

SUPREME COURT OF NEW JERSEY

Gannon v. American Home Products, Inc.

211 N.J. 454 (2012) · Decided August 15, 2012

SUMMARY

The New Jersey Supreme Court reviews a product-liability action alleging that a polio vaccine caused brain cancer. The Court holds that federal law governs the collateral-estoppel effect in state court of the prior federal judgment rejecting the plaintiffs’ causation evidence, and reverses the Appellate Division. The Court does not reach the sufficiency of the plaintiffs’ product-identification evidence.

CASE DETAILS

COURT	Supreme Court of New Jersey
WRITING FOR THE COURT	Justice Hoens; Hoens; Wefing
JURISDICTION	New Jersey
DECIDED	August 15, 2012
DISPOSITION	reversed
PROCEDURAL POSTURE	Plaintiffs appealed the Appellate Division's reversal of summary judgment entered for pharmaceutical defendants. The Supreme Court of New Jersey granted certification and reviewed whether a prior federal judgment had collateral-estoppel effect on plaintiffs' state product-liability claims.
STANDARD OF REVIEW	De novo review of the legal effect of a prior federal judgment and the grant or denial of summary judgment.
PRECEDENTIAL VALUE	Published, precedential New Jersey Supreme Court opinion
PARTIES	Jamie Gannon, Rebecca Gannon v. American Home Products, Inc., American Cyanamid Company, Lederle Laboratories, WyethLederle Vaccines

TOPICS

- summary judgment
- civil procedure
- products liability
- federalism

PRACTICE AREAS

- civil procedure
- torts
- products liability
- federalism
- health law

QUESTIONS PRESENTED

1. Whether federal or New Jersey law governs the collateral-estoppel effect in New Jersey of a judgment rendered by a federal court.
2. Whether plaintiffs had a full and fair opportunity to litigate general and specific causation in the prior federal proceeding.
3. Whether equitable considerations under Restatement (Second) of Judgments sections 28 and 29 permitted plaintiffs to relitigate causation despite the prior federal judgment.

HOLDINGS

1. The preclusive effect in a state-court proceeding of a judgment rendered by a federal court is determined under federal, not state, collateral-estoppel principles.
2. The federal judgment precluded plaintiffs from relitigating general and specific causation because the identical issues were decided, the federal judgment was final and on the merits, the parties were the same or in privity, and plaintiffs had a full and fair opportunity to litigate those issues.
3. The equitable considerations identified in Restatement (Second) of Judgments sections 28 and 29 did not permit plaintiffs to relitigate causation after a full and fair adjudication of that issue.

KEY QUOTATIONS

“(1) the identical issue was decided in a prior adjudication; (2) there was a final judgment on the merits; (3) the party against whom the bar is asserted was a party or in privity with a party to the prior adjudication; and (4) the party against whom the bar is asserted had a full and fair opportunity to litigate the issue in question.” (471-472)

“The mere speculation that, given a second chance, plaintiffs might be able to make a better record cannot equate with “compelling circumstances” in the face of a full and fair opportunity to litigate the precise issue in the federal proceeding.” (478)

“Courts applying the equitable considerations identified in the Restatement must be careful in their performance of that task. They must not regard those considerations to be a license to substitute generalized concerns about the imposition of collateral estoppel when the clearly established elements have been met.” (480-481)

FACTUAL BACKGROUND

Jamie Gannon received five doses of polio vaccine between 1973 and 1976 and was diagnosed with medulloblastoma in 2000. Plaintiffs alleged that the vaccine was contaminated with SV40 and that SV40 caused Jamie's cancer, but the manufacturer of the administered vaccine was disputed. In the federal action, plaintiffs were fully heard on general and specific causation, and the federal court found that they failed to prove either that SV40 causes cancer in humans or that it caused Jamie's tumor. The state action asserted product-liability claims against pharmaceutical entities allegedly associated with the vaccine.

PROCEDURAL HISTORY

Plaintiffs pursued parallel federal and state actions arising from Jamie Gannon's alleged brain cancer following childhood polio vaccinations. The federal action against the United States was dismissed after a bench trial under Federal Rule of Civil Procedure 52(c), and the Third Circuit affirmed. The New Jersey trial court granted defendants summary judgment both because plaintiffs lacked sufficient product-identification evidence and because the federal judgment collaterally estopped their causation claims. The Appellate Division reversed both grounds and remanded; the New Jersey Supreme Court reversed the Appellate Division based on collateral estoppel and did not reach product identification.

DISPOSITION

reversed

CASES CITED

- Gannon v. United States, 571 F. Supp. 2d 615 (E.D. Pa. 2007)
- Gannon v. United States, 292 F. App'x 170 (3d Cir. 2008)
- Gannon v. American Home Products, Inc., 414 N.J. Super. 507, 999 A.2d 522 (App. Div. 2010)
- Campagna v. American Cyanamid Co., 337 N.J. Super. 530, 767 A.2d 996 (App. Div. 2001)
- Shackil v. Lederle Laboratories, 116 N.J. 155, 561 A.2d 511 (1989)
- Sholtis v. American Cyanamid Co., 238 N.J. Super. 8, 568 A.2d 1196 (App. Div. 1989)
- Namm v. Charles E. Frosst & Co., Inc., 178 N.J. Super. 19, 427 A.2d 1121 (App. Div. 1981)
- In re Dawson, 136 N.J. 1, 641 A.2d 1026 (1994)
- Watkins v. Resorts International Hotel & Casino, Inc., 124 N.J. 398, 591 A.2d 592 (1991)
- Semtek International, Inc. v. Lockheed Martin Corp., 531 U.S. 497, 121 S. Ct. 1021, 149 L. Ed. 2d 32 (2001)
- Del Piano v. Merrill Lynch, 372 N.J. Super. 503, 859 A.2d 742 (App. Div. 2004)
- Tricarico v. Board of Review, 147 N.J. 581, 689 A.2d 124 (1997)
- Paramount Aviation Corp. v. Agusta, 178 F.3d 132 (3d Cir. 1999)
- Delaware River Port Authority v. FOP, Penn-Jersey Lodge 30, 290 F.3d 567 (3d Cir. 2002)
- Board of Trustees of Trucking Employees of North Jersey Welfare Fund, Inc. v. Centra, 983 F.2d 495 (3d Cir. 1992)
- Olivieri v. Y.M.F. Carpet, Inc., 186 N.J. 511, 897 A.2d 1003 (2006)
- In re Coruzzi, 95 N.J. 557, 472 A.2d 546 (1984)
- Duvall v. Attorney General of the United States, 436 F.3d 382 (3d Cir. 2006)
- National Railroad Passenger Corp. v. Pennsylvania Public Utility Commission, 288 F.3d 519 (3d Cir. 2002)
- Wells v. Rockefeller, 728 F.2d 209 (3d Cir. 1984)
- O'Shea v. Amoco Oil Co., 886 F.2d 584 (3d Cir. 1989)
- Yamaha Corp. of America v. United States, 961 F.2d 245 (D.C. Cir. 1992)
- Herbert v. Reinstein, 976 F. Supp. 331 (E.D. Pa. 1997)
- Rivard v. American Home Products, Inc., 391 N.J. Super. 129, 917 A.2d 286 (App. Div. 2007)
- Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)

- Selective Insurance Co. of America v. Rothman, 208 N.J. 580, 34 A.3d 769 (2012)
- Nieder v. Royal Indemnity Insurance Co., 62 N.J. 229, 300 A.2d 142 (1973)

OPINION

HOENS, J.

Justice HOENS delivered the opinion of the Court. Plaintiffs Jamie and Rebecca Gannon, asserting that plaintiff Jamie Gannon developed a form of brain cancer because of a series of polio vaccines he was given as a child, pursued various forms of relief in both federal and state courts.

In the federal court action, they sought relief from the United States pursuant to the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2671-80, contending that the federal government was negligent in permitting the polio vaccine to be sold to the public. Plaintiffs' federal action was dismissed following a partial bench trial, based on the government's motion for judgment on partial findings, Fed.R.Civ.P.

52(c); see *Gannon v. United States*, 571 F.Supp.2d 615, 616, 641 (E.D.Pa.2007), and that judgment was affirmed by the United States Court of Appeals for the Third Circuit, see *Gannon v. United States*, 292 Fed.Appx. 170, 175 (3d Cir.2008). *457Proceeding on a parallel track, plaintiffs sought relief in our state courts.

In the state court action, they raised product liability claims against defendants American Home Products, Inc., American Cyanamid Company, Lederle Laboratories, and WyethLederle Vaccines, which they asserted were the entities that had manufactured or distributed the polio vaccine given to plaintiff Jamie Gannon.

In the state court litigation, the trial court granted summary judgment in favor of defendants, R. 4:46-2, basing its decision on two grounds. First, the trial court concluded that plaintiffs lacked sufficient evidence to prove the identity of the manufacturer of the polio vaccine that plaintiff Jamie Gannon was given.

Second, the trial court concluded that plaintiffs were collaterally estopped from bringing the cause of action based on the prior judgment entered in federal court. The Appellate Division, in a published opinion, reversed both aspects of the trial court's judgment and remanded the matter for further discovery and for trial. *Gannon v. Am. Home Prods., Inc.*, 414 N.J.

Super. 507, 511, 999 A.2d 522 (App.Div.2010). The panel first concluded that the trial court had utilized an incorrect standard in evaluating the sufficiency of the product identification evidence because it failed to afford plaintiffs the benefit of the inferences to which they were entitled as the non-moving parties in the context of a summary judgment motion.

Id. at 516-18, 999 A.2d 522. The panel then concluded that there were equitable considerations that militated against granting collateral estoppel effect to the judgment of the federal court,

including the status of discovery in the state court matter and the pendency of similar state court litigation involving other plaintiffs. *Id.* at 526-30, 999 A.2d 522.

For both of those reasons, the panel reversed the trial court's grant of summary judgment and remanded the matter for further proceedings. Because we conclude that the Appellate Division's collateral estoppel analysis was in error, we reverse. Inasmuch as that conclusion resolves this matter, we do not address the arguments *458 of the parties concerning the panel's product identification discussion.

I. The facts relevant to this dispute can be summarized succinctly. Plaintiff Jamie Gannon was born in 1973. When he was a child, his mother took him to be seen by Dr. Frank Bender, a pediatrician who practiced in Upper Darby, Pennsylvania. It is undisputed that plaintiff received five doses of polio vaccine on specific dates between 1973 and 1976.

The identity of the manufacturer of the vaccine, however, was disputed and was the focus of significant discovery in the state court litigation. Plaintiff asserts that the vaccine was manufactured by defendant Lederle Laboratories. He finds support for this contention in a document kept by his mother on which the dates of the doses were recorded. That document was a preprinted form, identified as an Immunization and Health Record, that bore the name and corporate logo of Lederle Laboratories.

The form included a column denoting "Active Immunizations" where a number of possible childhood vaccines were listed. Among them there was a line for "Poliomyelitis Vaccine: Poliovirus Vaccine, Live, Oral, Sabin Strains, ORIMUNE® Trivalent." Defendants do not dispute that ORIMUNE® was a proprietary product manufactured by Lederle Laboratories.¹ The form includes a series of dates that were *459 handwritten in five boxes immediately to the right of this line, signifying the dates on which the polio vaccine was administered to plaintiff.

In response, defendants offered evidence in support of their assertion that the form was distributed as a promotional item by Lederle Laboratories and that it "w[as] not intended to be a doctor's official vaccination record." *Gannon*, *supra*, 414 N.J. Super. at 515, 999 A.2d 522. They point out that the form included spaces for many immunizations to be recorded, including several, such as mumps and measles vaccines, that Lederle Laboratories did not manufacture.

They further contend that the purpose of the form can be seen from printed language found directly above the corporate name and logo, which is obviously directed to a child's parent. That language advises, for example, "keep this immunization and health record... it will be useful at school registration time [or] when traveling," and it further advises that "if you move, show it to your new physician so that he may know of past immunizations." Defendants relied on testimony from David Standiford, the company's former district sales manager for the region where plaintiffs

pediatrician practiced, who testified that the form was merely a promotional item given to pediatricians so that they could pass it along to the parents of their patients.

Moreover, according to Standiford, he urged his sales representatives to distribute the forms “whether the particular doctor purchased Lederle products” or not. Standiford also stated that by the time plaintiff had filed his lawsuit and commenced discovery,² both Dr. Bender and his office *460manager had died and their office files could not be located.

In addition, he demonstrated that the company’s sales representative who had called on that office was also deceased. Dr. Bender’s nurse, consistent with the assertions made by Lederle Laboratories, certified that the document plaintiff relied upon to identify Lederle Laboratories was not part of the doctor’s office records, but was a place where the office manager would record the vaccinations that had been given so that the child’s parents could present it to school officials.

She could not identify the manufacturer of the vaccine actually administered to plaintiff based upon the document alone and had no recollection of which manufacturer supplied the vaccines to the office. In November 2000, plaintiff Jamie Gannon was diagnosed with medulloblastoma, a cancerous brain tumor. Contending that there was a link between that particular type of tumor and a simian viral contaminant found in polio vaccines that is known as SV40, plaintiffs commenced their federal and state court litigation.

Before the state action could be fully adjudicated, the federal action was dismissed based on a motion by the United States for judgment on partial findings, Fed.R.Civ.P. 52(c). Gannon, *supra*, 571 F.Supp.2d at 641. Our evaluation of the arguments raised on appeal requires that we address first the questions that were considered by the court in the federal litigation, following which we address the issues presented in the state court matter.

A. The Federal Claim Critical to our consideration of the matters raised on appeal is an explanation of the federal court proceedings in which plaintiffs *461were involved. Plaintiffs sued the United States in the United States District Court for the Eastern District of Pennsylvania, asserting claims arising pursuant to the Federal Tort Claims Act, 28 U.S.C. §§ 2671-2680, that related to the governmental approvals of the vaccines for marketing.

In that action, plaintiffs asserted that Lederle Laboratories failed to comply with the applicable standards imposed by the Food and Drug Act, 42 U.S.C. § 262(d), when its polio vaccine was manufactured and distributed.

In order to prevail on the federal claims, plaintiffs were required to prove that the United States had negligently licensed the oral polio vaccine and had improperly permitted it to be released to the public when it had not been manufactured in compliance with existing regulations governing its manufacture and testing. See generally *Campagna v. Am. Cyanamid Co.*, 337 N.J.Super.

530, 534-39, 767 A.2d 996 (App.Div.2001) (describing history of approval for marketing relating to ORIMUNE® polio vaccine). The focus of the claims against the United States was plaintiffs' assertion that the oral polio vaccine manufactured and distributed by Lederle Laboratories was contaminated with SV40.

In the federal litigation, therefore, plaintiffs were required to prove both general causation, meaning that SV40 causes cancer in humans, and specific causation, meaning that SV40 caused plaintiff Jamie Gannon's medulloblastoma.

In that context, plaintiffs presented proofs that were tried before a federal judge in the Eastern District of Pennsylvania. That proceeding began with a Daubert³ challenge to plaintiffs' expert, Dr. Adi Gazdar, who was called by plaintiffs to testify about both general and specific causation.

For the convenience of the parties, the trial court elected to combine the Daubert hearing, concerning the admissibility of Dr. Gazdar's testimony, with its consideration of all of the testimony *462relating to the disputed issues about causation.

As a result, the court heard Dr. Gazdar's complete testimony, followed by testimony from three experts called by the United States who opined on the subject of general and specific causation. Gannon, *supra*, 571 F.Supp.2d at 616. At the close of that testimony, the court denied the Daubert motion, concluding that Dr. Gazdar's testimony met the test established in Daubert for admissibility.

Id. at 617. The United States then moved for judgment in its favor based on the causation evidence that the court had received, relying on Fed.R.Civ.P. 52(c). That Rule permits the court to enter judgment if "a party has been fully heard on an issue and the court finds against the party on that issue," and if a favorable finding on that issue is necessary to maintain a claim or defense.

Ibid. In granting the Rule 52(e) motion for judgment, the trial court issued extensive findings of fact concerning the evidence that the parties had adduced on the questions of general and specific causation. See Gannon, *supra*, 571 F.Supp.2d at 621-38. Based on those findings of fact, the court reached three conclusions of law that are germane to the matter now before this Court.

First, the court specifically rejected plaintiffs' argument that there was additional expert evidence that might have supported their causation arguments, concluding that "[p]laintiffs were fully heard on the causation issues." *Id.* at 640.

Second, the court concluded that "[p]laintiffs have failed to demonstrate, by a preponderance of the evidence, that SV40 causes cancer, let alone medulloblastoma, in humans." *Ibid.* Third, the court concluded that "[p]laintiffs also have failed to demonstrate by a preponderance of the evidence that SV40 caused Mr. Gannon's medulloblastoma." *Ibid.* Plaintiffs appealed from that judgment, challenging all three of the trial court's conclusions.

In affirming the judgment of the trial court, the United States Court of Appeals for the Third Circuit rejected plaintiffs' attacks on the adequacy of the proceedings and the sufficiency of the evidence. See Gannon, *supra*, 292 Fed.Appx. at 173-75. *463 First, the Third Circuit agreed with the trial court that plaintiffs had been fully heard on the causation issues.

Id. at 173-74. Because the other expert witnesses that plaintiffs contended that they would have called, if permitted, only would have addressed the claim that the vaccine was contaminated, the court concluded that they could not have offered the epidemiological evidence needed to prove causation and therefore could not have altered the judgment. *Id.* at 174.

Second, the Third Circuit agreed with the trial court that plaintiffs' general causation evidence was inadequate. The appellate panel pointed out that Dr. Gazdar's opinion that SV40 causes cancer in humans was based on a flawed analytical framework and that the record contained abundant support for the proposition that the scientific evidence is inadequate to demonstrate general causation.

Ibid. Third, the Third Circuit concurred with the District Court's conclusion that the evidence in the record relating to specific causation also fell short. The appellate court noted that Dr. Gazdar himself had conceded that there was a possibility that his own tests derived results that were the product of contaminated samples and that the studies on which he relied could not necessarily be extrapolated to humans.

In short, as it relates to the question of specific causation, the Third Circuit concurred with the trial court's conclusion that "Dr. Gazdar failed to conduct accurate, complete and scientifically reliable testing on Mr. Gannon's medulloblastoma sample." *Ibid.* Based on this analysis of the findings and conclusions reached by the United States District Court, on September 8, 2008, the Third Circuit affirmed the judgment entered in favor of the United States pursuant to Rule 52(c).

Id. at 175. B. The State Court Claim Plaintiffs' product liability claims against the pharmaceutical defendants proceeded on a parallel track in the Superior Court, *464 where the parties engaged in discovery relating to the identification of the manufacturer of the particular vaccine that had been administered to plaintiff Jamie Gannon.

On June 8, 2007, defendants in the state court action moved for summary judgment, arguing that plaintiffs' evidence identifying Lederle Laboratories as the manufacturer of the vaccine was insufficient. Following the federal district court's decision to grant judgment to the United States in the federal litigation, on July 27, 2007, defendants amended their motion for summary judgment, arguing that the judgment of the United States District Court was entitled to collateral estoppel effect on the issue of causation.

On February 14, 2008, the trial court granted defendants' summary judgment motion, finding merit in both issues for reasons expressed in its written opinion. In short, the trial court analyzed

the evidence relating to product identification and found that although there was “some evidence” that Lederle Laboratories might have manufactured the vaccine that could be derived from the immunization and health record that plaintiff produced, it was insufficient to meet the standards set forth by this Court.

See *Shackil v. Lederle Laboratories*, 116 N.J. 155, 174, 561 A.2d 511 (1989) (rejecting market share theory as alternative to proof of product identification); see also *Sholtis v. Am. Cyanamid Co.*, 238 N.J.Super. 8, 23, 568 A.2d 1196 (App.Div.1989) (noting this Court’s rejection in *Shackil* of market share theory in vaccine context); *Namm v. Charles E. Frosst & Co., Inc.*, 178 N.J.Super.

19, 27, 427 A.2d 1121 (App.Div.1981) (concluding that plaintiff must prove, as an element of prima facie case, that defendant made the specific product that caused injury). Although its decision on the product identification question was dispositive, the trial court also addressed defendants’ argument that the claim was barred because the federal court judgment was entitled to collateral estoppel effect.

Reasoning that plaintiffs had a full and fair opportunity to litigate the causation issues in the federal proceeding, the trial court concluded that their state court claim would be barred by either federal or state collateral estoppel *465principles. See *In re Dawson*, 136 N.J. 1, 20-21, 641 A.2d 1026 (1994) (identifying elements of state-based collateral estoppel analysis); *Watkins v. Resorts Int’l Hotel & Casino, Inc.*, 124 N.J.

398, 411, 591 A.2d 592 (1991) (applying federal collateral estoppel principles to federal court judgment). The Appellate Division reversed both the trial court’s analysis of the sufficiency of the product identification evidence and its application of principles of collateral estoppel. *Gannon*, supra, 414 N.J.Super. at 518, 525-30, 999 A.2d 522.

The panel first concluded that defendants were not entitled to summary judgment on the question of product identification, reasoning that the trial court’s decision rested on a misapplication of the standards governing a motion for summary judgment. *Id.* at 516-18, 999 A.2d 522.

In addressing the sufficiency of the product identification evidence, the appellate court commented that there were reasonable inferences that could be drawn from the Immunization and Health Record and from deposition testimony that the trial court had overlooked.

In the panel’s estimation, those inferences, if believed by a finder of fact, could support the conclusion that plaintiff had been given the Lederle Laboratories product, thus making summary judgment inappropriate. *Id.* at 518, 999 A.2d 522.

In concluding that the judgment of the United States District Court was not entitled to preclusive effect, the appellate panel looked primarily to state law principles of collateral estoppel. *Id.* at 520-

22, 999 A.2d 522; see *Tarus v. Borough of Pine Hill*, 189 N.J. 497, 520, 916 A.2d 1036 (2007) (quoting *Sacharow v. Sacharow*, 177 N.J. 62, 76, 826 A.2d 710 (2003)); *Olivieri v. Y.M.F.*

Carpet, Inc., 186 N.J. 511, 521, 897 A.2d 1003 (2006). In conducting in that analysis, the panel found both in those state law principles, see *Olivieri*, supra, 186 N.J. at 521, 897 A.2d 1003, as well as in secondary sources, see Restatement (Second) of Judgments, §§ 28, 29 (1982) (Restatement), a basis on which to apply an equitable exception that would permit this dispute to proceed.

After the appellate panel denied defendants' motion for reconsideration, we granted defendants' petition for certification. 205 *466N.J. 101, 13 A.3d 364 (2011). Because we conclude that the Appellate Division's collateral estoppel analysis was in error, we reverse.

We therefore do not reach the arguments advanced respecting the sufficiency of plaintiffs' evidence concerning the identification of the product administered to plaintiff Jamie Gannon. II. Because of our disposition of this matter, we limit our discussion of the arguments presented by the parties to those that relate to the collateral estoppel analysis. Defendants assert that the appellate panel's rejection of their collateral estoppel argument is based on two critical errors.

First, they argue that the panel erred when it applied the collateral estoppel analysis consistent with New Jersey law rather than utilizing the principles for evaluating collateral estoppel found in federal case law. Defendants assert that controlling precedents from the United States Supreme Court, see *Semtek Int'l, Inc. v. Lockheed Martin Corp.*, 531 U.S. 497, 507, 121 S.Ct.

1021, 1027, 149 L.Ed.2d 32, 42 (2001), and from this Court, see *Watkins*, supra, 124 N.J. at 411-12, 591 A.2d 592, make plain that "federal law controls the preclusive effect of a federal court's judgment," *id.* at 411, 591 A.2d 592 (emphasis added); see *Semtek*, supra, 531 U.S. at 507, 121 S.Ct. at 1027, 149 L.Ed.2d at 42.

Moreover, defendants assert that had the appellate panel applied the elements of federal collateral estoppel as it should have, it would have concluded that plaintiffs' cause of action may not proceed. Second, defendants argue that the panel's analysis and application of the equitable exceptions⁴ found in the Restatement, see *467Restatement, supra, §§ 28, 29, was flawed.

They argue that the panel has misconstrued the breadth and application of the equitable exceptions. Specifically, defendants assert that, even were there a basis in federal or state law to apply these equitable considerations, the panel's approach has transformed them from rarely applied exceptions into a routine opportunity for litigants to have a second chance to overcome shortcomings in their proofs.

Furthermore, they argue that the panel both misunderstood and misapplied the consideration relating to "inconsistent determinations" found in section 29(4), by inappropriately equating the

previously-conducted proceedings in the federal court with entirely separate and distinct state court proceedings involving different parties, see *Gannon*, supra, 414 N.J.Super. at 526-30, 999 A.2d 522 (relying on *Rivard v. Am.*

Home Prods., Inc., 391 N.J.Super. 129, 917 A.2d 286 (App.Div.2007)). Finally, defendants argue that the panel improperly construed section 29(8) of the Restatement, extending it to permit the mere possibility that plaintiffs might discover new evidence to meet the “other circumstances” exception found there.

In summary, defendants assert that, if left uncorrected, the panel’s approach will replace sound collateral estoppel principles with an unstructured system in which losing litigants are granted opportunities to try to address issues already fairly adjudicated against them. They warn that, if permitted to stand, the panel’s analysis of collateral estoppel will not only confuse future applications of the doctrine, but also will breathe life into two obscure exceptions that have the potential to eviscerate the doctrine of any effect.

Plaintiffs urge this Court to affirm the panel’s judgment and to concur in its collateral estoppel analysis. They contend that the panel properly applied the exceptions found in the Restatement to this case and they argue that because the United States Supreme Court in *Semtek*, and this Court in *Watkins*, addressed the distinct doctrine of res judicata rather than collateral estoppel, defendants’ reliance on those precedents is misplaced.

Furthermore, plaintiffs argue that the appellate panel was not obligated to apply federal law exclusively, but was permitted to rely instead on state law principles. They note that the Appellate Division did so in reliance on precedents in which this Court has condoned such an approach. See *Gannon*, supra, 414 N.J.Super. at 524, 999 A.2d 522 (citing *Del Piano v. Merrill Lynch*, 372 N.J.Super.

503, 509, 859 A.2d 742 (App.Div.2004), certif. granted, 183 N.J. 218, 871 A.2d 95, dismissed as improvidently granted, 195 N.J. 512, 950 A.2d 901 (2005)). Finally, plaintiffs argue that defendants cannot demonstrate that the Appellate Division incorrectly applied the exceptions found in the Restatement. Rather, they urge us to conclude that the panel properly balanced the equitable issues implicated by the doctrine of collateral estoppel and that it clearly and correctly expressed why collateral estoppel was not appropriate.

III. This appeal presents this Court with three essential questions. First, we are called upon to decide whether federal or state law principles of collateral estoppel govern the analysis of the preclusive effect to be given to the judgment rendered by the United States District Court for the Eastern District of Pennsylvania.

Second, we consider whether plaintiffs were afforded a full and fair opportunity to litigate the issues of general and specific causation in the federal court proceeding sufficient to entitle the

judgment of that court to preclusive effect.

Third, we address whether the Appellate Division appropriately applied the equitable considerations found in the Restatement to permit plaintiffs' claim to proceed when traditional collateral estoppel principles would preclude it. *469A.

We begin with a consideration of what law applies to the determination of whether any particular judgment shall be given collateral estoppel effect. Defendants argue that because the judgment on which they rely was rendered by a federal court, its preclusive effect must be tested in accordance with federal principles. Plaintiffs, relying on the opinion of the appellate panel, contend that there are no meaningful differences between federal and state law principles, thus leaving the state court "free to consider the issues raised under the particular facts of this case in accordance with New Jersey law 'as well as analogous federal decisions.'" Gannon, *supra*, 414 N.J.Super. at 524, 999 A.2d 522 (quoting Del Piano, *supra*, 372 N.J.Super. at 509, 859 A.2d 742).

This Court has previously settled the question about the proper analytical framework for testing the collateral estoppel effect of federal judgments, and we have made it plain that the issue is governed by reference to federal rather than to state law principles. Watkins, *supra*, 124 N.J. at 411-12, 591 A.2d 592. Our conclusion that federal principles must govern the preclusive effect of a federal judgment is grounded on our recognition that "cohesion between state and federal courts is necessary for the continuing vitality of the federalist system." *Id.* at 410, 591 A.2d 592.

As such, we commented that "Maintaining a cohesive federal system requires not only that federal courts honor state court judgments... but also that state courts honor federal court judgments." *Ibid.* As part of our analysis in Watkins, we observed that "[i]n general, the binding effect of a judgment is determined by the law of the jurisdiction that rendered it," and that this rule applies with equal force when considering the effect to be given to a federal court judgment in a state court proceeding.

Id. at 411, 591 A.2d 592 (citations omitted). Although we concluded that federal concepts of res judicata would not bar state law claims that could have been, but were not, raised as pendent claims in the federal action, see *id.* at 413, 591 A.2d 592, our essential holding was *470grounded on an analysis of generally applicable federal principles of claim preclusion.

Although acknowledging this clear command, see Gannon, *supra*, 414 N.J.Super. at 520, 999 A.2d 522, the Appellate Division instead looked to general choice of law principles, believing that it should determine whether there was a conflict between state and federal law relating to collateral estoppel. *Id.* at 524, 999 A.2d 522.

The panel found support for this approach in an appellate court decision employing a choice of law analysis to federal and state law claims in the arbitration context, see Del Piano, *supra*, 372 N.J.Super. at 508-09, 859 A.2d 742, and found further support for its view in this Court's eventual

determination to vacate certification of questions arising from that published decision, see *Del Piano*, supra, 195 N.J.

512, 950 A.2d 901. The panel's reasoning, however, was flawed in three respects. First, this Court in *Watkins* settled the question of the manner in which the preclusive effect of a federal judgment is to be evaluated, holding that federal and not state court principles govern. See *Watkins*, supra, 124 N.J. at 412, 591 A.2d 592.

Second, the choice of law analysis in *Del Piano* was unrelated to any consideration of collateral estoppel, resting instead on a comparison between federal and state arbitration statutes. *Del Piano*, supra, 372 N.J.Super. at 508-09, 859 A.2d 742.

Finally, a decision of this Court to vacate certification as improvidently granted is not the functional equivalent of an affirmance of an appellate court's decision by this Court, nor could it under any analysis operate to overrule sub silentio a prior substantive decision of this Court. See *Pressler & Verniero*, Current N.J. Court Rules, comment on R. 2:12-11 (2012) (explaining this Court's authority to vacate a previous grant of certification); *Tricarico v. Bd. of Review*, 147 N.J.

581, 582, 689 A.2d 124 (1997) (Stein, J., dissenting) (noting that dismissal of an appeal as improvidently granted "lacks any substantive content that clarifies or informs the Court's dismissal of [the] appeal"). To the extent that the Appellate Division determined that it could rely on choice of law principles to decide an issue already *471settled by this Court or that it could therefore use state law principles of collateral estoppel to evaluate the effect to which a federal court's judgment was entitled, it erred.

In doing so, the panel ignored this Court's clear embrace of the fundamental proposition that the preclusive effect of a judgment is "determined by the law of the jurisdiction that rendered it." *Watkins*, supra, 124 N.J. at 411, 591 A.2d 592 (preclusive effect in state court of prior federal judgment is determined by federal law).

Here, the court that rendered the judgment that defendants seek to apply is a federal court, and we therefore look to federal law to determine that judgment's preclusive effect. See, e.g., *Paramount Aviation Corp. v. Agusta*, 178 F.3d 132, 145 (3d Cir.1999); *Watkins*, supra, 124 N.J. at 411, 591 A.2d 592. Adhering to that approach is significant, not because the substantive tests for collateral estoppel used in federal court are vastly different from the test established by this Court, for the essential elements of the federal and state court tests are quite similar.

Rather, using the approach we adopted in *Watkins* serves to remind our courts that we are constrained by the federal court framework and they are not permitted to adopt a broader test as they might be inclined to think appropriate when evaluating state law principles.

Thus, for purposes of evaluating the collateral estoppel effect that our courts must accord to the prior judgment in this matter, the appropriate source of authority is found in the controlling decisions of the United States Court of Appeals for the Third Circuit. That Court has held that in order for a judgment to be entitled to be given the effect of collateral estoppel, or issue preclusion, there must be a coalescence of four factors, which have been identified as follows: (1) the identical issue was decided in a prior adjudication; (2) there was a final judgment on the merits; (3) the party against whom the bar is asserted was a party or in privity with a party to the prior adjudication; and (4) the party against whom the bar is asserted had a full and fair opportunity to litigate the issue in question. *472[*Del River Port Auth. v. FOP, Penn-Jersey Lodge 30*, 290 F.3d 567, 574 n. 10 (3d Cir.2002) (citing *Bd. of Trs. of Trucking Emps. of N. Jersey Welfare Fund, Inc. v. Centra*, 983 F.2d 495, 505 (3d Cir.1992)).]

To the extent that the appellate panel effectively applied a different articulation of the rules governing collateral estoppel, its approach was in error. We turn, then, to the proper application of the federal framework. B. Although the issue, for purposes of federal collateral estoppel, is whether the four essential elements identified by the United States Court of Appeals for the Third Circuit have been met in the record before this Court, plaintiffs in this appeal have based their challenge on only the last of these questions.

That is, they argue only that they were deprived of a full and fair opportunity to litigate the question of causation in the context of the proceedings in the federal district court. We find this argument to be without merit, for two reasons.

First, the determination that the federal district court made in the Tort Claims Act proceedings relating to the safety of the oi'al polio vaccine was based on the motion for judgment on partial findings filed on behalf of defendant, the United States. See Fed.R.Civ.P. 52(c). An integral part of the analysis that the federal district court is required to undertake in deciding whether to grant a motion for judgment pursuant to Rule 52(e) is whether the parties have been given an opportunity to fully and fairly present the question that is being decided.

The Rule, by its terms, limits its operation by referring to that opportunity, providing, in relevant part, that relief may only be granted “[i]f a party has been fully heard on an issue during a nonjury trial.” *Ibid.* Compliance with this essential premise of the Rule was directly in issue in the proceedings before the federal courts, because plaintiffs raised that specific challenge in opposing the motion for relief pursuant to the Rule.

They argued forcefully before the district court that although they had an adequate opportunity to *473present the testimony of Dr. Gazdar on the questions of specific and general causation, there were other experts they intended to present whose testimony would have altered the evidence before the court. *Gannon*, *supra*, 571 F.Supp.2d at 618-19. That is, plaintiffs argued that they were

planning to call other experts, each of whom would have offered testimony that they asserted would have demonstrated that they were entitled to recover.

Ibid. In rejecting that argument, the district court analyzed the anticipated testimony of each of the other witnesses that plaintiffs had identified and concluded that it would not have altered the outcome on the causation questions. *Id.* at 618-20.

As the court explained, all of the other testimony to which plaintiffs pointed would only have been relevant to the issue of whether the vaccine was contaminated. *Id.* at 619. Because the judgment on partial findings was based on the question of causation, however, the fact of contamination was presumed.

The question for the court was simply whether the contaminated vaccine could have caused cancer in humans and, specifically, whether it did cause the particular cancer that plaintiff Jamie Gannon had. In analyzing that argument, the court explained: Plaintiffs' key objection to this present Motion is that the polio vaccine contamination issue [a]ffects the epidemiological data which in turn [a]ffects the causation issue.

This objection obscures the issue at hand: whether SV40 causes human cancer and whether it caused Mr. Gannon's medulloblastoma. The testimonies of Dr. Gazdar and Defendant's three expert witnesses addressed these issues of general and specific causation.

The vaccine contamination issue involves whether [the oral polio vaccine] that Mr. Gannon received was contaminated with SV40. These are distinct and separate issues. Plaintiffs are merely trying to graft the issue of vaccine contamination onto the issue of causation to prevent their case from ending. [*Id.* at 620-21.]

As the district court concluded, no amount of added testimony or evidence on the fact of contamination could have altered the court's findings and conclusions as to the absence of sufficient proof on the issues of general or specific causation. *Id.* at 620.

As a result, in response to plaintiffs' arguments in opposition to the Rule 52(c) motion, the federal district court specifically considered whether plaintiffs had been afforded a full and fair opportunity to litigate the issues of causation and concluded that they had. *Id.* at 621. Plaintiffs challenged the federal district court's finding and conclusion that they had been afforded a full and fair opportunity to litigate the questions of general and specific causation as part of their appeal in the federal courts.

In affirming the judgment of the district court, however, the Third Circuit likewise concluded that plaintiffs had been afforded a full and fair opportunity to litigate the issues and the motion for judgment was affirmed in part on that ground. *Gannon, supra*, 292 Fed.Appx. at 174-75.

We therefore conclude that, for collateral estoppel purposes, plaintiffs were afforded a full and fair opportunity to address the questions of general and specific causation, and those questions have been resolved against them. C. Plaintiffs' challenge to the application of collateral estoppel to preclude them from proceeding on their state law cause of action found support before the Appellate Division in the context of a further attack based on fairness.

As part of the appellate panel's analysis, it noted that collateral estoppel is essentially a doctrine that rests on principles of fairness, with the result that its application is similarly subject to equitable considerations, see *Gannon*, supra, 414 N.J.Super. at 521, 999 A.2d 522 (citing *Olivieri*, supra, 186 N.J. at 521-22, 897 A.2d 1003).

In its discussion, the panel relied on two sections found in the Restatement that bear generally on the equitable concerns that might be relevant to collateral estoppel, Restatement, supra, §§ 28, 29, and considered whether in the context of the issues raised on appeal, those equitable considerations would permit this matter to proceed.

We conclude that the appellate panel, in applying those equitable considerations, erred. Our evaluation must begin with a brief explanation of the panel's analysis of the equitable considerations. The Appellate *475Division found that three specific subsections of the Restatement supported the conclusion that the equities made collateral estoppel inappropriate.

See *id.* §§ 28(4), 29(4), 29(8). The equitable considerations set forth in these provisions and their implications for the appellate panel's analysis may be summarized briefly. Section 28(4) essentially explains that it may be inappropriate to impose collateral estoppel against a party if that party, in the first proceeding, bore a "significantly heavier burden of persuasion with respect to the issue." Section 29(4), which relates to subsequent litigation with other parties, provides that issue preclusion may be inappropriate if the earlier-decided issue "was itself inconsistent with another determination of the same issue." Section 29(8) provides that it may also be inappropriate to impose collateral estoppel if "[o]ther compelling circumstances make it appropriate that the party be permitted to relitigate the issue." In analyzing the implications of these sections, the panel began by commenting generally on the state and federal precedents that recognize that these equitable considerations play a role in the collateral estoppel analysis.

See *Gannon*, supra, 414 N.J.Super. at 522-24, 999 A.2d 522. It then based its evaluation of the equities represented by these sections on two facts, namely, the status of discovery in this matter and the claims being raised about ORIMUNE® by the plaintiff in *Rivard*. Both aspects of the panel's reasoning demonstrate a fundamental misunderstanding of collateral estoppel principles in general and of the limited role to be played in that analysis by these equitable considerations.

First, as we have concluded, the panel erroneously focused on state law, rather than federal concepts of collateral estoppel, and did so in its recitation of the equitable considerations outlined

in sections 28 and 29 of the Restatement that might appropriately limit the application of the doctrine. More significant, for purposes of this appeal, is the panel's apparent translation of mere observations by both this Court and the federal courts about the general significance of the equitable considerations into broad *476 substantive commands about the extent to which they can overcome the ordinary preclusive effects of prior judgments.

It is certainly true that this Court has observed that we will, in appropriate circumstances, rely on equitable considerations to prevent the application of collateral estoppel. See *Olivieri*, supra, 186 N.J. at 521-22, 897 A.2d 1003 (declining to afford preclusive effect to denial of unemployment benefits in CEPA litigation); *In re Coruzzi*, 95 N.J. 557, 568, 472 A.2d 546 (1984) (observing that "sufficient countervailing interests" may make collateral estoppel inappropriate).

It is equally true, as the panel noted, see *Gannon*, supra, 414 N.J. Super. at 523, 999 A.2d 522, that the Third Circuit has commented on the equitable considerations found in the Restatement, see *Duvall v. AG of the United States*, 436 F.3d 382, 390-91 (3d Cir.2006) (commenting that doctrine is "flexible" and referring to exceptions identified in section 28); *Nat'l R.R.*

Passenger Corp. v. Pa. Pub. Util. Comm'n, 288 F.3d 519, 525 (3d Cir.2002) (noting Restatement section 28 summarizes equitable factors to be considered); *Wells v. Rockefeller*, 728 F.2d 209, 214-15 (3d Cir.1984) (recognizing relevance of Restatement section 29); see also *O'Shea v. Amoco Oil Co.*, 886 F.2d 584, 593-94 (3d Cir.1989) (recognizing that comment (f) to Restatement 28 could permit equitable exception to issue preclusion when higher burden of proof was imposed in first proceeding).

In its analysis, however, the Appellate Division simply referred to the state and federal decisions as support for the general proposition that equitable concerns are relevant; it failed to recognize that none of them lends support for its expansive view of the role to be played by the exceptions on which it relied. This is particularly true when considering the federal precedents.

A brief review of the Third Circuit decisions that the panel cited demonstrates the panel erroneously presumed that those decisions might support its view of the matter on appeal. In point of fact, the Third Circuit's observations about the equitable considerations identified in the Restatement are offered in the context of *477a broader, and more general, explanation of the governing legal principles.

See *Nat'l R.R.*, supra, 288 F.3d at 525, 528 (rejecting contentions that Eleventh Amendment immunity or change in applicable law created equitable bar to collateral estoppel); *Wells*, supra, 728 F.2d at 214-15 (citing Restatement § 29 in eviction action as illustrative of significance of identity of parties in determining whether counterclaims are deemed "compulsory").

Although in one of the cases cited by the panel, the Third Circuit did find that the equities demanded that collateral estoppel yield, it did so in the most unusual of circumstances. *Duvall*,

supra, 436 F.3d at 391-92.

In Duvall, the Immigration and Naturalization Services had terminated deportation proceedings because the purported alien refused to provide information relevant to alien status and because the INS failed to comply with certain agency rules relating to proofs. 436 F.3d at 394-95.

The purported alien, who thereafter continued to commit deportable criminal offenses, attempted to rely on collateral estoppel to prevent the INS from challenging his status based on the prior proceeding. Although the Third Circuit commented that the equitable considerations found in the Restatement counseled against permitting the alien to claim the benefit of collateral estoppel, *id.* at 391, the court made clear that it did so because of the unusual circumstances with which it had been presented, *id.* at 392.

Absent in that opinion is the sort of broad application of equities that the Appellate Division found appropriate. Although it was accurate to point out that the federal court has recognized that equitable concerns may impact upon the collateral estoppel analysis, nothing in that court's decisions suggests that it would find any equitable bar to the imposition of collateral estoppel bar against plaintiffs given the circumstances presented in this appeal.

Our review of the issues raised on appeal requires us to consider the way in which the Restatement sections apply in the context of the record now before us. Section 28(4) would permit the court to conclude that imposition of collateral estoppel is inappropriate if the party bore a "significantly heavier burden of *478persuasion" in the first proceeding.

In considering this section, the appellate panel correctly concluded that there is no basis on which to apply section 28(4), because the burden of persuasion is no different in the two matters. *Gannon*, supra, 414 N.J.Super. at 525, 999 A.2d 522. Whether proceeding against the United States under the Federal Tort Claims Act or proceeding against the pharmaceutical defendants in state court, plaintiffs were required to prove that SY40 causes cancer in humans and that it caused plaintiff Jamie Gannon's cancer in particular.

The federal courts imposed no greater burden on plaintiffs in that regard than they would face in the state court litigation. Nonetheless, the appellate panel then turned to section 29(8) and concluded that there may be "other compelling circumstances" that would permit plaintiffs to relitigate their claims. *Gannon*, supra, 414 N.J.Super. at 525-26, 999 A.2d 522.

That conclusion was based on the panel's analysis of the status of the record in the state court proceeding. In short, the panel faulted the trial court for basing its decision on the judgment of the federal court and for granting the collateral estoppel motion without permitting plaintiffs to pursue discovery and name experts in their state court litigation.

Id. at 526, 999 A.2d 522. In particular, the panel thought it appropriate to afford plaintiffs an opportunity to “conduct new tests” and “develop additional evidence of causation.” Ibid. However, in doing so, the appellate panel expanded the narrow parameters of “compelling circumstances” to permit plaintiffs to do that which collateral estoppel forbids. See *Yamaha Corp. of Am. v. United States*, 961 F.2d 245, 254-55 (D.C.Cir.1992) (observing that “[preclusion cannot be avoided simply by offering evidence in the second proceeding that could have been admitted, but was not, in the first”); *Herbert v. Reinstein*, 976 F.Supp. 331, 337 (E.D.Pa.1997) (same).

The mere speculation that, given a second chance, plaintiffs might be able to make a better record cannot equate with “compelling circumstances” in the face of a full and fair opportunity to litigate the precise issue in the federal proceeding. *479 Finally, the panel found support for its view in section 29(4) of the Restatement. That analysis, likewise, was based on a flawed understanding of the equitable exception.

Section 29(4) addresses the preclusive effect of judgments in the context of a “determination [that]... was itself inconsistent with another determination of the same issue.” Restatement, *supra*, § 29(4). In analyzing this section, the panel observed that plaintiffs’ state law claim had initially been consolidated for discovery purposes with complaints filed by other plaintiffs who asserted that they had been injured by oral polio vaccines.

Using that connection, and relying on the fact that defendants had not been granted summary judgment in one of those other cases, see *Rivard*, *supra*, 391 N.J.Super. at 138-39, 917 A.2d 286, the panel believed that in some fashion it would be unfair to prevent plaintiffs in this case from continuing in state court.

The *Rivard* appeal involved the claim by defendants that they should have been granted summary judgment because there was insufficient evidence in that record to demonstrate that ORIMUNE® was contaminated or that it caused *Rivard*’s tumor. Based on the limited record that had been established in that matter, the Appellate Division concluded that, in light of the favorable inferences to be applied in the context of a motion for summary judgment, *Rivard* had presented sufficient evidence to be permitted to proceed.

Id. at 151, 917 A.2d 286. In concluding that plaintiffs in this matter should be relieved of the bar of collateral estoppel that would otherwise be imposed as a result of the federal district court’s decision, the panel essentially believed that it would be unfair to preclude plaintiffs from proceeding while the plaintiff in *Rivard* was permitted to do so. See *Gannon*, *supra*, 414 N.J.Super. at 526-29, 999 A.2d 522.

In part reasoning that applying collateral estoppel in this matter might lead to inconsistent results between this case and *Rivard*, and in part relying on plaintiffs’ argument that discovery in

Gannon's state court matter is not complete, the panel applied a general equitable approach. Such an approach, however, overlooks the stark facts in the record before this Court.

Plaintiffs in this matter, as noted by both the Third Circuit and the federal district court, had a full and fair opportunity to present evidence of both general and specific causation. The possibility that plaintiffs could present additional evidence to support the essential element of causation is insufficient to prevent the application of collateral estoppel.

See *Yamaha*, supra, 961 F.2d at 254-55; *Herbert*, supra, 976 F.Supp. at 337. Regardless of what evidence the plaintiff in *Rivard* might have produced, these plaintiffs had a full and fair opportunity to place their proofs in evidence and to have their essential claims litigated on the merits. Were we to adopt the panel's rationale, we would create an avenue for endless re-litigation of issues already adjudicated based only on the happenstance of another plaintiff with another expert or another disease or another approach.

To equate the mere existence of another similar litigant, as did the appellate panel, to the threat of inconsistency sufficient to serve as an equitable exception to the doctrine is not only plainly inconsistent with the principles of collateral estoppel but would effectively obliterate the doctrine. Courts applying the equitable considerations identified in the Restatement must be careful in their performance of that task.

They must not regard those considerations to be a license to substitute generalized concerns about the imposition of collateral estoppel when the clearly established elements have been met. There is, in the end, nothing unusual or out of the ordinary, for collateral estoppel purposes, about the successive litigation in which plaintiffs have engaged.

As this appeal demonstrates, plaintiffs were afforded a full and fair opportunity to be heard on the essential claims of their dispute. Those claims were decided against them, and that judgment was sustained on appeal. Their assertion that they should be heard anew or that other plaintiffs with similar claims might have other evidence is not a sufficient ground on which to conclude that the imposition of collateral estoppel principles is so unfair that equity demands that they be permitted to have their claims heard again.

IV. The judgment of the Appellate Division is reversed. The relationship among the defendants is complex. As they explained, at the time relevant to this dispute, Lederle Laboratories was an unincorporated division of American Cyanamid Company.

In 1994, American Home Products Corporation acquired American Cyanamid and changed its name to Wyeth Holdings Company, a wholly-owned subsidiary of American Home Products Corporation. Thereafter, American Home Products Corporation changed its name to Wyeth, at which point Wyeth Holdings Corporation became its wholly-owned subsidiary.

Although Wyeth Laboratories Inc., which is now known as Wyeth Pharmaceuticals Inc., also manufactured and distributed an oral polio vaccine during the 1960s and 1970s, that entity was not named as a defendant in this litigation, and is distinct from both defendant Lederle Laboratories and defendant American Cyanamid Company. Discovery relating to the identification of the product's manufacturer was conducted only in connection with the state court action.

Although the published opinions in the federal court proceedings comment that plaintiff was given a Lederle Laboratories product, *Gannon*, supra, 292 Fed.Appx. at 172, that litigation rested on claims about the government's role in approving the vaccine, and the evidence adduced in those proceedings related to product testing and development rather than to product identification.

Ibid. As a result, the federal *460 court was not called upon to consider the adequacy of the proofs relating to product identification, and made no finding about the identity of the manufacturer of the product administered to plaintiff. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) (setting forth framework for challenge to admissibility of scientific evidence).

Defendants note that plaintiffs did not raise these equitable exceptions before the Appellate Division, urging us to decline to consider them. See *Selective Ins. Co. of Am. v. Rothman*, 208 N.J. 580, 586, 34 A.3d 769 (2012); *Nieder v. Royal Indemn. Ins. Co.*, 62 N.J. 229, 234, 300 A.2d 142 (1973).

Because we conclude *467 that the panel's substantive analysis is in error, we have elected to address the merits of this argument.