on the other hand, demands an investigation into the underlying science prior to admission.²⁷¹ It is apparent that the *Blackwell* court performed the latter in this case. To account for this shift in the court's analysis, litigants must be prepared to argue for or against the actual science employed by the proffered expert and not simply discuss its acceptance or rejection by the relevant scientific community. Such a shift also alters the role of the trial judge in assessing the admissibility of expert testimony discussing novel scientific theories. Both Judge Berger and the Court of Appeals considered more than the relevant scientific community's ultimate conclusion regarding Dr. Geier's testimony, and specifically addressed why Dr. Geier's methodology, theory, and analytical framework were not "generally accepted."

^{265.} Blackwell, 408 Md. at 608, 971 A.2d at 255 (quoting Joiner, 522 U.S. at 146).

^{266.} *Id.* at 615–16, 617, 971 A.2d at 259, 260 (citing Ruggiero v. Warner-Lambert Co., 424 F.3d 249 (2d Cir. 2005); Doe v. Ortho-Clinical Diagnostics, Inc., 440 F. Supp. 2d 465 (M.D.N.C. 2006)); *Blackwell*, No. 24-C-04-004829, slip op. at 48 (citing these same cases).

^{267. 424} F.3d 249.

^{268. 440} F. Supp. 2d 465.

^{269.} *Ruggiero*, 424 F.3d at 253, 254 ("[T]his method does not (necessarily) support an opinion on general causation, because, like any process of elimination, it assumes that the final, suspected cause remaining after this process of elimination must actually be *capable* of causing the injury." (citations and internal quotation marks omitted)); *Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d at 469, 477 ("Generally, it is not appropriate to rely on a differential diagnosis to prove general causation.").

^{270.} See supra Part II.A.1.

^{271.} See supra Part II.B.

C. The Court of Appeals Should Have Acknowledged Frye/Reed's Collapse into Daubert in Maryland Case Law and Replaced the Frye/Reed Standard with Daubert to Avoid Inconsistencies in Both Application and Appellate Review Standards, and to Promote a True "Gatekeeper" Role for Trial Judges

In the wake of *Daubert*, several states have either adopted the entire *Daubert* trilogy,²⁷² portions of the *Daubert* trilogy,²⁷³ or found the *Daubert* trilogy instructive.²⁷⁴ Arguably, Maryland falls into the final category, as Maryland case law has merged with the federal *Daubert* standard by relying upon *Daubert* precedent and considering several *Daubert* factors in its exclusion of expert testimony in *Blackwell*.²⁷⁵ To avoid inconsistent applications of expert testimony admissibility standards²⁷⁶ and the different appellate standards of review required by *Frye/Reed* and *Daubert*,²⁷⁷ the Court of Appeals should have adopted the *Daubert* standard because of its broader applicability and true "gatekeeper" role for trial judges, which permits actual consideration of the science behind expert testimony.²⁷⁸

 The Court of Appeals Should Have Acknowledged Frye/Reed's Collapse into Daubert and Replaced the Frye/Reed Standard with Daubert to Avoid Inconsistent Applications of Expert Admissibility Standards in Maryland Courts

While continuing to state adherence to *Frye/Reed*,²⁷⁹ the Maryland Court of Special Appeals and the Maryland Court of Appeals have found *Daubert* instructive on several occasions,²⁸⁰ culminating in the *Blackwell* court's reliance on *Joiner* and the *Daubert* factors in excluding

^{272.} David E. Bernstein & Jeffrey D. Jackson, *The Daubert Trilogy in the States*, 44 Jurimetrics J. 351, 357 (2004).

^{273.} Id. at 357-58.

^{274.} Id. at 361.

^{275.} See supra Part IV.B.

^{276.} See infra Part IV.C.1.

^{277.} See infra Part IV.C.2.

^{278.} See infra Part IV.C.3.

^{279.} See Wilson v. State, 370 Md. 191, 201, 803 A.2d 1034, 1039 (2002) ("[T]his Court adopted the standard set forth in Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), for determining the admissibility of scientific evidence and expert testimony."); Burral v. State, 352 Md. 707, 737–38, 724 A.2d 65, 80 (1999) (stating that despite the Supreme Court's rejection of Frye, "we have not abandoned Frye or Reed"); Giant Food, Inc. v. Booker, 152 Md. App. 166, 184 n.11, 831 A.2d 481, 491 n.11 (2002) ("Maryland courts still adhere to the Reed-Frye 'general acceptance' standard." (citations omitted)), cert. denied, 378 Md. 614, 837 A.2d 926 (2003).

^{280.} See Wood v. Toyota Motor Corp., 134 Md. App. 512, 523 n.13, 760 A.2d 315, 322 n.13 (2000) ("[Maryland] case law is consistent with the amendments to Rule 702 of the Federal Rules of Evidence."), cert. denied, 362 Md. 189, 763 A.2d 735 (2000); Giant Food,

Dr. Geier's testimony.²⁸¹ This inclusion and deference to *Daubert*, however, has not been uniform throughout Maryland courts. Therefore, the Court of Appeals should have adopted *Daubert* to maintain consistency in the application of expert testimony admissibility standards.

In recent years, the trend in Maryland courts has been toward greater acceptance of the trial judge's "gatekeeper" role in assessing the admissibility of expert testimony. Beginning with *Wilson v. State*, ²⁸² the Court of Appeals stated that trial judges had "wide latitude in determining whether expert testimony is sufficiently reliable to be admissible" pursuant to Rule 5-702. ²⁸³ Five years later, in *Montgomery Mutual Insurance Co. v. Chesson*, ²⁸⁴ the court referenced the trial judge's "wide latitude" in assessing the reliability of expert testimony, and further articulated that the *Frye/Reed* standard required both general acceptance in the scientific community and a reliable method. ²⁸⁵ This trend culminated in *Blackwell* when the court stated "our [*Frye/Reed*] jurisprudence engages trial judges in a serious gate-keeping function." ²⁸⁶

This trend, however, has not been consistent. In CSX Transportation, Inc. v. Miller, ²⁸⁷ the Court of Special Appeals criticized Kumho Tire Co. v. Carmichael "as a tediously fact-specific 'tempest in a teapot,' in large measure over whether the term 'gatekeeper' [could] be applied to characterize a judge ruling on the admissibility of expert opinion testimony." According to the court, the term "gatekeeper" seemed to be "loaded with some sort of magical cachet," highlighting that not all Maryland courts embraced this role for trial judges making evidence admissibility determinations. Whether a judge performs a "gatekeeper" role and assesses the science prior to admission of expert testimony or whether a judge simply defers to the relevant scientific

Inc., 152 Md. App. at 183–84, 831 A.2d at 491 (using language from FRE 702 to describe Maryland's approach to the admissibility of scientific evidence).

^{281.} See supra Part IV.B.

^{282. 370} Md. 191, 803 A.2d 1034.

^{283.} Id. at 200, 803 A.2d at 1039.

^{284. 399} Md. 314, 923 A.2d 939 (2007).

^{285.} Id. at 326-27, 923 A.2d at 946.

^{286.} Blackwell v. Wyeth, 408 Md. 575, 591, 971 A.2d 235, 245 (2009).

^{287. 159} Md. App. 123, 858 A.2d 1025 (2004), cert. granted, 384 Md. 581, 865 A.2d 589 (2005), cert. dismissed, 387 Md. 351, 875 A.2d 702 (2005).

^{288. 526} U.S. 137 (1999).

^{289.} CSX Transp., Inc., 159 Md. App. at 183, 858 A.2d at 1059 (citing Kumho, 526 U.S. 137).

^{290.} Id.

community are different functions for trial judges that the Court of Appeals should reconcile.

Maryland courts' consideration of Daubert precedent when conducting a Frye/Reed analysis highlights a separate convergence trend within Maryland case law.²⁹¹ In Wood v. Toyota Motor Corp.,²⁹² the court referenced the 2000 amendment to FRE 702 and opined that "[Maryland] case law is consistent with the amendments to Rule 702 of the Federal Rules of Evidence."293 The Blackwell court adopted this stance by relying on Joiner, Ortho-Clinical Diagnostics, Inc., and Ruggiero to support its reasoning.²⁹⁴ This trend, however, is also inconsistent within Maryland courts. First, the 2000 amendment to FRE 702 referenced in Wood derived in part from Kumho, 295 and, as noted above, the Court of Special Appeals rejected Kumho in CXS Transportation, Inc. 296 The court in CXS Transportation, Inc., also criticized as highly questionable the appellant's reliance on the following: "1) Daubert . . . a Supreme Court case dealing exclusively with the federal law of evidence; 2) the Federal Rules of Evidence; and 3) lower federal court cases dealing with the federal law of evidence."297 These two different understandings of the relevance of *Daubert* precedent to a *Frye/Reed* analysis cannot be reconciled and necessitate a clear instruction from the Court of Appeals.

^{291.} Maryland courts have utilized *Daubert* precedent to support their *Frye/Reed* holdings. *See, e.g.*, Montgomery Mutual Ins. Co. v. Chesson, 399 Md. 314, 330–31, 923 A.2d 939, 948 (2007) (supporting its application of the *Frye/Reed* standard to expert medical testimony attempting to establish that mold exposure causes illness by reviewing similar holdings in *Daubert* and *Frye* jurisdictions); Conaway v. Deane, 401 Md. 219, 292–94 n.57, 932 A.2d 571, 615–16 n.57 (2007) (observing that no *Frye* or *Daubert* jurisdictions admitted scientific or sociological studies attempting to prove that homosexuality was an immutable characteristic).

^{292. 134} Md. App. 512, 760 A.2d 315 (2000), cert. denied, 362 Md. 189, 763 A.2d 735 (2000).

^{293.} Id. at 523 n.13, 760 A.2d at 322 n.13.

^{294.} See supra text accompanying notes 262-69.

^{295.} See Fed. R. Evid. 702 advisory committee's note (explaining that the amendments were a result of *Daubert* and other cases applying *Daubert*, including *Kumho*).

^{296.} See supra notes 287-90 and accompanying text.

^{297.} CSX Transp., Inc v. Miller, 159 Md. App. 123, 182–83, 858 A.2d 1025, 1059 (2004), cert. granted, 384 Md. 581, 865 A.2d 589 (2005), cert. dismissed, 387 Md. 351, 875 A.2d 702 (2005); see also supra note 142 (highlighting several Maryland cases articulating a continued adherence to Frye/Reed).

2. The Reasoning Behind Frye/Reed's De Novo Appellate Review Standard Does Not Translate to Maryland Courts' Application of the Daubert Standard

The unstated collapse of Maryland's *Frye/Reed* standard into the federal *Daubert* standard fails to account for the differences in appellate review standards and the reasoning behind each. Maryland courts review trial judges' *Frye/Reed* admissibility determinations de novo.²⁹⁸ In *Reed*, the Court of Appeals of Maryland reasoned the following:

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.²⁹⁹

In contrast, the United States Supreme Court in *Joiner* reasoned that a trial judge's gatekeeping role screening evidence necessitated an abuse of discretion standard of review. According to the *Joiner* Court, [c]ases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous. In *Blackwell*, however, the court found Maryland's *Frye/Reed* jurisprudence to be consistent with a "gatekeeping" trial judge role but reviewed Judge Berger's *Frye/Reed* evidentiary determinations de novo. This articulation is not consistent with the above reasoning set forth in *Joiner* or *Reed*.

^{298.} Wilson v. State, 370 Md. 191, 201 n.5, 803 A.2d 1034, 1040 n.5 (2002).

^{299.} Reed v. State, 283 Md. 374, 381, 391 A.2d 364, 367 (1978).

^{300.} Gen. Elec. Co. v. Joiner, 522 U.S. 136, 141-42 (1997).

^{301.} *Id.* at 142 (emphasis added) (alteration in original) (internal quotation marks omitted) (quoting Spring Co. v. Edgar, 99 U.S. 645, 658 (1878)).

^{302.} Blackwell v. Wyeth, 408 Md. 575, 591, 971 A.2d 235, 245 (2009).

^{303.} Id. at 580 n.9, 971 A.2d at 238 n.9.

^{304.} A gatekeeping approach to evidentiary determinations is not consistent with a de novo standard of review. *See, e.g.*, Brief for Aluminum Co. of America et al. as Amicus Curiae in Support of Petitioners at *9–10, Gen. Elec. Co. v. Ingram, 513 U.S. 1190 (1995) (No. 94-1070), 1995 WL 17107881 (arguing that "the Third Circuit's one-way 'hard look' approach . . . will only undermine [the Supreme Court's] ruling in *Daubert* and discourage trial judges from continuing to follow its mandate to act as gatekeepers." According to the brief, the Third Circuit's "'hard look'" was virtually a de novo appellate review standard. *Id.* at *3.

3. The Court of Appeals Should Have Adopted Daubert Because of Its Broader Applicability and the Trial Judge's "Gatekeeper" Role Requires Actual Consideration of Science

The Court of Appeals should have adopted Daubert because Daubert's broader applicability resolves many problems inherent in the Frye/Reed standard. 305 In Frye jurisdictions, a court must resolve whether the proffered expert testimony incorporates scientific evidence,306 whether that evidence is novel prior to conducting a "general acceptance" analysis, 307 and how "general acceptance" can be demonstrated.³⁰⁸ In addition, the jurisdiction must also have a separate articulated standard for all other expert testimony.³⁰⁹ Daubert removes all of these issues. First, Daubert does not simply apply to novel scientific theories: "Although the Frye decision itself focused exclusively on 'novel' scientific techniques, [the Supreme Court did] not read the requirements of [FRE] 702 to apply specially or exclusively to unconventional evidence."310 Further, in Kumho, the United States Supreme Court stated that "as a matter of language, [FRE 702] applies its reliability standard to all 'scientific,' 'technical,' or 'other specialized' matters within its scope."311 According to the Court, there was no reason not to extend Daubert's "basic gatekeeping obligation" to all expert testimony.³¹²

Application of the *Frye/Reed* standard also does not require "[t]he court itself . . . to comprehend the science involved"; indeed, "[it] only had to assure itself that among the people involved in the field, the technique was accepted as reliable." Further, this "general ac-

^{305.} See Bernstein, supra note 237, at 404–07 (arguing that Daubert and FRE 702 apply to an expert's reasoning and non-scientific opinion testimony, and require trial judges to "grappl[e] with the quality of the scientific evidence before them"); Andrew R. Stolfi, Note, Why Illinois Should Abandon Frye's General Acceptance Standard for the Admission of Novel Scientific Evidence, 78 Chi-Kent L. Rev. 861, 887 (2003) (articulating three problems raised by Frye's application to only novel scientific evidence: "(1) defining 'novel,' (2) defining 'scientific evidence,' and (3) determining what standard to apply to the admission of other types of expert evidence").

^{306. 22} Charles Alan Wright & Kenneth W. Graham, Jr., Federal Practice and Procedure 87 n.10 (1978) ("What is 'scientific evidence' to which the test applies? When a witness testifies that he saw the defendant throw a rock at the victim, the inferences to be drawn from this testimony involve a number of principles of physics, but few courts would apply the Frye test.").

^{307.} Stolfi, *supra* note 305, at 887.

^{308.} Bernstein, supra note 237, at 407.

^{309.} Id. at 405; Stolfi, supra note 305, at 887.

^{310.} Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 592 n.11 (1993).

^{311.} Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147 (1999).

^{312.} Id.

^{313.} Weinstein & Berger, supra note 242, § 702.05[1].

ceptance" standard remains "remarkably vague." The court must determine what field of science is at issue prior to determining the identity of the relevant scientific community and what exactly constitutes "general acceptance." In contrast, the *Daubert* standard does not allow courts "to avoid grappling with the quality of the scientific evidence before them." According to Judge Grimm, "[u]nder *Daubert*... the trial court [is] forced to reckon with the factors that really do determine whether the evidence is reliable, relevant and 'fits' the case at issue." The Court of Appeals ought to adopt *Daubert* to require consideration of the science upon which expert testimony is based.

Finally, the reasoning behind the *Frye/Reed* standard actually favors the *Daubert* approach as *Daubert* has proven to be the stricter standard. According to *Reed*, "*Frye* was deliberately intended to interpose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles." The court in *Blackwell* reaffirmed this approach to admissibility: Fairness to the litigant permits "the 'Frye standard [to] retard[] somewhat the admission of proof based on new methods of scientific investigation.' Therefore, to remain consistent with the reasoning behind the *Frye/Reed* standard, the court should have adopted the stricter *Daubert* standard.

V. Conclusion

In *Blackwell v. Wyeth*, the Maryland Court of Appeals addressed the admissibility of expert testimony attempting to prove a causal connection between thimerosal-containing vaccines and autism.³²¹ The court held the testimony of the Blackwells' proffered epidemiological expert inadmissible pursuant to the *Frye/Reed* standard because his methodology, theory, and analytical framework were not generally accepted within the relevant scientific community.³²² The court also

^{314.} Wright & Graham, supra note 306, at 87.

^{315.} McCormick's Handbook of the Law of Evidence 490 (Edward W. Clearly ed., 2d ed. 1972) ("The difficulty [is] of determining how to distinguish scientific evidence from other expert testimony, of deciding what is the particular field of science to which the evidence belongs, and of settling what is general acceptance").

^{316.} Bernstein, supra note 237, at 406.

^{317.} United States v. Horn, 185 F. Supp. 2d 530, 553 (D. Md. 2002).

^{318.} Bernstein, supra note 237, at 404.

^{319.} Reed v. State, 283 Md. 374, 386, 391 A.2d 364, 370 (1978) (internal quotation marks omitted) (quoting People v. Kelly, 549 P.2d 1240, 1245 (Cal. 1976)).

^{320.} Blackwell v. Wyeth, 408 Md. 575, 586, 971 A.2d 235, 242 (2009) (citations and internal quotation marks omitted) (citing *Reed*, 283 Md. at 385, 391 A.2d at 369–70).

^{321.} Id. at 577, 971 A.2d at 236-37.

^{322.} Id. at 585, 608-09, 617-18, 971 A.2d at 241, 255, 260-61.

found the plaintiff's remaining experts lacked the necessary qualifications to testify as to disease causation pursuant to Maryland Rule of Evidence 5-702.³²³ In so holding, the court accurately excluded the expert testimony,³²⁴ but collapsed the Maryland *Frye/Reed* admissibility standard into the federal *Daubert* standard by relying on *Daubert* precedent and considering several *Daubert* factors.³²⁵ This unacknowledged collapse does not account for differences in the potential arguments to be raised by litigants, the roles of trial judges in determining admissibility of expert testimony discussing novel scientific theories, and finally, the appellate review standards associated with the *Frye/Reed* and *Daubert* standards. Instead, the court should have formally adopted *Daubert* to avoid inconsistencies in expert testimony admissibility standards³²⁶ and to promote a true "gatekeeper" role for trial judges.³²⁷

^{323.} Id. at 618, 630, 971 A.2d at 261, 268.

^{324.} See supra Part IV.A.

^{325.} See supra Part IV.B.

^{326.} See supra Part IV.C.1-2.

^{327.} See supra Part IV.C.3.