

**United States Court of Appeals
for the Federal Circuit**

**THERESA CEDILLO AND MICHAEL CEDILLO,
(AS PARENTS AND NATURAL GUARDIANS OF),
MICHELLE CEDILLO,
*Petitioners-Appellants,***

v.

**SECRETARY OF HEALTH AND HUMAN
SERVICES,
*Respondent-Appellee.***

2010-5004

Appeal from the United States Court of Federal
Claims in 98-VV-916, Judge Thomas C. Wheeler.

Decided: August 27, 2010

RONALD C. HOMER, Conway, Homer & Chin-Caplan,
P.C. of Boston, Massachusetts, argued for petitioners-
appellants.

LYNN E. RICCIARDELLA, Trial Attorney, Torts Branch,
Civil Division, United States Department of Justice, of
Washington, DC, argued for respondent-appellee. With
her on the brief were TONY WEST, Assistant Attorney

General, TIMOTHY P. GARREN, Director, and GABRIELLE M. FIELDING, Assistant Director.

MARY HOLLAND, Attorney-at-Law, of New York, New York, for amicus curiae Elizabeth Birt Center for Autism Law and Advocacy, et al.

Before NEWMAN, LINN, and DYK, *Circuit Judges*.
DYK, *Circuit Judge*.

This case is one of approximately five thousand cases that have been filed under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (“Vaccine Act”) in the Court of Federal Claims claiming a link between childhood vaccines and autism. The Special Masters created the Omnibus Autism Proceeding (“OAP”) to determine the relationship, if any, between vaccines and autistic spectrum disorders.

Petitioners Theresa and Michael Cedillo seek compensation on behalf of their daughter, Michelle Cedillo (“Michelle”). Their case is a part of the OAP proceeding. The Cedillos alleged that the measles-mumps-rubella (“MMR”) vaccine together with thimerosal-containing vaccines (“TCVs”) caused Michelle to suffer from various medical conditions, including autism. A Special Master denied the Cedillos’ petition, and the Court of Federal Claims affirmed. *Cedillo v. Sec’y of Health & Human Servs.*, 89 Fed. Cl. 158 (2009) (“*Final Decision*”). We affirm.

BACKGROUND

I

Michelle Cedillo was born on August 30, 1994. The pregnancy and birth were uncomplicated. Michelle's pediatric visits during her first sixteen months were unremarkable. During her first fifteen months of life, she received routine childhood vaccinations, some of which contained a mercury-based preservative called thimerosal. On December 20, 1995, at fifteen months of age, she received an MMR vaccination. She next saw her pediatrician on January 6, 1996. The record of the visit shows that one week after her MMR vaccination, Michelle had a fever and rash. Although the initial fever improved, she experienced another fever on January 5, 1996, accompanied by coughing, gagging, and vomiting. By the morning of January 6, 1996, Michelle's temperature was 105.7 degrees. Her temperature at the pediatrician's office was 100.3 degrees, and she had a "purulent postnasal drip." *Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, slip op. at 4 (Fed. Cl. Feb. 12, 2009) ("*Initial Decision*"). The pediatrician diagnosed "sinusitis vs. flu," and prescribed antibiotics. *Id.* Michelle next saw her pediatrician on March 15, 1996, for an eighteen-month well-child visit. No significant health concerns were recorded, and Michelle was noted to "stool[] well." *Id.* Her doctor also noted that Michelle was "talking less since ill in Jan." *Id.* A pediatric visit on April 24, 1997, noted "developmental delay suspected," and subsequent medical records confirmed that Michelle's development was indeed very abnormal. *Id.* In July 1997, Michelle was diagnosed with "severe Autism" as well as "profound Mental Retardation." *Id.*

In addition to Michelle's autism and severe mental retardation, Michelle has suffered from other medical problems. She has experienced chronic constipation and diarrhea. She has also suffered from possible gastroesophageal reflux disease, erosive esophagitis, and fecal impaction. At times, Michelle has also displayed symptoms of arthritis and pancreatitis and has experienced seizures.

II

Petitioners filed for compensation under the Vaccine Act on December 9, 1998. To obtain compensation for a vaccine-related injury or death, a petitioner must file a petition in the United States Court of Federal Claims and must show, by a preponderance of the evidence, that he or she received a vaccine listed on the Vaccine Injury Table and suffered a corresponding listed injury, in which case causation is presumed ("Table injury"), or that a listed vaccine in fact caused or significantly aggravated any injury ("non-Table injury"). See 42 U.S.C. § 300aa-11(a), -11(c), -12(a), -12(b), -13(a). Petitioners' theory of the case here is "causation-in-fact" (a non-Table injury claim), meaning that petitioners were required to prove causation. Once a petitioner establishes a prima facie case, the government then bears the burden of establishing alternative causation by a preponderance of the evidence. *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007).

The question at the heart of this proceeding is whether Michelle Cedillo's admitted autism has been shown to have been caused by certain childhood vaccines. Petitioners claim that the ethyl mercury in thimerosal in various childhood vaccines damaged Michelle's immune system, and that due to her immune deficiency, she was

unable to clear from her body the measles virus contained in the MMR vaccine. As a result, the vaccine-strain measles virus persisted and replicated in Michelle's body, causing her to suffer inflammatory bowel disease. Finally, the Cedillos "contend that the measles virus ultimately entered her brain, causing inflammation and autism." *Final Decision*, 89 Fed. Cl. at 163.

At the Cedillos' request, Michelle's case was consolidated into the OAP. In December of 2005, counsel representing the petitioners in the OAP, known as the Petitioners' Steering Committee ("PSC"), proposed a "test case" approach to present general causation evidence and then designated Michelle Cedillo's case as a lead claim to be tried in June 2007. *Hazlehurst v. Secretary of Health & Human Services*, No. 03-654V, and *Snyder v. Secretary of Health & Human Services*, No. 01-162V, were also designated as test cases. Special Master Hastings presided over the *Cedillo* case and two other Special Masters were assigned to the *Hazlehurst* and *Snyder* cases. Though the general causation evidence from the three cases was considered by the Special Masters in each of the cases, each individual case was considered individually on its own merits by a single Special Master.¹

A three-week evidentiary hearing in this case was held in June of 2007, in which both general causation

¹ The Special Masters in *Hazlehurst* and *Snyder* denied the respective petitions and the Court of Federal Claims affirmed in both cases. *Snyder v. Secretary of Health and Human Services*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009), was not appealed to this court. While this appeal was pending, we issued an opinion in *Hazlehurst v. Secretary of Health and Human Services*, 604 F.3d 1343 (Fed. Cir. May 13, 2010), in which we affirmed the denial of the petition for compensation.

evidence and evidence specific to the *Cedillo* case was presented. Petitioners presented testimony on general causation from six expert witnesses. Central to petitioners' theory of causation was testing done by Unigenetics Ltd. Laboratory in Dublin, Ireland ("Unigenetics") that reported successful use of the polymerase chain reaction technique ("PCR") to identify and amplify measles virus genetic material from the blood and intestinal tissue of autistic children who had received the MMR vaccine, including Michelle Cedillo. The Unigenetics research formed the basis for a 2002 article ("the Uhlmann article"). The Unigenetics laboratory, which is no longer in business, was a for-profit, non-accredited institution that was established to support United Kingdom ("UK") civil litigation against vaccine manufacturers in which it was alleged that the MMR vaccine caused autism. The Unigenetics testing on Michelle Cedillo was performed in 2002. Due to Michelle's gastrointestinal problems, she had undergone multiple endoscopies. Following one such procedure, in 2002, a tissue sample was taken from her intestine and a measles virus detection test was performed on the biopsied tissue by Unigenetics. The March 15, 2002, report of that test stated that "measles virus was detected" in the tissue. *Initial Decision*, slip op. at 5.

Petitioners' expert witnesses, Drs. Hepner and Kennedy, testified that Unigenetics had reliably detected persistent vaccine-strain measles in the bodies of children with autism and gastrointestinal dysfunction, including Michelle Cedillo. Drs. Kennedy and Hepner also offered opinions supporting petitioners' vaccine-strain measles/causation theory. Petitioners' expert Dr. Kinsbourne testified that vaccine-strain measles virus persisted in Michelle's body, damaged her brain, and thereby caused her autism. Petitioners also relied on testimony from Dr. Corbier from the *Hazlehurst* case to support their causa-

tion claim. Dr. Corbier testified in *Hazlehurst* that the MMR vaccine can play a role in causing autism, either by itself or in conjunction with thimerosal-containing vaccines, in persons with a genetic susceptibility to autism. Petitioners' expert Dr. Byers testified that Michelle has a weakened immune system due to thimerosal from vaccines, and petitioners' expert Dr. Aposhian testified that "thimerosal-containing vaccines can harm infant immune systems." *Initial Decision*, slip op. at 14. Petitioners' expert Dr. Kringsman testified as to an autism-gastrointestinal dysfunction link and opined that the MMR vaccine can cause chronic gastrointestinal dysfunction. He testified in particular that Michelle's gastrointestinal symptoms and ultimately, her autism, were caused by persistent measles virus from the MMR vaccine. Petitioners' theory of causation depended on the Unigenetics finding that the measles virus was present in Michelle Cedillo's body.

In response to petitioners' evidence concerning the Unigenetics testing, the government offered evidence that the Unigenetics testing was unreliable and that therefore, Unigenetics can not be said to have found evidence of persisting measles virus in the intestinal tissue of any of the children studied, including Michelle Cedillo. In particular, in order to establish the unreliability of the Unigenetics testing, the government offered expert testimony and reports from, among others, Dr. Stephen Bustin, a molecular biologist who was an expert in the UK litigation. In connection with those proceedings, Dr. Bustin was hired by vaccine manufacturers to evaluate the testing methods used by Unigenetics and to assess the validity of the Unigenetics work. After analyzing Unigenetics equipment and notebooks, he concluded that the procedures used by Unigenetics rendered the testing unreliable. On June 7, 2007, four days before the sched-

uled start of the evidentiary hearing, the government filed copies of expert reports Dr. Bustin had prepared and filed in 2003 and 2004 in the course of the UK litigation. These reports were under seal in the UK. However, the government succeeded in securing their release from the UK court. No request was made for the underlying notebooks or other data. Over objection, the Special Master provisionally admitted the reports and permitted Dr. Bustin to testify, but deferred a decision as to whether or not he would rely upon the Bustin testimony in deciding the case.

The government responded with testimony from nine expert witnesses as well as with other written reports and fact testimony. The government's experts testified that the evidence did not support a finding that TCVs can harm infant immune systems; that the MMR vaccine cannot cause autism in general; and that the evidence did not support a finding that the MMR vaccine can cause chronic gastrointestinal dysfunction.

Following the hearing in this case, the hearing in *Hazlehurst* was held in October of 2007 and the hearing in *Snyder* was held in November of 2007. At petitioners' request, the general causation evidence from *Hazlehurst* and *Snyder* was filed in the *Cedillo* record. The Special Master closed the evidentiary record in this case on July 30, 2008. The full record encompasses tens of thousands of pages of medical literature, more than four thousand pages of hearing testimony, and fifty expert reports.

In a lengthy initial decision dated February 12, 2009, after reviewing the voluminous record, including materials from *Cedillo*, *Hazlehurst*, *Snyder*, and the OAP master file, the Special Master denied Michelle's petition for compensation. He concluded that petitioners did not

demonstrate either that TCVs can harm infant immune systems, or that they harmed Michelle's immune system. He also concluded that the evidence did not demonstrate that the MMR vaccine alone or in combination with TCVs can cause autism in general, or that the MMR vaccine alone or in combination with TCVs caused Michelle's autism. The Special Master further concluded that the evidence did not demonstrate that the MMR vaccine can cause chronic gastrointestinal dysfunction in general, or that the MMR vaccine did cause Michelle's gastrointestinal problems.

In particular, the Special Master evaluated the evidence pertaining to the Unigenetics testing and concluded that the Unigenetics testing for the detection of measles virus suffered from significant flaws and was not reliable. The Special Master relied on the Bustin testimony in his decision, but also noted that he would have reached the same conclusions as to the unreliability of the Unigenetics work even in the absence of Dr. Bustin's testimony. In doing so, he noted that the main points in his rejection of the Unigenetics testing were "(1) the fact that the laboratory failed to publish any sequencing data to confirm the validity of its testing, (2) the failure of other laboratories to replicate the Unigenetics testing, and (3) the demonstration by the D'Souza group that the Uhlmann primers were 'nonspecific,'" meaning that they were not specific to measles virus genetic material.² *Initial Decision*, slip op.

² A 2006 article by D'Souza and colleagues detailing their attempts to replicate the Unigenetics work concluded that the data published in the Uhlmann article "is unlikely to be true." *Initial Decision*, slip op. at 26. Their primary explanation for why the Uhlmann researchers erroneously concluded that they had found measles virus in the tissue samples was that the primers used in the Uhlmann study were not as "specific" as they needed to be

at 51. He stated that the testimony by Dr. Bustin, along with testimony from other experts from the UK litigation, merely provided “a secondary, additional reason to doubt the reliability of the Unigenetics testing.” *Id.*

On March 13, 2009, petitioners filed a motion for reconsideration of the Special Master’s decision and attached materials not previously filed. The Special Master denied the motion as untimely and also on the ground that the petitioners had failed to demonstrate that reconsideration should be granted. Petitioners then moved for review of the Special Master’s decision by the Court of Federal Claims. On August 6, 2009, the court affirmed the Special Master’s initial decision, as well as his determination not to consider certain post-hearing evidence. Petitioners timely appealed to this court, and we have jurisdiction under 42 U.S.C. § 300aa-12(f).

DISCUSSION

We review de novo a ruling by the Court of Federal Claims on a Special Master’s decision to grant or deny entitlement to compensation under the Vaccine Act. *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). We review the Special Master’s legal conclusions without deference and discretionary rulings for abuse of discretion. *Id.*; *Saunders v. Sec’y of Dept. of Health and Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994). We review the Special Master’s factual

to positively identify measles virus and *only* measles virus. *Id.* The D’Souza researchers concluded that the Uhlmann primers (pieces of DNA that bind to and permit the identification and amplification of specific target DNA material) were non-specific enough that they caused the mistaken identification of human genetic material as measles virus material.

findings using an “arbitrary or capricious” standard. *Lampe*, 219 F.3d at 1360. We “do not sit to reweigh the evidence. [If] the Special Master’s conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.” *Id.* at 1363. Our role is not to “second guess the Special Master[']s fact-intensive conclusions” particularly in cases “in which the medical evidence of causation is in dispute.” *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993).

Here, petitioners were required to demonstrate by a preponderance of the evidence that the MMR vaccine or thimerosal-containing vaccines contributed to the causation of Michelle’s autism or her gastrointestinal symptoms. *See Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010). To prove causation, a petitioner in a Vaccine Act case must show that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). In doing so, petitioners’ burden

is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). If petitioners succeed in establishing a prima facie case of causation, the burden then shifts to the government to prove alternative causation by a

preponderance of the evidence. *Walther*, 485 F.3d at 1151.

I

Petitioners assert that the Special Master used an incorrect legal standard to determine causation, in particular they assert that the Special Master erred in using the *Daubert* standard to judge the reliability of the expert testimony. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593-94 (1993).

We see no legal error in the standards applied by the Special Master either in judging causation or in utilizing *Daubert*. The Special Master applied the correct *Althen* standards for causation. We have previously held that Special Masters may look to the *Daubert* standards in evaluating expert testimony.³ Vaccine Rule 8(b)(1) pro-

³ *See Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (“Although a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness”) (citing *Daubert*); *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (citing *Daubert* to support the conclusion that the special master may assess the reliability of expert testimony by considering whether the theory enjoys general acceptance in the scientific community); *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (approving the Special Master’s use of the *Daubert* factors “as a tool or framework for conducting the inquiry into the reliability of the evidence”); *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994) (citing *Daubert* to support the conclusion that a vaccine petitioner’s proof regarding the “logical sequence of cause and effect” “must be supported by a sound and reliable medical or scientific explanation”); *Perreira v. Sec'y of Health & Human Servs.*, 33 F.3d 1375,

vides that the special master will “consider all *relevant and reliable* evidence.” (emphasis added). By inclusion of the terms “relevant and reliable,” Vaccine Rule 8(b)(1) necessarily contemplates an inquiry into the soundness of scientific evidence to be considered by special masters. In *Daubert*, the Supreme Court set forth four factors for determining the admissibility of scientific evidence at trial. These factors are (1) general acceptance in the scientific community, (2) whether the theory has been subjected to peer review and publication, (3) whether the theory can and has been tested, and (4) whether the known potential rate of error is acceptable. *Daubert*, 509 U.S. at 593-94.

It is thus quite clear that the *Daubert* factors may be used in vaccine cases to assess expert witnesses’ methodology, but petitioners contend that the Special Master erroneously used these factors in assessing the reliability of the experts’ ultimate conclusions. In our decision in *Althen v. Secretary of Health & Human Services*, we held that petitioners in vaccine cases were not required to establish “an injury recognized by the medical plausibility evidence and literature.” 418 F.3d 1274, 1281 (Fed. Cir. 2005). Contrary to petitioners, the Special Master here did not interpret *Daubert* to undermine *Althen* and to require “proof of confirmation of medical plausibility from the medical community and literature.” Petitioners’ Reply Br. 11 n.16. While *Daubert* does not require that the experts’ ultimate conclusions be generally accepted in the scientific community, and the focus of a *Daubert* inquiry must generally be “on principles and methodology, not on the conclusions they generate,” “conclusions

1377 n.6 (Fed. Cir. 1994) (citing *Daubert* for the proposition that “[a]n expert opinion is no better than the soundness of the reasons supporting it”).

and methodology are not entirely distinct from one another A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (quoting *Daubert*, 509 U.S. at 595); see also *Smith v. Cangietter*, 462 F.3d 920, 924 (8th Cir. 2006) (finding no error in the use of *Daubert* to assess whether a particular conclusion may be reliably drawn from the evidence). We do not think that the Special Master here went beyond what is permissible under *Daubert*. We see no error in the Special Master’s decision applying *Daubert* in evaluating the reliability of the parties’ scientific evidence.

II

Apart from the argument concerning *Daubert*, petitioners’ primary contention on appeal is that the Special Master erred in permitting the government to introduce the expert reports and testimony of Dr. Bustin because the government did not make available the underlying Unigenetics documents upon which Dr. Bustin relied.

Dr. Bustin first testified as an expert in the UK litigation concerning the existence of a potential link between vaccines and autism. He was employed by vaccine manufacturers and asked to assess the validity of the Unigenetics laboratory findings as reported by the Uhlmann article. The documents obtained by Dr. Bustin from the Unigenetics laboratory provided crucial support for both of his expert reports filed in the UK. Once the government determined that petitioners’ causation theory would depend, in part, on the validity of the Unigenetics testing, the government petitioned the UK court to unseal the litigation file and release the Bustin reports. The government received the reports on June 7, 2007, and filed them within about an hour of receiving them. The gov-

ernment did not request any underlying laboratory notebooks or other data reviewed or relied on by Bustin in the preparation of the reports. Nor did the government supply any information as to the location of the underlying data. The government explained at oral argument that UK counsel informed them that an application to the UK court requesting “everything” from the UK litigation would be denied as overbroad, and as a result, they needed to narrow their request to the most essential items. The government therefore subsequently “honed down” their request to cover solely the three reports, two of which were filed by Dr. Bustin, that they eventually obtained. Oral Arg. 26:33-27:20.

It is unclear from the record to what extent the underlying data were submitted to the UK court along with Bustin’s reports or whether the underlying data, or portions thereof, still remain under seal with the UK court. However, both parties seem to assume that at least some of the Unigenetics materials relied on by Bustin in preparing his reports were submitted to the UK court, where they remain under seal.

In connection with the UK vaccine-autism litigation, Dr. Bustin spent more than 1500 hours analyzing the validity of the Unigenetics work as reported by the 2002 Uhlmann article. He was granted physical access to the Unigenetics laboratory, was able to utilize and inspect the lab’s equipment, and had access to all of the laboratory notebooks and data compiled by the researchers in the Uhlmann study. He also prepared an expert report in *Cedillo* and testified during the evidentiary hearing, wherein he again relied extensively on the Unigenetics documents and data.

In both his UK expert reports and in his testimony in this case, Dr. Bustin concluded that the Unigenetics testing with respect to the detection of measles virus was “severely flawed, and should not be considered reliable.” *Initial Decision*, slip op. at 29. He explained what he saw as the many problems with the laboratory and its work. Dr. Bustin explained that in one-third of Unigenetics procedures, the laboratory obtained positive results for negative controls—samples which definitely do not include the targeted genetic material. He testified that such a result means that contamination was rampant in the Unigenetics laboratory. He also explained a particular problem with the layout of the laboratory which may have resulted in the contamination he believes infected the laboratory. He testified to problems with the laboratory notebooks, which, in his view, had been improperly altered after the fact, in perhaps, a fraudulent manner. He observed that the laboratory was not accredited, declined to participate in a quality control program, and that no independent assessment of the laboratory’s work was ever performed. He detailed problems with the physical equipment used at the lab, inconsistencies in the laboratory procedures, and the poor quality of the ribonucleic acid (“RNA”) used for testing, all problems that could contribute to inaccurate results. He explained that testing of certain non-equivalent samples generated equivalent outcomes, a result that could only occur if the test was detecting a contaminant, rather than the measles virus. He also noted that on two occasions, not involving Michelle Cedillo, technicians failed to perform a necessary step in the protocol, yet still reported positive results—an impossible result which can only be explained by contamination. He also testified that sometimes duplicate samples which should both either register as positive, or negative, sometimes tested positive for one sample and negative for the other. Unigenetics would then report

such samples as “positive,” an unacceptable laboratory practice, rather than rerunning the tests. He concluded that overall, the Unigenetics testing was detecting a contaminant, and not measles virus, and was wholly unreliable.

Petitioners objected to the introduction of the Bustin reports and testimony on the grounds that those two reports were filed shortly before the hearing in this case, and because Dr. Bustin had access to the Unigenetics laboratory and to their records and data which were not made available to petitioners and their experts. The Special Master refused to exclude the Bustin testimony, but as described below, afforded petitioners additional time to attempt to secure the underlying material, and offered to assist in that effort.⁴

In civil litigation conducted pursuant to the Federal Rules of Civil Procedure, under Rule 26, a party must disclose in discovery information “considered by” testifying experts. Fed. R. Civ. P. 26. In particular, an expert report must contain “a complete statement of all opinions the witness will express and the basis and reasons for them” and “the data or other information considered by the witness in forming them.” *Id.* 26(a)(2)(B). *See Clear-*

⁴ The same problem existed with respect to the government’s expert, Dr. Bertus Rima, who testified in the *Snyder* case, and the government’s expert, Dr. Thomas MacDonald, who testified in *Hazlehurst*. Both of these experts also had access to Unigenetics data that was not supplied to petitioners. *Initial Decision*, slip op. at 30, 31. No objection was made to their testimony on the ground that the underlying data were not supplied, but for the same reasons that there was no error with respect to the Bustin reports and testimony, there was no error with respect to the testimony of Drs. Rima and MacDonald.

value Inc., v. Pearl River Polymers, Inc., 560 F.3d 1291, 1302 (Fed. Cir. 2009); *Neiberger v. Fed Ex Ground Package Sys., Inc.*, 566 F.3d 1184, 1191 (10th Cir. 2009); *Smith v. Botsford Gen. Hosp.*, 419 F.3d 513, 516-17 (6th Cir 2005). This right to underlying documentation is viewed as important for effective cross-examination, and as being fundamental to the fairness of litigation. See Fed. R. Civ. P. 26 advisory committee's note ¶ 2 (1993 amend.); *Fidelity Nat'l Title Ins. Co. of N.Y. v. Intercounty Nat'l Title Ins. Co.*, 412 F.3d 745, 751 (7th Cir. 2005). As we noted in *In re Pioneer Hi-Bred International, Inc.*, 238 F.3d 1370, 1375 (Fed Cir. 2001), "[t]he revised rule proceeds on the assumption that *fundamental fairness* requires disclosure of all information supplied to a testifying expert in connection with his testimony." (emphasis added). Virtually the same requirement appears in the rules of the Court of Federal Claims ("RCFC"). See RCFC 26(a)(2)(B); see also *Sparton Corp. v. United States*, 77 Fed. Cl. 1, 3-4 (2007). Under the Federal Rules of Civil Procedure and the Rules of the Court of Federal Claims, if a party fails to provide information required by Rule 26(a), the party is "not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1); RCFC 37(c)(1).

However, these discovery rules do not apply to proceedings under the Vaccine Act. Rather, such proceedings are governed by Vaccine Rule 8(b)(1) with respect to the admission of evidence, which provides that "[i]n receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties." Vaccine R. 8(b)(1). Vaccine Rule 7(a) further provides that in vaccine cases, "[t]here is no discovery as a matter of right. The informal

and cooperative exchange of information is the ordinary and preferred practice.” *Id.* 7(a). Formal discovery in vaccine cases is, however, available by motion. Under the Vaccine Rules, “[i]f a party believes that informal discovery is not sufficient, the party may move the Special Master, either orally during a status conference or by filing a motion, to employ any of the discovery procedures set forth in RCFC 26-37.” *Id.* 7(b)(1).

We agree with petitioners that the government’s failure to produce or even to request the documentation underlying Dr. Bustin’s reports is troubling, but we think that in the circumstances of this case, that failure does not justify reversal. In our recent decision in *Hazlehurst*, we specifically addressed this question and held that the failure to exclude the testimony and reports of Dr. Bustin did not constitute reversible error. *See Hazlehurst*, 604 F.3d at 1348-52. In particular, we concluded that the Special Master’s decision to admit and consider Dr. Bustin’s testimony was “in full accord with the principle of fundamental fairness” under Vaccine Rule 8(b)(1) and did not “contravene[] the purpose[] of the Vaccine Act” to avoid proceedings resembling tort litigation. *Id.* at 1351. We also concluded that even if the admission of the Bustin evidence was improper, the Special Master would have reached the same conclusions regarding the unreliability of the Unigenetics testing in the absence of the Bustin evidence. *Id.* Curiously, neither the government nor petitioners in this case ever mentioned the *Hazlehurst* decision. And while *Hazlehurst* did not consider the bearing of Rule 26 on this case, we think that the decision in *Hazlehurst* was correct and that it governs here. That is so for several reasons.

First, here, as in *Hazlehurst*, petitioners themselves relied on expert testimony as to the validity of Unigenet-

ics laboratory work without producing the underlying data. Petitioners' expert, Dr. Kennedy, was also an expert in the British litigation, and testified as to the reliability of the Unigenetics work. He was not affiliated with Unigenetics. He testified that the Unigenetics laboratory had a good reputation and that it had its work published in peer-reviewed medical journals. He also stated his opinion that the laboratory used proper procedures and took appropriate measures to avoid contamination. In reaching his conclusions, he relied in part on documentary information received from Unigenetics, including many of their laboratory notebooks. However, like Dr. Bustin, he did not produce any underlying data together with his testimony. The government was entitled to respond to this testimony, as our opinion in *Hazlehurst* recognizes. *See id.* at 1349-50. As we noted in *Hazlehurst*, "[a]lthough not obligated to do so, the petitioners chose to introduce the Unigenetics data and thus placed its validity squarely at issue. Fairness dictated that the government be given an opportunity to refute that critical evidence." *Id.* at 1349.

Second, petitioners did not request that the Special Master apply Rule 26 or order the government to secure the underlying information.

Third, petitioners themselves did not seek to access the data from the UK court, nor did they examine Dr. Bustin as to the current location of the data he relied upon in creating his reports. In the Special Master's evidentiary ruling denying petitioners' motion to exclude Bustin's reports and testimony, he encouraged petitioners' counsel to seek the underlying data from the UK court, and pledged to join any request. Thereafter, the Special Master then gave petitioners over a year to petition the British court for access to the information. Petitioners

also requested that the OAP Special Masters provide a letter supporting a possible request, which the Special Masters did. Petitioners considered making such a request from the UK court, but never did so. They contend that British counsel informed them that it was unlikely that the UK court would permit disclosure of the expert reports without the consent of the experts, which petitioners stated that they could not obtain. But Dr. Bustin did consent to the release of his reports. Once his consent for the release of his reports had been obtained by the government, there is no reason why the data underlying his reports could not also have been requested.

Finally, the Special Master specifically found that even if he were to disregard Dr. Bustin's expert reports and hearing testimony—and if he were to disregard all of the testimony from all of the experts that participated in the British litigation—he would have still concluded that the Unigenetics testing was not reliable. In doing so, he noted that the main points in his rejection of the Unigenetics testing were “(1) the fact that the laboratory failed to publish any sequencing data to confirm the validity of its testing, (2) the failure of other laboratories to replicate the Unigenetics testing, and (3) the demonstration by the D’Souza group that the Uhlmann primers were ‘nonspecific.’” *Initial Decision*, slip op. at 51. As we held in *Hazlehurst*, the Special Master’s reasoned conclusion that he would have reached the same result in the absence of the Bustin testimony supports a conclusion that any error in considering the Bustin testimony was, in fact harmless, as it did not affect the outcome of the proceeding. *See* 604 F.3d at 1351.

Petitioners also argue that they were prejudiced by the late introduction of Dr. Bustin’s reports from the UK litigation after the deadline set by the Special Master for

the submission of expert reports and on the eve of trial. As we noted, petitioners were given over a year thereafter to rebut the material in the reports. The Special Master also offered a second evidentiary hearing in which to present such new evidence. Petitioners never requested the second hearing, nor did they request additional cross-examination of Dr. Bustin, a request that the Special Master indicated he would have granted. The Special Master did not err in allowing the late filing of the Bustin reports.

In light of our decision sustaining the Special Master's conclusion as to the unreliability of the Unigenetics testing, we also sustain the Special Master's finding that petitioners have failed to establish that vaccine-strain measles virus was present in Michelle Cedillo's body. Thus, petitioners' theory based on the assumed presence of measles virus in Michelle Cedillo's body necessarily fails. As the Special Master found, petitioners established no other credible theory of causation. Under these circumstances, we need not address other alternative grounds for the Special Master's decision.

III

Petitioners also raise other allegations of legal error relating to the procedures utilized in the OAP. In particular, they contend that three Special Masters should not have been used to decide the three test cases, and that the Special Master assigned to this case should not have considered the evidence from all three test cases. This argument ignores the procedural history of this case. Petitioners chose to enter the OAP in 2002 and agreed to be the first test case in the OAP, in which the majority of the general causation evidence would be offered. Petitioners also affirmatively requested that the evidence

from *Hazlehurst* and *Snyder* be considered in this case. A review of the record makes clear that petitioners were only required to persuade Special Master Hastings of the merits of their case and that each Special Master reached an independent conclusion. Although petitioners objected to the appointment of two other special masters (arguing that the same special master should have decided all three cases), Judge Wheeler of the Court of Federal Claims specifically asked petitioners' counsel during oral argument "to identify any prejudice" from having three special masters involved in the proceeding. *Final Decision*, 89 Fed. Cl. at 174. Petitioners' counsel responded, "I don't know that there was any, Your Honor." *Id.*

Petitioners also argue that it was "unfair" for the Special Master to rely on testimony from Dr. Bertus Rima, offered in *Snyder*, to reject Michelle's petition, when petitioners had no opportunity to cross-examine him. Dr. Rima, also an expert from the British litigation, testified in *Snyder* as to the reliability of the Unigenetics testing, explaining that fundamental flaws in the testing methodology and laboratory practices used by Unigenetics cast doubt upon the validity of all its test results. Again, we observe that petitioners were the ones who requested that all evidence from *Snyder* be admitted into the record in this case. They did not object to the admission of Dr. Rima's testimony. Moreover, at no time after the *Snyder* hearing and before the evidentiary record was closed in this case did petitioners submit supplemental evidence or argument addressing his testimony, nor did petitioners ever request to cross-examine Dr. Rima. Finally, we note again the Special Master stated that he would have reached the same conclusion in the absence of any of the experts from the UK litigation. We can discern no re-

versible error in the Special Master's treatment of Dr. Rima's testimony.⁵

IV

Petitioners also contend that the Special Master abused his discretion in "ignor[ing]" certain concessions made by the government's experts or in "refus[ing] to consider" certain evidence. However, the Special Master did not ignore relevant testimony and explicitly considered the evidence in question with a few limited exceptions. Petitioners primarily argue that the Special Master considered, but erroneously declined to credit, certain evidence, or to draw from it conclusions favorable to petitioners. We have reviewed petitioners' arguments and we find them to be unpersuasive. In the Special Master's careful and thorough opinion, he considered, weighed, and stated his reasons for rejecting or discounting each item of evidence in which the petitioners relied. With respect to many of petitioners' claims of error, no discussion is necessary because there is no possible basis

⁵ Petitioners observe that Dr. Rima made a mathematical error in his testimony in *Snyder*. Dr. Rima testified that certain of the petitioner in *Snyder*'s test results from Unigenetics were so unbelievably high as to be biologically implausible. Both the Special Master and the Court of Federal Claims cited this testimony. This error occurred when Dr. Rima attempted to perform a mathematical calculation in his head while testifying and is not contained in his reports or his affidavit. Again, because the Special Master concluded that he would have reached the same conclusion in the absence of Dr. Rima's testimony, and because though Dr. Rima may have erred, his testimony was unequivocal that the Unigenetics results were unreliable whether the particular value at issue was high or low, we find that any error in his testimony was harmless.

for the claim of error. We discuss only petitioners' primary claims.

1. Petitioners contend that the Special Master ignored a number of significant concessions regarding the reliability of the Unigenetics laboratory testing. They argue that in view of these concessions, the Special Master erred in finding the Unigenetics testing to be unreliable.

In particular, petitioners describe Dr. Bustin's and Dr. Rima's testimony regarding the reliability of the Unigenetics work as equivocal, or as only applying to some of the Unigenetics results, but not all. However, as both the Special Master and the court noted, Dr. Bustin and Dr. Rima clearly testified that their criticisms were not simply limited to certain of Unigenetics' results and that they found all of the Unigenetics work to be unreliable. Petitioners also urge that a letter written by a Dr. Michael Oldstone, which was filed in *Snyder*, supports the reliability of the Unigenetics work. To the contrary—Dr. Oldstone's letter is clear in stating that he could not reliably replicate the Unigenetics results and that the 20 percent error rate he encountered completely undermined his confidence in the testing. It was on this basis that he declined further work with the laboratory. We find that the Special Master considered all of the evidence in context and did not err in concluding that the Unigenetics testing was unreliable.

2. Petitioners contend that British researcher Dr. Finbar Cottor was able to replicate the Unigenetics testing, and that he was able to reach similar results to those achieved by Unigenetics. Petitioners argue that the Special Master erred in discounting his work as evidence supporting the reliability of the Unigenetics testing. We

see no error in the Special Master's treatment of the evidence concerning Dr. Cottor's work. The only evidence concerning Dr. Cottor's work consisted of conflicting statements made by both parties' experts, who disagreed as to whether or not Dr. Cottor's laboratory was able to duplicate the Unigenetics results. No records of Dr. Cottor's work and no testimony or statement from him were presented. Also, Dr. Cottor's work was never published. Given the limited record concerning Dr. Cottor's work, the Special Master reasonably concluded that "it is simply impossible to draw any conclusions *either way*" about Dr. Cottor's work. *Initial Decision*, slip op. at 32 (emphasis in original).

3. Petitioners also argue that the Special Master "re-fus[ed] to consider" that immunohistochemistry testing by Unigenetics showed that measles virus protein was present in the children tested. Petitioners' Br. 48. This testing was different than the PCR testing discussed above. At the hearing, petitioners' expert Dr. Kennedy testified that he orally received information from Unigenetics regarding the successful use of immunohistochemistry to identify measles virus protein. Petitioners allege that the Special Master improperly discounted this testimony and that the Special Master improperly discounted references in the Uhlmann paper itself to the Unigenetics immunohistochemistry work.

The Special Master observed that though the Uhlmann paper "mentioned" immunohistochemistry, it provided no data or details concerning the use of the technique. *See Initial Decision*, slip op. at 38-40. Further, he noted that there was nothing in the article that stated that any immunohistochemistry work had identified measles virus protein. *Id.* at 39. The Special Master noted the lack of a written record or details about any of

the testing and found the evidence to be unconvincing that immunohistochemistry performed at Unigenetics “demonstrated the presence of measles protein in the tissue of autistic children.” *Id.* We see no error in the Special Master’s rejection of Dr. Kennedy’s conclusory testimony, which relied solely on unsubstantiated oral communications from Unigenetics personnel. We also see no error in the Special Master’s conclusion that the Uhlmann article itself does not demonstrate that any immunohistochemistry work performed by Unigenetics demonstrated the presence of measles protein in the tissue of autistic children.

4. Petitioners argue that the Special Master discounted evidence concerning allelic discrimination, a technique allegedly used by Unigenetics to distinguish between wild-type and vaccine-strain measles virus. One issue in this case is whether any measles virus genetic material allegedly recovered by Unigenetics from autistic children in general, or from Michelle Cedillo in particular, was vaccine-strain in origin or whether it was of the naturally occurring type (“wild-type”). The Uhlmann article does not purport to show that the measles virus allegedly found in the children’s biopsies was vaccine-strain measles virus. Similarly, the results of Michelle’s biopsy state only that measles virus was identified—not vaccine-strain measles virus.

On January 31, 2008, months after the evidentiary hearing, petitioners attempted to establish that the recovered genetic material was indeed vaccine-strain in origin by providing the synopsis of an article by certain Unigenetics principal researchers that suggested that Unigenetics successfully used allelic discrimination to determine that measles virus genetic material extracted from the autistic children was in fact vaccine-strain

measles virus. The actual article itself was not submitted. The article synopsis did not include any information specific to the results of Michelle Cedillo's tests. The Special Master specifically discussed the article synopsis and clearly articulated why he ascribed little weight to it, noting in particular that petitioners provided only a brief synopsis of the article which included no details and observed that none of petitioners' experts offered any testimony as to the research described in the synopsis or endorsed its accuracy. He also noted that there is no evidence that the work described in the synopsis was ever submitted for peer review and publication. *See Initial Decision*, slip op. at 41-42; *see also Final Decision*, 89 Fed. Cl. at 173. Further, as the Court of Federal Claims observed, it is irrelevant whether allelic discrimination was used to determine whether any measles virus recovered was vaccine in origin in light of the conclusion that Unigenetics was unable to reliably identify measles virus at all. *Final Decision*, 89 Fed. Cl. at 173.

We see no error in the Special Master's decision to ascribe little weight to the article synopsis.

5. Petitioners also argue that the Special Master "refus[ed] to consider" that the government's expert Dr. Griffin had herself published an article in which she detected measles genetic material in the blood of immunodeficient children, children with HIV. *See* Petitioners' Br. 39-40, 44-45. In the article, she concluded that the measles virus was active and replicating in the children studied. The article does not conclude that there is a connection between the administration of vaccines and the presence of measles virus. Petitioners offer this article as evidence that the government concedes that the recovery of measles genetic material from immunocompromised individuals is evidence of persistent, replicating,

measles virus, and that the recovery of measles protein is not necessary for one to reach a conclusion in any particular instance that the measles virus was persisting and replicating. The Special Master did not discuss this article in his decision. As the Court of Federal Claims observed, petitioners' counsel never asked Dr. Griffin about this article during cross-examination, and none of petitioners' expert witnesses relied upon this article. See *Final Decision*, 89 Fed. Cl. at 178. Given that there was no testimony offered by any expert as to the validity or import of such an article for this case, the Special Master did not err in disregarding such evidence, which at best addressed a peripheral issue.

6. Petitioners also argue that the Special Master erred in rejecting the opinion of Dr. Krigsman, petitioners' gastroenterology expert and one of Michelle's treating physicians. Dr. Krigsman testified that Michelle has inflammatory bowel disease and that the MMR vaccine caused her gastrointestinal symptoms. The Special Master noted that he did not find Dr. Krigsman to be a credible witness. He also concluded that Dr. Krigsman's opinion should be rejected because 1) he relied on the discredited Unigenetics testing in forming his opinion, 2) he misunderstood Michelle's medical history and his testimony was inconsistent with her medical records, and 3) his conclusion that Michelle suffered from chronic gastrointestinal inflammation was substantially outweighed by Michelle's medical records and the testimony of the government's experts.

Under the Vaccine Act, Special Masters are accorded great deference in determining the credibility and reliability of expert witnesses. Indeed, we have held that a Special Master's "credibility determinations are virtually unreviewable." *Hanlon v. Sec'y of Health & Human*

Servs., 191 F.3d 1344, 1349 (Fed. Cir. 1999) (quotation omitted). We will not disturb the Special Master’s analysis and credibility assessment on appeal, especially where, as here, the Special Master clearly articulated his reasons for discrediting the expert’s opinion. We can discern no error in the Special Master’s evaluation of the evidence. Further, even if one were to credit Dr. Krigsmann’s opinion, his testimony provides no support as to the crucial issue in this case—the reliability of the Unigenetics testing.

7. Petitioners also contend that the Special Master erred in discounting the opinions of Michelle’s treating physicians, several of whom associated her illness with her MMR vaccine. Petitioners argue that under our decision in *Capizzano v. Sec’y of Health & Human Affairs*, the opinions of treating physicians should be given significant probative weight. *See* 440 F.3d 1317, 1326 (Fed. Cir. 2006) (observing that “medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect shows that the vaccination was the reason for the injury”) (quotation omitted). The treating physicians did not testify. Petitioners cited nine notations in Michelle’s records from eight individuals, including four physicians who treated Michelle and four non-physicians who examined Michelle, in which the treating physicians mentioned her vaccinations, as support for the proposition that these individuals concluded that her autism was caused by her MMR vaccine.

The Special Master did not err in failing to afford significant weight to the opinions of Michelle’s treating physicians. As the Special Master observed in his decision, in seven of the nine notations, the physician was

simply indicating an awareness of a *temporal*, not causal, relationship between the fever Michelle experienced after her MMR vaccine and the emergence of her autistic symptoms sometime thereafter. *Initial Decision*, slip op. at 100. In one of the other notations, the physician simply noted that an exemption for Michelle from vaccination requirements could be arranged. In the other notation, the physician speculated that Michelle's fevers might have caused her neurological abnormalities. However, he expressly stated that it would be "difficult to say" whether this was "a post-immunization phenomenon, or a separate occurrence." *Id.* at 100. Thus, "none of the treating physicians concluded that the MMR vaccine caused Michelle's autism." *Final Decision*, 89 Fed. Cl. at 176. The Special Master clearly articulated why he declined to afford significant weight to the notations made by Michelle's treating physicians, and we see no error in his treatment of that evidence.

V

Petitioners contend that the Special Master abused his discretion in denying their motion for reconsideration in light of "significant" post-hearing evidence. Petitioners' Br. 51. The Special Master denied the motion for reconsideration because it was untimely, because all but one of the items submitted with the motion were available before the filing of his decision, and because in light of the new material submitted with the motion, reconsideration was not warranted.

Petitioners filed their motion for reconsideration with the Special Master on March 13, 2009, outside of the 21-day period for filing such motions and three days before a motion for review would have been due in the Court of Federal Claims. See Vaccine Rule 10(e)(1) (providing that

“[e]ither party may file a motion for reconsideration of the special master’s decision within 21 days of the issuance of the decision if a judgment has not been entered and no motion for review under Vaccine Rule 23 has been filed”). It is undisputed that petitioners did not file a timely motion for reconsideration and they have offered no explanation for the late filing. Therefore, the Special Master did not abuse his discretion in denying the motion for reconsideration on the grounds that it was untimely.

Petitioners also argue that, even if the motion was untimely, the Special Master abused his discretion in denying the motion because significant new evidence submitted with the motion rendered it in the interest of justice to reconsider the decision. *See id.* R. 10(e)(3) (providing that “[t]he special master has the discretion to grant or deny the motion [for reconsideration], in the interest of justice”). However, the Special Master reviewed the materials submitted with the motion and observed that with the exception of one medical journal article, all of the materials were available prior to the filing of his decision. The Special Master did not abuse his discretion in declining to grant reconsideration in view of evidence that was previously available and which did not in fact support petitioners’ position on the central issues.⁶

⁶ Petitioners suggest that they submitted an article that constituted “compelling new evidence with respect to the reliability of [Unigenetics]” and which “proved that the [Unigenetics] operating techniques and results were reliable.” Petitioners’ Reply Br. 6. The article describes a study which assessed the possibility of a connection between measles virus vaccines, autism, and gastrointestinal problems. In the course of the study, measles virus RNA was recovered from one child with autism and gastrointestinal dysfunction, and from one child in the

The one new article was published in the March 2009 issue of the journal *Pediatrics*. The record reflects that petitioners downloaded it from www.pediatrics.org on March 4, 2009, and the Special Master's decision was issued on February 12, 2009. The article was not available before the original decision. Nevertheless, the Special Master did not err in refusing to reopen the proceeding based on the article. The Special Master found the article to be "of very dubious relevance." *Final Decision*, 89 Fed. Cl. at 181. Petitioners argue here, as they did before the Special Master, that the article "sheds further light on the relationship between autism and gastrointestinal problems." J.A. 473. However, though the article discusses a potential link between autism and gastrointestinal dysfunction, we agree with the Special Master that it does not assist in repairing what he viewed as the "*fatal deficiency* in the petitioner's causation theories: the lack of any persuasive evidence that the *measles vaccine* can contribute to the causation of autism or gastrointestinal dysfunction." *Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V (Fed. Cl. Mar. 16, 2009)

control group, who only exhibited gastrointestinal dysfunction. There is no indication that the children tested by Unigenetics were tested in this study. The fact that measles virus could be present in some autistic children, does not confirm the reliability of the Unigenetics testing or suggest that measles virus was present in the children tested by Unigenetics. The article explicitly concludes that there is no link between measles virus vaccine, autism and gastrointestinal dysfunction. The article is titled "Lack of Associated between Measles Virus Vaccine and Autism with Enteropathy: A Case-Control Study," and it states that "this study provides strong evidence against association of autism with persistent [measles virus] RNA in the GI tract or MMR exposure." J.A. 626.

(order denying motion for reconsideration). Indeed, the Special Master noted in his initial decision that

it is not necessary for me to determine, in this case, to what extent autistic children have an increased risk for gastrointestinal dysfunction, or to determine why, in general, autism or regressive autism might be associated with excessive GI problems. Rather, the issues relevant here concern whether the *MMR vaccine* plays a *causal* role concerning chronic GI symptoms in autistic children

Initial Decision, slip op. at 97-98 (footnote omitted). As the Special Master explicitly declined in his initial decision to address the issue to which the article was directed, he did not err in declining to grant reconsideration in light of additional evidence possibly pertaining to a link between autism and gastrointestinal dysfunction. In any event, the article is irrelevant to the issue of the Unigenetics testing. Accordingly, we find that the Special Master did not act against the interests of justice in denying the motion for reconsideration.

Finally, Petitioners accuse the Special Master of abdicating his duty to be fair and impartial. We see no basis for questioning the fairness or the impartiality of the Special Master.

VI

In conclusion, we have carefully reviewed the decision of the Special Master and we find that it is rationally supported by the evidence, well-articulated, and reasonable. We therefore affirm the denial of the Cedillos' petition for compensation.

AFFIRMED

COSTS

No costs.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Questions and Answers

Petitions for Panel Rehearing (Fed. Cir. R. 40)
and
Petitions for Hearing or Rehearing En Banc (Fed. Cir. R. 35)

Q. When is a petition for panel rehearing appropriate?

A. Petitions for panel rehearing are rarely considered meritorious. Consequently, it is easiest to first answer when a petition for panel rehearing is not appropriate. A petition for panel rehearing should not be used to reargue issues already briefed and orally argued. If a party failed to persuade the court on an issue in the first instance, they do not get a second chance. This is especially so when the court has entered a judgment of affirmance without opinion under Fed. Cir. R. 36, as a disposition of this nature is used only when the appellant/petitioner has utterly failed to raise any issues in the appeal that require an opinion to be written in support of the court's judgment of affirmance.

Thus, as a usual prerequisite, the court must have filed an opinion in support of its judgment for a petition for panel rehearing to be appropriate. Counsel seeking panel rehearing must be able to identify in the court's opinion a material error of fact or law, the correction of which would require a different judgment on appeal.

Q. When is a petition for rehearing en banc appropriate?

A. En banc decisions are extraordinary occurrences. To properly answer the question, one must first understand the responsibility of a three-judge merits panel of the court. The panel is charged with deciding individual appeals according to the law of the circuit as established in the court's precedential opinions. While each merits panel is empowered to enter precedential opinions, the ultimate duty of the court en banc is to set forth the law of the Federal Circuit, which merits panels are obliged to follow.

Thus, as a usual prerequisite, a merits panel of the court must have entered a precedential opinion in support of its judgment for a petition for rehearing en banc to be appropriate. In addition, the party seeking rehearing en banc must show that either the merits panel has failed to follow decisions of the Supreme Court of the United States or Federal Circuit precedential opinions, or that the

merits panel has followed circuit precedent, which the party seeks to have overruled by the court en banc.

Q. How frequently are petitions for panel rehearing granted by merits panels or petitions for rehearing en banc granted by the court?

A. The data regarding petitions for panel rehearing since 1982 shows that merits panels granted some relief in only three percent of the petitions filed. The relief granted usually involved only minor corrections of factual misstatements, rarely resulting in a change of outcome in the decision.

En banc petitions have been granted less frequently. Historically, the court has initiated en banc review in a few of the appeals decided en banc since 1982.

Q. Is it necessary to have filed either of these petitions before filing a petition for certiorari in the U. S. Supreme Court?

A. No. All that is needed is a final judgment of the Court of Appeals.

