**809 A.2d 77 (2002)**
**174 N.J. 412**

**Delisha KEMP, a minor, by her parent and natural guardian, Debra WRIGHT, and Debra Wright, in her own right, Plaintiffs-Appellants,**

**v.**

**STATE of New Jersey, County of Burlington, Riverside Board of Education and Riverside High School, Defendants-Respondents, and**

**John Does Manufacturers (1-10); Richard Roes Distributors (1-10); and Robert Does (1-10) (fictitious names) individually, jointly, severally, and/or in the alternative, Defendants.**

**Supreme Court of New Jersey.**

Argued October 10, 2001.
Decided August 20, 2002.

78 *78 David K. Cuneo, Collingswood, argued the cause for appellants (Cuneo & Hensler, attorneys).

Glenn R. Jones, Deputy Attorney General, argued the cause for respondent **State** of New Jersey (John J. Farmer, Jr., Attorney General of New Jersey, attorney; Michael J. Haas, Assistant Attorney General, of counsel; Karen L. Jordan, Deputy Attorney General, on the brief).

Timothy E. Annin, argued the cause for respondent County of Burlington.

Frank G. Basile, Vineland, argued the cause for respondents Riverside Board of Education and Riverside High School (Basile & Testa, attorneys; Mr. Basile and Renee E. Scrocca, on the brief).

The opinion of the Court was delivered by STEIN, J.

In this appeal we consider whether plaintiffs' expert's opinion, determined by the trial court to be scientifically unreliable, properly was excluded from evidence. Plaintiffs, Delisha **Kemp** (Delisha), a minor, by her mother and guardian, Debra **Wright** (Debra), and Debra **Wright** individually, appeal from the judgment of the Appellate Division affirming the trial court's grant of summary judgment dismissing their personal injury action against defendants **State** of New Jersey, Burlington County and Riverside Board of Education (Riverside).

Plaintiffs allege in their complaint that defendants negligently had administered a rubella virus vaccine to Debra while she was pregnant with Delisha, claiming that the vaccine caused Delisha to develop Congenital Rubella Syndrome (CRS). The trial court determined that plaintiffs' medical expert's opinion, elicited in the course of defendants' deposition of the expert, that concluded that the rubella vaccine was the proximate cause of Delisha's CRS condition could not be presented to the jury because it was scientifically unreliable. Because the expert's testimony was essential to plaintiffs' *prima facie* case, the
79 trial court granted defendants' motion for summary *79 judgment. The Appellate Division affirmed. Although we agree with the courts below that the expert's opinion in its present form is not admissible, we now reverse and remand to the Law Division to conduct a *N.J.R.E.* 104 hearing and redetermine the admissibility of the expert's testimony.

# I

## A

During the spring of 1975, an outbreak of measles and rubella of near epidemic proportions occurred in Burlington County. In response, Burlington County health officials, with the cooperation of the Riverside Board of Education and the New

Jersey Department of Health, organized and operated a free immunization clinic at Riverside High School. On April 18, 1975, Debra, a senior at the high school, was given a rubella vaccine at the clinic. Debra either was pregnant or soon to become pregnant when she received the vaccine. On December 28, 1975, she gave birth to Delisha. Delisha was born with CRS and is currently afflicted with severe birth defects that require continuing medical treatment.

In 1973 and 1974, the product information provided for the rubella vaccine specifically recommended that pregnant women not be given the vaccine. The product information also recommended that women of child-bearing age not be considered for vaccination unless there was no possibility of pregnancy at the time of the injection or in the following two to three months. Defendants **state** that the standard practice at the Riverside High School clinic was to counsel all females of childbearing age about the risks of vaccination and to refrain from inoculating any female who was pregnant or sexually active. They also assert that a pre-vaccination screening was conducted during which students were questioned about the status of their sexual activity.

In October 1992, plaintiffs filed a complaint alleging that the rubella vaccination that defendants administered to Debra caused an infection in the fetus resulting in Delisha's CRS. The plaintiffs further alleged that defendants were negligent in failing to ascertain prior to her vaccination whether Debra was pregnant or sexually active. In addition, plaintiffs alleged that Debra was not informed that she should not be vaccinated if she were pregnant because the vaccine could cause severe birth defects to an unborn child.

At an early **state** of the litigation, the Law Division dismissed plaintiffs' complaint, holding that defendants were immune from suit pursuant to the provisions of the Tort Claims Act, *N.J.S.A.* 59:1-1 to *N.J.S.A.* 59:13-10. The Appellate Division affirmed. However, this Court reversed the judgment of the Appellate Division and reinstated plaintiffs' complaint. ***Kemp** v. **State***, 147 *N.J.* 294, 297, 687 *A.*2d 715 (1997).

Defendants subsequently moved again for summary judgment, asserting on the basis of their deposition of plaintiffs' expert that plaintiffs had failed to provide a scientifically reliable medical expert report to demonstrate that the rubella vaccination was the cause of Delisha's CRS. Defendants claimed that the report submitted by plaintiffs' medical expert constituted a net opinion, was scientifically unreliable and thus inadmissible. The trial court, without conducting an evidentiary hearing on the issue of the admissibility of expert's opinion, determined that plaintiffs' expert, Dr. George Huggins, failed to proffer a scientifically acceptable basis for his opinion that the rubella immunization Debra received in
80 April 1975 caused Delisha to develop CRS. Accordingly, the trial *80 court held that Dr. Huggins' opinion was inadmissible. Because plaintiffs were unable to prove their *prima facie* case without Dr. Huggins' report, the court granted defendants' motion for summary judgment dismissing plaintiffs' complaint. Plaintiffs' motion for reconsideration was denied.

In an unpublished opinion, the Appellate Division affirmed the ruling of the trial court that Dr. Huggins' opinion was inadmissible. The Appellate Division, quoting *Rubanick v. Witco Chemical Corp.*, 125 *N.J.* 421, 449, 593 *A.*2d 733 (1991), observed that "Dr. Huggins' opinion that a causal relation exists is not sufficiently reliable because it is not `based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field.'" The court continued:

> Indeed it can be said that he applied no methodology at all in reaching his conclusion. He acknowledges that no study, report, medical journal, treatise, epidemiological or toxicology data, or other recognized authority has demonstrated a correlation between attenuated rubella vaccines and congenital rubella syndrome in a child born with congenital rubella syndrome. His opinion has not been the subject of peer review or adopted by any recognized scientific disciplines. Because he could identify no such data or scientific study, it cannot be said that his opinion is founded on a scientifically tested and accepted methodology recognized by the medical community.

We granted plaintiffs' petition for certification. ***Kemp** v. **State**,* 167 *N.J.* 635, 772 *A.*2d 937 (2001).

## B

Dr. Huggins' credentials are impressive. He presently is Chairman of the Department of Obstetrics & Gynecology at Johns Hopkins Bayview Medical Center in Baltimore, Maryland. Since 1995, he has been a Professor of Obstetrics and Gynecology at Johns Hopkins University School of Medicine. Dr. Huggins has held faculty appointments at the University of Mississippi School of Medicine and the University of Pennsylvania School of Medicine. He also has held a fellowship appointment as a visiting professor with the Department of Community Medicine and General Practice at Oxford University in Oxford, England. Dr. Huggins has written numerous articles and book chapters on women's reproductive health.

During discovery, Dr. Huggins submitted two reports on behalf of plaintiffs dated October 22, 1990, and November 6, 1990, and was deposed by defendants' counsel on June 13, 1997. Dr. Huggins concluded in his reports that it could be determined within a reasonable degree of medical certainty that Delisha suffers from CRS as a result of the rubella immunization that Debra received in April 1975. He also concluded that "[b]ecause the program and care givers did not determine the pregnancy status or the possibility of pregnancy in Delisha **Kemp's** mother, in my opinion, they significantly deviated from standard of care at that time."

Dr. Huggins explained in his report and testified at his deposition that his methodology included a review of Debra's obstetrical admission records from Burlington County Memorial Hospital where Delisha was born. He also reviewed several medical reports by various doctors, including a cardiologist, a neurologist and an ophthalmologist, each of whom had evaluated Delisha's condition after her birth. Dr. Huggins testified during his deposition that those medical reports established that Delisha has a "constellation of mental retardation, microcephaly, cardiac abnormalities, cataracts, hearing
81 loss, *81 which is compatible with rubella syndrome," and that Delisha has what is medically recognized and diagnosed as CRS.

Dr. Huggins also testified that the rubella vaccine, which is a live attenuated virus, is capable of crossing the placenta and entering the developing fetus or embryo. Dr. Huggins explained that that attribute of the vaccine has been established through scientific studies that confirm the presence of the attenuated rubella virus in the fetal tissue of the offspring of women who did not carry to term and who had received the rubella inoculations during pregnancy, or within three months of becoming pregnant. During his deposition Dr. Huggins testified:

> We know from basic studies ... that the rubella vaccine is a live attenuated vaccine, and that when it's injected into an individual it replicates and causes a mild infection in that particular individual, which is what stimulates the immune system to develop antibodies to the virus. We know that in humans this virus in the vaccine crosses the placenta and enters the developing fetus and/or embryo. And there have been basic studies done in the laboratory which have documented the presence of the virus in placenta and in fetal tissue. Whenever there is documentation of infection by a virus that is known to be a teratogen [drug, virus or agent that can cause congenital malformation], it's reasonable to conclude that if a recognized syndrome develops in someone who's been given the vaccine early in pregnancy, that there is proximate cause that the virus that was injected into the individual indeed did cause the rubella syndrome.

Defendants acknowledge that the attenuated virus can cross the placenta and be present in the fetus.

Dr. Huggins further testified that there is no medical evidence that Debra contracted the wild Rubella virus before or during her pregnancy. Dr. Huggins points out that "[t]here is no indication in the medical records of a clinical rubella infection during pregnancy." Dr. Huggins concluded that the only documented exposure of Delisha in utero to the live rubella virus was the rubella vaccine that Debra received immediately before or during her pregnancy.

Dr. Huggins referred to the recommendation of the FDA proscribing the administration of the rubella vaccine in early pregnancy to avoid the risk of infecting the fetus. In addition, Dr. Huggins testified that when the vaccine was first administered it was recommended that pregnant women who were inadvertently inoculated should consider aborting the fetus. He acknowledged that there are some physicians who now believe that inadvertent inoculation of a pregnant woman is not an absolute indication for abortion.

During Dr. Huggins' deposition defendants' counsel identified and referred to two editions of the Red Book, published by the American Academy of Pediatrics. The 1994 edition stated that abortion *ordinarily* is not indicated to interrupt

pregnancy when a pregnant woman has received a rubella vaccination. Defendants' counsel pointed out that the 1997 edition contained a revised statement to the effect that rubella vaccination during pregnancy is *not* an indication for interruption of pregnancy.

Defendants argue that Dr. Huggins did not arrive at his conclusion using an accepted scientific methodology. They note the absence of any medical support or scientific evidence confirming that there is a causal connection between the rubella
82 vaccination and CRS. The trial court and the Appellate Division also noted the absence *82 of medical studies or reports establishing a causal connection between rubella vaccination during pregnancy and CRS. Furthermore, defendants argue that it is well established that the wild rubella virus, if contracted by a pregnant woman, can cause CRS and that Debra was exposed to the wild rubella virus during the rubella outbreak. Defendants also claim that studies conducted by the Center for Disease Control (CDC) confirm that the attenuated virus does not cause CRS.

The CDC findings are summarized and explained in an article entitled "Fetal Risk Associated with Rubella Vaccine: An Update." Sandra W. Bart, et al., "Fetal Risk Associated with Rubella Vaccine: An Update," 7 *Reviews of Infectious Diseases* 95 (Supp.Mar.-Apr.1985). That article states that in 1970, at a symposium held by the National Institute of Health, data was presented indicating the ability of the rubella vaccine virus to cross the placenta and infect the developing fetus, leading to concerns about teratogenicity.[1] In order to monitor the risks to the fetus after exposure to the attenuated rubella virus, the CDC maintained a register of women who received rubella vaccinations shortly before or after they became pregnant. The women were then observed to determine the outcome of their pregnancies. Significantly, the data was obtained by means of a passive reporting system, in which reports were submitted voluntarily by physicians, patients and **state** and local health departments. The CDC recognized that that method of reporting increased the likelihood that the data collected might be incomplete.

Reported women were classified into one of three categories of immune status: 1) susceptible—seronegativity (negative reaction to serological test) for rubella antibody documented within one year of vaccination; 2) immune—seropositivity (positive reaction to serological test) before or within two weeks after vaccination; and 3) unknown immune status. Between 1971 and April 1979, the CDC received reports concerning 149 susceptible pregnant women who received the Cendehill or HPV-77 strain of vaccine, and also received reports from 1979 to 1983 concerning 157 susceptible pregnant women who received the RA 27/3 vaccine. (In 1979, the RA27/3 vaccine was introduced and replaced the Cendehill and HPV-77 vaccines. Because Debra was vaccinated in 1975, we assume that she received either the Cendehill or HPV-77 strain of vaccine.) Of those 149 susceptible women who were vaccinated with Cendehill or HPV-77, the outcome of the pregnancies (live birth, stillbirth, or abortion) was known and reported for 143 of the women. Out of the 143 women, 94 (65.7%) delivered living infants. Three of those infants had "laboratory evidence of subclinical rubella infection at birth."[2] *Id.* at 98. However, subsequent reports revealed that they were all growing and developing normally at least two years after their births. Of the 157 susceptible pregnant women who received the RA27/3 vaccine, 119 women delivered 121
83 living infants. One of those infants had "laboratory *83 evidence of subclinical rubella infection" but subsequent reports also revealed that the infant was developing normally. *Ibid.*

The CDC concluded that because no infants with CRS were born to 214 susceptible mothers (94 who received the Cendehill or HPV-77 vaccines, 119 who received the RA27/3 vaccine and one who received a vaccine of unknown strain), "the *observed* risk to date is zero." *Id.* at 101 (emphasis added). Nevertheless, the CDC suggested that "[t]he occurrence of any congenital defect after maternal vaccination during pregnancy deserves careful analysis and follow-up." *Ibid.* In addition, the CDC noted that the available data on the RA27/3 vaccine seems to indicate a lower, almost negligible, potential risk of CRS to the developing fetus for women who received that vaccine compared to the greater risk for women who received the Cendehill or HP-77 vaccines prior to April 1979. The CDC added that "[h]owever, because of the theoretical—albeit minimal-risks of CRS, women known to be pregnant should not be vaccinated" and that "[r]easonable precautions before vaccination include asking women if they are pregnant." *Ibid.*

Finally, a summary of the report appearing at the beginning of the article states:

> One hundred nineteen women susceptible to rubella received RA27/3 vaccine, 94 received either Cendehill or HPV-77, and one received a vaccine of unknown strain in the three months before or after their

> estimated date of conception. They gave birth to 216 living infants [including two sets of twins] free of abnormalities compatible with the congenital rubella syndrome(CRS). The maximum theoretical risk for CRS for these infants was 1.7%. Four of these infants born to susceptible women had laboratory evidence of subclinical infection (three after receiving Cendehill or HPV-77 vaccines and one after receiving RA27/3 vaccine) but were normal at birth and at subsequent follow-up examinations. *Rubella virus was isolated from the products of conception for only 3% (1 of 32) of cases involving susceptible women who received RA27/3 vaccine; the reported rate of virus isolation for Cendehill and HPV-77 vaccine is 20%. The available data indicate that if vaccination occurs within three months of conception, the risk is negligible. However, since the actual risk may not be zero, women known to be pregnant should not be vaccinated, and conception should be avoided for three months after vaccination.*

During his deposition, Dr. Huggins acknowledged that the CDC found no evidence of CRS in any of the babies born to mothers who had received the vaccine during pregnancy. Dr. Huggins also criticized the CDC studies, stating that the studies are inconclusive and that the medical community still advises against rubella vaccination during pregnancy. Specifically, Dr. Huggins testified that the CDC studies are misleading and incomplete because the conclusions are based on a passive reporting system that permits the possibility of significant under-reporting, noting that the CDC did not independently corroborate any of the information sent to them. Dr. Huggins also observed that there was an incomplete follow-up for purposes of the study of the eight infants reported to have a subclinical rubella infection at birth. Therefore, Dr. Huggins asserts that the CDC study does not disprove a causal connection between rubella vaccination during pregnancy and CRS, but rather indicates only that the study found no reported cases.

84 Finally, Dr. Huggins concedes that Delisha's CRS would be the first reported case *84 in the medical history and literature of rubella in which the inoculation of a pregnant woman caused the child to develop CRS. Dr. Huggins also acknowledged that there are no medical studies confirming that the attenuated virus, although capable of crossing the placenta, also can cause the CRS condition in the offspring of vaccinated pregnant women.

## II

## A

New Jersey Rule of Evidence 702 governs the admission of expert testimony. The Rule tracks *Fed.R.Evid.* 702 in its pre-amendment form[3] and provides:

> 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.
>
> [*N.J.R.E.* 702]

The Rule imposes three basic requirements: "(1) the intended testimony must concern a subject matter that is beyond the ken of the average juror; (2) the field testified to must be at a **state** of the art such that an expert's testimony could be sufficiently reliable; and (3) the witness must have sufficient expertise to offer the intended testimony." *Landrigan v. Celotex Corp.*, 127 *N.J.* 404, 413, 605 *A.*2d 1079 (1992)(citing ***State** v. Kelly*, 97 *N.J.* 178, 208, 478 *A.*2d 364 (1984)). Defendants do no contest that the subject of the expert's testimony is beyond the comprehension of the average juror nor do they dispute Dr. Huggins' qualifications. At issue is the second requirement, that the expert's testimony be sufficiently reliable in the field of scientific research.

In the past, in order to meet that requirement the proponent of the expert testimony was required to demonstrate that the expert's opinion or theory was generally accepted within the scientific community. *Rubanick v. Witco Chemical Corp.*, 125 *N.J.* 421, 432, 593 *A.*2d 733 (1991) (citing *Kelly, supra,* 97 *N.J.* at 210, 478 *A.*2d 364). In a relatively new field of scientific research there were three ways a proponent of expert testimony could prove general acceptance: "(1) the testimony of

knowledgeable experts; (2) authoritative scientific literature; and (3) persuasive judicial decisions which acknowledge such general acceptance of expert testimony." *Ibid.* (citation omitted).

However, in order to gain general acceptance in the scientific community, the expert's opinion or theory had to satisfy an extraordinarily "high level of proof based on prolonged, controlled, consistent, and validated experience." *Rubanick, supra,* 125 *N.J.* at 436, 593 *A.*2d 733. Therefore, this Court relaxed the standard for admissibility of scientific evidence due to the "extraordinary and unique burdens" plaintiffs faced when they sought to prove medical causation in toxic tort cases. *Id.* at 433, 593 *A.*2d 733. "[P]laintiffs in toxic-tort litigation, despite strong and indeed compelling indicators that they have been tortiously harmed by toxic exposure, may never recover if required to await general acceptance by the scientific community of a reasonable, but as yet not certain, theory of causation." *Id.* at 434, 593 *A.*2d 733.

85 *85 In *Rubanick,* the Court noted that other courts also had taken a more flexible approach to the admission of causation theories in toxic tort litigation. For example, in *Ferebee v. Chevron Chemical Co.,* 736 *F.2d* 1529 (1984), the Court of Appeals for the District of Columbia stated:

> [A] cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. *As long as the basic methodology employed to reach such a conclusion is sound, ... products liability law does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical.*
>
> [*Rubanick, supra,* 125 *N.J.* at 439, 593 *A.*2d 733 (quoting *Ferebee, supra,* 736 *F.2d* 1529, 1535-36) (emphasis added).]

We held in *Rubanick,* that a theory of causation that had not yet reached general acceptance in the scientific community "may be found to be sufficiently reliable if it is based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field." *Id.* at 449, 593 *A.*2d 733. We noted that in determining whether a scientific methodology is sound, courts should consider whether others in the field use similar methodologies in forming their opinions and also should consider factors that are normally relied on by medical professionals, such as medical tests, patient examinations and scientific literature on the subject. *Id.* at 449-50, 593 *A.*2d 733 The appropriate inquiry is not whether the court thinks the expert's reliance on the underlying data was reasonable, but rather whether comparable "`experts in the field [would] actually rely' on that information.'" *Id.* at 452, 593 *A.*2d 733 (quoting *Ryan v. KDI Sylvan Pools,* 121 *N.J.* 276, 289, 579 *A.*2d 1241 (1990)).

The United States Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 *U.S.* 579, 587, 113 *S.Ct.* 2786, 2793, 125 *L.Ed.*2d 469, 479 (1993), also has relaxed the standard for the admissibility of expert scientific evidence. The Court determined that the "general acceptance" test developed at common law had been superseded by the Federal Rules of Evidence. *Ibid.* The Supreme Court stressed that a proffer of expert scientific testimony requires the trial court, at an evidentiary hearing, to assess "whether the reasoning or methodology underlying the testimony is scientifically valid and [ ] whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93, 113 *S.Ct.* at 2796, 125 *L.Ed.*2d at 482. The Court added that the inquiry is a "flexible one," and that its focus must be "solely on principles and methodology, not on the conclusions that they generate." *Id.* at 594-95, 113 *S.Ct.* at 2797, 125 *L.Ed.*2d at 484. Recently, in *Kumho Tire Co., Ltd. v. Carmichael,* 526 *U.S.* 137, 141, 119 *S.Ct.* 1167, 1171, 143 *L.Ed.*2d 238 (1999), the Court expanded application of the *Daubert* holding to testimony based on technical and other specialized knowledge.

## B

Notably, we stated in *Rubanick* that when a trial court is "faced with a not yet generally accepted theory of causation in toxic-tort litigation," the trial court "should use the *Evidence Rule 8* hearing [now *N.J.R.E.* 104] to assess the soundness of the proffered methodology and the qualifications of the expert." *Rubanick, supra,* 125 *N.J.* at 454, 593 *A.*2d 733 (citations omitted). *N.J.R.E.* 104(a) provides:

86 *86 When the qualifications of a person to be a witness, or the admissibility of evidence,... is subject to a condition, and the fulfillment of the condition is in issue, that issue is to be determined by the judge ... The judge may hear and determine such matters out of the presence or hearing of the jury.

[*N.J.R.E.* 104(a).]

The Rule 104 hearing allows the court to assess whether the expert's opinion is based on scientifically sound reasoning or unsubstantiated personal beliefs couched in scientific terminology. *Landrigan, supra,* 127 *N.J.* at 414, 605 *A.*2d 1079.

In the course of the Rule 104 hearing, an expert must be able to identify the factual basis for his conclusion, explain his methodology, and demonstrate that both the factual basis and underlying methodology are scientifically reliable. *Id.* at 417, 605 *A.*2d 1079. The court's role is to "determine whether the expert's opinion is derived from a sound and well-founded methodology that is supported by some expert consensus in the appropriate field." *Id.* at 417, 605 *A.*2d 1079 (citing *Rubanick, supra,* 125 *N.J.* at 449-50, 593 *A.*2d 733). Support for an expert's methodology may be found in professional journals, texts, conferences, symposia, or judicial opinions accepting the methodology. *Ibid.* (citation omitted). Courts also may consider testimony from other experts in the field who use similar methodologies. *Rubanick, supra,* 125 *N.J.* at 449-50, 593 *A.*2d 733.

In both *Rubanick, supra,* 125 *N.J.* at 424, 593 *A.*2d 733, and *Landrigan, supra,* 127 *N.J.* at 411, 605 *A.*2d 1079, the trial courts had conducted evidentiary hearings in order to determine the admissibility of expert testimony. However, in both cases the trial courts had applied the "general acceptance" standard in determining the admissibility of scientific evidence. *Ibid.* Applying that standard, the courts excluded expert testimony proffered by plaintiffs resulting in a summary judgment in *Rubanick* and a directed verdict in *Landrigan* in favor of defendants. *Ibid.* We reversed and remanded both matters for the court to conduct another evidentiary hearing and to reconsider the experts' testimony applying the less stringent standard set forth in *Rubanick.* *Rubanick, supra,* 125 *N.J.* at 454, 593 *A.*2d 733; *Landrigan, supra,* 127 *N.J.* at 428, 605 *A.*2d 1079 (citing *In re Paoli Railroad Yard PCB Litigation,* 916 *F.*2d 829, 835 (3d Cir.1990), where Court of Appeals set aside directed verdict and remanded to trial court to conduct another evidentiary hearing in accordance with *Rubanick* inquiry.).

We also note that the Third Circuit has "long stressed the importance of *in limine* hearings under Rule 104(a) in making the reliability determination required under Rule 702 and *Daubert.*" *Padillas v. Stork-Gamco, Inc.,* 186 *F.*3d 412, 417 (1999). That court has recognized that the most efficient procedure for determining the reliability of expert testimony is an *in limine* hearing. *Ibid.* (citing *United States v. Downing,* 753 *F.*2d 1224, 1241 (3d Cir.1985)). However, an *in limine* hearing is not "required whenever a *Daubert* objection is raised to a proffer of expert testimony." *Id.* at 418.

> Whether to hold one rests in the sound discretion of the district court. But when the ruling on admissibility turns on factual issues, as it does here, at least in the summary judgment context, failure to hold such a hearing may be an abuse of discretion.
>
> [Ibid.]

In *Padillas, supra,* 186 *F.*3d at 417, the court acknowledged the importance of providing the party defending the admission of evidence a fair and adequate opportunity to be heard, especially when summary judgment may result from exclusion of
87 the *87 evidence. The court noted that in *In re Paoli, supra,* 916 *F.*2d at 854, it had reversed a summary judgment for defendants because the trial court, "in excluding expert evidence under Rule 703, had failed to `provide [ ] the plaintiffs with sufficient process for defending their evidentiary submissions.'" *Padillas, supra,* 186 *F.*3d at 417. In addition, the court stated that "`[t]he detailed factual record requirement, firmly entrenched in our jurisprudence, requires adequate process at the evidentiary stage, particularly when a summary judgment may flow from it.'" *Ibid.* (quoting *In re Paoli,* 916 *F.*2d at 854).

The trial court in *Padillas* held that the expert's report was inadmissible because, among other reasons, the expert did "not set forth in his report the methodology by which he made his determinations in this case." *Padillas, supra,* 186 *F.*3d at 416. The Third Circuit however, did not determine or address whether the trial court had abused its discretion in holding the expert report inadmissible. Rather, that court was concerned with the process the trial court afforded to the proponent of

the expert's report, holding that failure to hold an *in limine* hearing was an abuse of discretion. *Id.* at 418. The court observed that the "district court's analysis of the [expert's report] does not establish that [the expert did] not have `good grounds' for his opinions," but rather that they were not sufficiently explained and the "reasons and foundations for them inadequately and perhaps confusingly explicated." *Ibid.*

Although the plaintiff in *Padillas* had not requested a hearing, the Court of Appeals determined that that omission was immaterial, in part because the trial court "has an independent responsibility for the proper management of complex litigation," and also because the plaintiff bears the burden of establishing admissibility and deserves to have the opportunity to be heard on the critical issues of scientific reliability and validity. *Id.* at 417 (citation omitted). The court stated that if the trial court were concerned about the admissibility of the evidence, it should have allowed the plaintiff the opportunity to respond to the court's concerns by conducting an *in limine* hearing. *Id.* at 418. Therefore, the Third Circuit reversed the summary judgment in favor of the defendant and remanded to the trial court to conduct an *in limine* hearing. *Ibid.*

## III

## A

This Court has been cautious in applying the more relaxed *Rubanick* standard for the admissibility of scientific evidence in other contexts. ***State** v. Harvey,* 151 *N.J.* 117, 170, 699 *A.*2d 596 (1997). However, even prior to *Rubanick* we have emphasized aspects of the *Rubanick* analysis in other types of cases. For example, in ***State** v. Harvey,* 121 *N.J.* 407, 426-28, 581 *A.*2d 483 (1990), in considering the admissibility of expert testimony estimating a person's height from the size of their shoe print, the Court determined that the expert's methodology was not scientifically reliable, observing that the **State** had failed to "provide evidence that anyone in the scientific community other than [the expert] himself vouches for his methods." *Id.* at 428, 581 *A.*2d 483. *See also Harvey, supra,* 151 *N.J.* at 173, 699 *A.*2d 596 (finding that polymarker test (used for DNA analysis) was generally accepted in scientific community because independent tests validated its reliability, highly-regarded laboratories used test, scholarly and scientific publications approved test and other jurisdictions admitted results of test; thus, court did not err in admitting expert testimony with regard to results of test).

88 *88 The obstacles plaintiffs generally confront concerning reasonable but unconfirmed theories of medical causation are not confined to toxic tort litigation. Several other varieties of tort litigation exist in which a medical cause-effect relationship has not been confirmed by the scientific community but compelling evidence nevertheless suggests that such a relationship exists. The same concerns arise in those cases, as in toxic tort litigation, if a plaintiff is barred from recovery because a novel or relatively new scientific theory of causation has not, as yet, satisfied the "extraordinarily high level of proof" required in order to gain "general acceptance" in the scientific community. *Rubanick, supra,* 125 *N.J.* at 436, 593 *A.*2d 733. We conclude that the *Rubanick* standard applies to the causation issue in this case, and that the proper inquiry is whether Dr. Huggins' opinion that the rubella vaccination caused Delisha's CRS is based on a "sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field." *Id.* at 449, 593 *A.*2d 733.

Accordingly, the trial court on remand must ascertain whether the scientific medical community accepts the process by which Dr. Huggins arrived at his conclusion as one that is consistent with sound scientific principles. It is his analysis and reasoning process (applied to the facts of this case) that is at issue in determining whether his testimony is scientifically reliable.

## B

Plaintiffs' burden is to demonstrate that the methodology used by Dr. Huggins in reaching his conclusion that the rubella vaccine administered to Debra was the cause of Delisha's CRS is consistent with sound scientific principles and methodologies accepted in the medical and scientific communities. If it is not, the court cannot consider his expert opinion

reliable and should exclude it. From the record before us, we find that plaintiffs did not adequately verify Dr. Huggins' methodology as a scientifically sound analytical method accepted and used by other experts in the same field.

Dr. Huggins' testified during his deposition that his opinion was based on studies that show the existence of the attenuated virus in the fetuses of inoculated pregnant women, as well as the medical recommendation to avoid the inoculation of pregnant women with the rubella vaccine. He also reviewed Debra's and Delisha's medical records. He testified that he ruled out the possibility that Debra's contraction of the wild rubella virus during the outbreak of measles in 1975 was the cause of Delisha's CRS, instead of the attenuated virus in the vaccine, because the medical records he examined did not indicate that Debra had clinical symptoms of rubella. He testified that he based his conclusion that Debra's vaccination with the rubella vaccine caused Delisha's CRS on numerous factors, including Debra's and Delisha's medical records, the CDC study, scientific evidence that the virus in the vaccine was capable of crossing the placenta, and his own extensive medical and scientific experience.

Our review of Dr. Huggins' deposition testimony, however, reveals that Dr. Huggins did not attempt to demonstrate or verify that the scientific methodology he used in concluding that the rubella vaccination caused Delisha to develop CRS was consistent with that used by other qualified medical and scientific experts. Dr. Huggins did not establish that his analysis and methodology is comparable to that used by other experts in the medical community in reaching analogous
89 opinions, or that other experts in the field would *89 rely on similar studies, data and medical records in considering whether the rubella vaccine could cause CRS. Nor did he refer to analogous conclusions with regard to comparable viruses by other experts in the field, based on similar studies and clinical data. In short, the record reveals that plaintiffs failed to demonstrate that their expert's methodology was scientifically sound.

However, we are persuaded that the lack of a Rule 104 hearing may adversely have affected plaintiffs' ability to present their expert's testimony in its best light. Because Dr. Huggins' testimony was taken only at defendants' deposition, the trial court did not have the benefit of an orderly and comprehensive presentation of his expert testimony elicited by plaintiffs counsel. Rather, Dr. Huggins' deposition afforded defendants' counsel the opportunity to challenge and cast doubt on the reliability of his opinion. We are not satisfied that the record of that deposition fairly reflects the more balanced and complete presentation of his opinion that a Rule 104 hearing would have afforded.

Although the parties did not request a Rule 104 hearing, we hold that it was plain error for the trial court not to conduct an evidentiary hearing in order to determine the reliability of plaintiffs' expert testimony. We fully agree with the Third Circuit's observation in *In re Paoli, supra,* 916 *F.2d* at 854 (internal citations omitted):

> The adversarial process upon which our legal system is based assumes that a fact finder will give the parties an adequate opportunity to be heard; if it does not, it cannot find facts reliably. Thus, the detailed factual record requirement, firmly entrenched in our jurisprudence, requires adequate process at the evidentiary stage, particularly when a summary judgment may flow from it.

Moreover, although the need for a hearing is remitted to the trial court's discretion, in cases in which the scientific reliability of an expert's opinion is challenged and the court's ruling on admissibility may be dispositive of the merits, the sounder practice is to afford the proponent of the expert's opinion an opportunity to prove its admissibility at a Rule 104 hearing.

## IV

We reverse the judgment of the Appellate Division and remand the matter to the trial court for a Rule 104 hearing in order to determine the reliability and admissibility of Dr. Huggins' expert opinion. In remanding this matter to the Law Division, we neither express nor imply any view on whether the expert's testimony should be admitted.

PORITZ, C.J., dissenting.

In my view, the trial court properly performed its "gatekeeper function" when it ruled that there was no scientific basis for the opinion offered by plaintiffs' expert, Dr. Huggins. Ordinarily, when the trial court is "`faced with a not generally accepted theory of causation,'" a *Rule* 104 hearing is appropriate "`to assess the soundness of the proffered methodology.'" *Ante* at

426, 809 *A.*2d at 85 (citation omitted). In this case, Dr. Huggins' theory has been considered by the scientific community and *no* basis for a causal connection between the rubella vaccine and Congenital Rubella Syndrome has been found. I would not remand this case on the slender proffer rejected by the trial court, but would instead affirm the well-reasoned decision of the Appellate Division upholding the trial court's grant of summary judgment dismissing plaintiffs' complaint.

90 I agree with the majority that the more relaxed standard of *Rubanick v. Witco* *90 *Chem. Corp.,* 125 *N.J.* 421, 449, 593 *A.*2d 733 (1991), should be applied not only in the toxic tort context but whenever "a medical cause-effect relationship has not been confirmed by the scientific community but compelling evidence nevertheless suggests that such a relationship exists." *Ante* at 430, 809 *A.*2d at 88. The problem here is that plaintiffs have not put forward anything resembling compelling evidence. It is not contested that live attenuated vaccine passes through the placenta to the fetus or that the wild virus can cause Congenital Rubella Syndrome. Dr. Huggins admits, however, that no case has been documented demonstrating that the *vaccine* causes Congenital Rubella Syndrome. Indeed, there are substantial studies indicating an "observed risk ... [of] zero" from vaccination. Sandra W. Bart, et al., "*Fetal Risk Associated with Rubella Vaccine: An Update" 7 Reviews of Infectious Diseases* 95, 101 (Supp.Mar.-Apr.1985). Because the studies are based on voluntary reporting, plaintiffs' expert claims there may be significant underreporting that could affect the results. Nonetheless, he can point to no documented link in any of the literature to support his theory.

Most troubling, plaintiffs' expert admits that because there was a rubella epidemic (hence the county's vaccination program), the mother "could have had a high probability of exposure" to the wild virus. Based on a lack of medical records indicating a "clinical rubella infection during pregnancy," the expert concludes "with a reasonable degree of medical certainty" that the immunization caused the syndrome. Yet, it is uncontroverted that many people who are infected with the rubella virus are essentially asymptomatic. In the facts as presented, the expert's conclusion simply cannot withstand scrutiny.

The *Rubanick* standard is now an important part of our jurisprudence. In *Landrigan v. Celotex Corp.,* 127 *N.J.* 404, 605 *A.*2d 1079 (1992), we reaffirmed and further explained its application. We also focused on the need for a sufficient demonstration of reliability so that the trial courts can exercise their discretion to exclude unreliable opinions. See *id.* at 417, 605 *A.*2d 1079 (holding that "experts ... must be able to identify the factual bases for their conclusions, explain their methodology, and demonstrate that both the factual bases and the methodology are scientifically reliable"). We must allow the trial courts to act as gatekeepers in such cases. See *Gen. Elec. Co. v. Joiner,* 522 *U.S.* 136, 141-42, 118 *S.Ct.* 512, 517, 139 *L.Ed.*2d 508, 516 (1997) (affirming that district courts, performing their "gatekeeper" role under Federal Rules of Evidence, must ensure that admitted scientific evidence is reliable). Without that discretion, we have no standard at all.

For the reasons stated, I would affirm the judgment of the Appellate Division.

Justices VERNIERO and LaVECCHIA join in this opinion.

*For reversing and remanding*—Justices STEIN, COLEMAN, LONG, and ZAZZALI—4.

*For affirming*—Chief Justice PORITZ and Justices VERNIERO and LaVECCHIA—3. join.

[1] A teratogen is "[a]nything that adversely affects normal cellular development in the embryo or fetus. Known teratogens include certain chemicals, some therapeutic and illicit drugs, radiation, and intrauterine viral infections." *Taber's Cyclopedic Medical Dictionary,* Clayton L. Thomas, M.D., M.P.H. (18th ed.1997).

[2] A total of eight infants born to women who had received Cendehill or HPV-77 vaccinations, including those classified as immune and immune status unknown in addition to susceptible, had laboratory evidence of subclinical rubella infection at birth but were all developing normally in follow-up reports. Three of those infants were born to susceptible mothers.

[3] At this juncture, New Jersey has not amended Rule 702 to incorporate the three-factor test for the admissibility of expert testimony that is part of the Federal rule as amended in response to*Daubert v. Merrill Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) on December 1, 2000. We do not intend by this opinion to incorporate the *Daubert* factors into *N.J.R.E.* 702.