United States Court of Appeals for the Federal Circuit

2009-5128

ROLF HAZLEHURST and ANGELA HAZLEHURST,
parents of WILLIAM YATES HAZLEHURST,

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

Curtis R. Webb, Webb, Webb & Guerry, of Twin Falls, Idaho, 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, Mark W. Rogers, Deputy Director, and Gabrielle M. Fielding, Assistant Director.

Appealed from: United States Court of Federal Claims

Senior Judge John P. Wiese

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Appeal from the United States Court of Federal Claims
in 03-VV-654, Senior Judge John P. Wiese.

DECIDED: May 13, 2010

Before NEWMAN and BRYSON, Circuit Judges, and GUILFORD, District Judge.[*]

BRYSON, Circuit Judge.

This is one of a large number of cases involving claims for compensation on behalf of autistic children whose condition is alleged to have been caused by childhood vaccinations. In this case, Rolf and Angela Hazlehurst filed a claim for their son, Yates Hazlehurst, seeking compensation under the National Childhood Vaccine Injury Act of 1986 ("the Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34. The Hazlehursts alleged that the measles, mumps, and rubella ("MMR") vaccine, which was administered to Yates

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[*] The Honorable Andrew J. Guilford, District Judge, United States District Court for the Central District of California, sitting by designation.

shortly before his first birthday, caused him to develop regressive autism. A special master denied the Hazlehursts' petition, and the Court of Federal Claims affirmed. Hazlehurst v. Sec'y of Heath & Human Servs., 88 Fed. Cl. 473 (2009). On appeal to this court, the Hazlehursts argue that the special master improperly relied on certain evidence that should have been excluded and disregarded other evidence that should have been considered. We affirm.

I

The Office of Special Masters consolidated this case with several others as part of what was termed the Omnibus Autism Proceeding, an effort by the Office of Special Masters to identify and adjudicate certain test cases as a means of addressing the principal issues in approximately 5,000 autism claims that have been filed under the Vaccine Act. The objective of the omnibus proceeding was to determine the relationship, if any, between vaccines and autism spectrum disorders. This case was considered together with two others, Cedillo v. Secretary of Health and Human Services, No. 98-916V, and Snyder v. Secretary of Health and Human Services, No. 01-162V, in one of the groups of test cases. In the Cedillo and Snyder cases, the petitioners presented a theory of causation based on the combined effect of the MMR vaccine and vaccines containing thimerosal, a vaccine preservative. The Hazlehursts initially presented that theory of causation, but in post-hearing briefing they relied on the theory that Yates's autism was caused by the MMR vaccine alone. Although each of the three cases was decided by a different special master, the record in this case includes all of the general causation evidence admitted in Cedillo and Snyder. The full record encompasses tens of thousands of pages of medical literature, more than four

thousand pages of hearing testimony, and fifty expert reports containing the opinions of seven experts for the petitioners and eighteen experts for the government.

The evidence at the hearing showed that Yates Hazlehurst was born on February 11, 2000, and developed normally during his first year of life. On February 8, 2001, three days before his first birthday, Yates received an MMR vaccination. Within a month after his MMR vaccination, according to his family, Yates became "wild," "very hyperactive," and "out of control." By the summer of 2001, Yates had lost all meaningful speech, even though he had previously used words such as "mama," "please," and "thank you." At about the same time, he developed chronic diarrhea and abdominal pain. Following a series of evaluations in July 2002, Yates was diagnosed as exhibiting a pattern of behavior consistent with autism.

In 2003, the Hazlehursts filed a petition for vaccine injury compensation under the Vaccine Act. The special master summarized their theory of causation as follows:

> [P]etitioners assert that the measles component of the MMR vaccine causes an immune dysfunction that impairs the vaccinee's ability to clear the measles virus. Unable to properly clear the measles virus from the body, the vaccinee experiences measles virus persistence which leads to chronic inflammation in the gastrointestinal system and, in turn, chronic inflammation in the brain. Petitioners argue that the inflammation in the brain causes neurological damage that manifests as autism.

Hazlehurst v. Sec'y of Health & Human Servs., No. 03-654V, 2009 WL 332306, at *86 (Fed. Cl. Feb. 12, 2009). The Hazlehursts acknowledged that the linchpin of their theory was the discovery of persistent measles virus in certain autistic children who had received the MMR vaccine. That evidence derived from the research of Dr. Andrew Wakefield of the Royal Free Hospital in London and his colleagues at the Unigenetics

laboratory in Dublin, and the research of Dr. Stephen Walker and his colleagues at the Wake Forest University School of Medicine.

Dr. Wakefield was the primary proponent of the hypothesis that the MMR vaccine could cause autism in certain children. His work led to civil litigation against certain vaccine manufacturers in the United Kingdom ("the UK litigation"). The Unigenetics laboratory was a for-profit, non-accredited institution that was established to support the UK litigation by testing children for the presence of measles virus in certain body tissues. The Unigenetics research, which reported successful use of the polymerase chain reaction technique ("PCR") to identify and amplify measles virus genetic material in the blood and intestinal tissues of autistic children, formed the basis for a 2002 article co-authored by Dr. Wakefield (the Uhlmann article) on which the Hazlehursts primarily rely. In addition, the Hazlehursts rely on preliminary research results reported by the Walker group. In an abstract and poster presentation delivered at the June 2006 International Meeting for Autism Research ("IMFAR"), the Walker group claimed to have replicated the positive results reported by Unigenetics.

The Hazlehursts' key witness at their hearing was Yates's pediatric neurologist, Dr. Jean-Ronel Corbier. Dr. Corbier relied heavily on the results of the Unigenetics and Walker studies as support for his opinion that Yates's February 8, 2001, MMR vaccination played a substantial role in causing Yates's autism. Dr. Corbier testified that those studies suggested that the MMR vaccine may contribute to the development of regressive autism in children who fit a particular clinical profile, including normal development prior to receipt of the MMR vaccination, display of symptoms of regressive

autism within one to nine months after receipt of the MMR vaccination, and development of gastrointestinal problems during that period.

The special master also heard testimony from Dr. Karin Hepner and Dr. Arthur Krigsman, two of the researchers in the Walker group. Drs. Hepner and Krigsman cited their own work as evidence of the reliability and reproducibility of the Unigenetics test results. They also stated that the Walker group had confirmed its results through genetic sequencing. Dr. Krigsman testified that the group had verified, at least for some samples, that the genetic material identified and amplified by PCR contained the same nucleotide sequence as the targeted product, i.e., vaccine-strain measles virus.

In response to the petitioners' evidence concerning the presence of measles virus in autistic children, the government offered expert testimony and reports from, among others, Dr. Stephen Bustin, a molecular biologist who had appeared as an expert in the UK litigation. In connection with the UK proceedings, Dr. Bustin had been hired by vaccine manufacturers to evaluate the testing methods of the Unigenetics laboratory. After analyzing Unigenetics' equipment and notebooks, Dr. Bustin concluded that the Unigenetics researchers had failed to follow their own standard operating procedures, had failed to abide by certain standard laboratory practices, and had failed to comply with standards set forth by the manufacturers of the laboratory testing equipment, all of which undermined the reliability of the laboratory's test results. Dr. Bustin memorialized his conclusions in reports that were filed under seal in the UK litigation and later released to the government in the Omnibus Autism Proceeding.

Over objection, the government sought to introduce Dr. Bustin's reports and testimony regarding the Unigenetics laboratory, which, by that time, had gone out of

business.[1] The special master in the Cedillo case provisionally admitted the evidence. The three special masters in the omnibus proceeding then deferred decision on whether to rely on that evidence and stated that they would "favorably consider joining in a request" by the petitioners "for the release of relevant reports" from the UK litigation. The record remained open for more than a year following the Cedillo hearing to afford the petitioners sufficient time to present rebuttal evidence, to conduct additional cross-examination of Dr. Bustin, and to obtain documents from the British court. However, none of the petitioners recalled Dr. Bustin for further questioning or applied for access to any of the materials from the UK litigation.

The special master subsequently denied the Hazlehursts' motion to strike Dr. Bustin's reports and testimony. She explained that Dr. Bustin's evidence was highly relevant and that fairness had been achieved by affording the petitioners a generous period of time in which to obtain any additional relevant information.

In her decision on the merits, the special master concluded that the Hazlehursts had failed to prove that Yates's MMR vaccination had caused his autism. In a lengthy opinion, the special master analyzed the evidence of record in detail and addressed each aspect of the petitioners' general and case-specific theories of causation. In particular, the special master found that the Wakefield, Unigenetics, and Walker studies were flawed or unreliable and that Dr. Corbier's opinion regarding causation, which was largely predicated on those studies, was entitled to little weight.

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[1] The Unigenetics laboratory was closed following the discontinuation of the UK litigation.

The special master found that Dr. Wakefield's work had been largely discredited within the scientific community and that none of the studies indicating the presence of measles virus in autistic children had been successfully replicated by an accredited laboratory independent of Dr. Wakefield or Unigenetics. In particular, the special master found that Dr. Wakefield's early 1990s research on persistent measles infections was reviewed by the Medical Research Council of the United Kingdom and found to lack important controls and sufficiently specific reagents for detecting measles virus. She also found that Dr. Wakefield's subsequent research was dismissed by the scientific community as methodologically unsound. In that regard, she noted that 10 of 12 co-authors on Dr. Wakefield's controversial 1998 article in the medical journal The Lancet subsequently retracted their support for the article's conclusion that there is a potential causal link between the MMR vaccine and autism.

Relying in part on Dr. Bustin's testimony and reports, the special master also found that Unigenetics employed "flawed laboratory practices" that rendered its test results "scientifically unreliable." She concluded that the laboratory practices at Unigenetics differed considerably not only from the standard practices for conducting PCR testing, but also from the operating procedures established within the laboratory. For example, the special master cited Dr. Bustin's testimony that the Unigenetics researchers (1) tested degraded genetic material rather than discarding it; (2) used inconsistent procedures to extract and evaluate the genetic material; (3) omitted key steps necessary to prepare samples for PCR amplification; (4) failed to heed the equipment manufacturer's instruction to exclude from analysis the first three cycles of amplification; and (5) reported positive findings, rather than re-running tests, when

duplicate assays showed inconsistent results (one positive and one negative). The special master also highlighted testimony suggesting the presence of contamination, including Dr. Bustin's observation that approximately one-third of the test runs displayed positive results in the negative controls, which were specifically designed not to contain any of the targeted genetic material.

The special master further concluded that the unpublished and preliminary findings of the Walker group should not be accorded significant weight. She observed that Dr. Hepner had declined to "draw any conclusions about the biological significance" of the investigators' findings and had testified that negative controls were not included with each experimental run. The special master also noted that the petitioners' experts based their opinions on the characteristics of the "wild-type" measles virus, as opposed to the vaccine-strain measles virus, which is far less virulent and replicates poorly in the human body.

Based on all the evidence of record, the special master concluded that the Hazlehursts' causation theory depended on evidence that was discredited, unreliable, or inapposite. The special master therefore denied the petition for compensation. The Hazlehursts then appealed to the Court of Federal Claims, which affirmed the special master's decision in a comprehensive opinion. The Hazlehursts appealed that decision to this court.

II

The Hazlehursts argue that the special master improperly relied on Dr. Bustin's testimony and reports criticizing the Unigenetics laboratory's procedures, and that she failed to consider relevant evidence from Dr. Hepner indicating that the Walker group

had verified its test results through genetic sequencing. They urge that those errors require us to overturn the special master's ultimate conclusion as to causation.

We review de novo the judgment of the Court of Federal Claims reviewing a special master's grant or denial of compensation under the Vaccine Act. Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1524 (Fed. Cir. 1991); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000). By statute, the Court of Federal Claims may set aside the special master's decision "only if the special master's fact findings are arbitrary and capricious, its legal conclusions are not in accordance with law, or its discretionary rulings are an abuse of discretion." Turner v. Sec'y of Health & Human Servs., 268 F.3d 1334, 1337 (Fed. Cir. 2001), citing 42 U.S.C. § 300aa-12(e)(2)(B). We apply the same standard when reviewing the judgment of the Court of Federal Claims. Id.

"[W]e do not sit to reweigh the evidence," Lampe, 219 F.3d at 1363, or to make credibility determinations, which are "uniquely within the purview of the special master," Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993). Our review pursuant to the Vaccine Act is "uniquely deferential"; we may not second-guess the special master's fact-intensive conclusions, particularly where the medical evidence of causation is in dispute. Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993). If the special master has considered the relevant evidence of record, drawn plausible inferences, and articulated a rational basis for the decision, "reversible error will be extremely difficult to demonstrate." Hines, 940 F.2d at 1528.

Because Yates Hazlehurst's injury is not on the Vaccine Injury Table, 42 U.S.C. § 300aa-14, the Hazlehursts cannot avail themselves of the statutory presumption of

causation that applies to Table injuries. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010). They were therefore required to demonstrate by a preponderance of the evidence that the MMR vaccine caused Yates's condition. Id.

A

The Hazlehursts argue that the special master should have excluded Dr. Bustin's testimony and reports criticizing Unigenetics' laboratory practices. They contend that her consideration of that evidence violated the provision of the Vaccine Rules requiring evidentiary determinations to be governed by principles of fundamental fairness. According to the Hazlehursts, the admission of Dr. Bustin's testimony and reports gave the government an unfair advantage because the petitioners could not adequately respond to Dr. Bustin's criticisms without access to the materials he had examined, such as Unigenetics' laboratory equipment and notebooks. Those materials are no longer in existence or are under seal following the closing of the Unigenetics laboratory and the termination of the UK litigation. In any event, the petitioners argue, it would have been prohibitively expensive for the petitioners to have their own experts review that evidence.

Vaccine Rule 8 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) (2009). That rule echoes the statutory requirement that the special master "shall consider . . . all . . . relevant medical and scientific evidence." 42 U.S.C. § 300aa-13(b)(1). The rule, like the statute, directs the special master to consider all relevant and reliable evidence, unencumbered by traditional rules of admissibility, while

being guided by principles of fairness. We conclude that the special master complied with that directive when considering Dr. Bustin's evidence.

The special master's decision to admit and consider Dr. Bustin's testimony and reports was in full accord with the principle of fundamental fairness. Although not obligated to do so, the petitioners chose to introduce the Unigenetics data and thus placed its validity squarely in issue. Fairness dictated that the government be given an opportunity to refute that critical evidence. See de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief."); see also United States v. Nobles, 422 U.S. 225, 239-40 (1975) (party introducing evidence may not invoke attorney work-product doctrine to avoid challenges to that evidence).

As the special master noted, Dr. Bustin's testimony and reports are highly relevant. They speak directly to the reliability of evidence central to the petitioners' theory of causation: the detection of persistent measles virus in autistic children who received the MMR vaccine. As the Court of Federal Claims observed, once the petitioners introduced that evidence, "the special master was duty-bound to assess the reliability of those studies." Hazlehurst, 88 Fed. Cl. at 483. Dr. Bustin's evidence was directly pertinent to that assessment. Moreover, the special master determined that Dr. Bustin's evidence was reliable. She found Dr. Bustin to be a credible witness and his testimony to be consistent with that of other witnesses for both parties regarding PCR testing and Unigenetics' laboratory techniques.

We recognize, as did the trial court, that the unavailability of the Unigenetics equipment and records limited the Hazlehursts' ability to respond to Dr. Bustin's criticisms of the Unigenetics evidence. See Hazlehurst, 88 Fed. Cl. at 483-84. Nevertheless, probative evidence need not be excluded simply because circumstances make it difficult to challenge that evidence. See Payne v. Tennessee, 501 U.S. 808, 823 (1991) (probative evidence not inadmissible because it would be difficult to rebut). Moreover, the special master appropriately sought to mitigate the difficulty presented by Dr. Bustin's evidence by giving the petitioners more than a year in which to obtain additional information to counter Dr. Bustin's analysis. See Hines, 940 F.2d at 1526 (post-hearing taking of judicial notice of medical evidence did not violate "principles of fundamental fairness" where the petitioner was given a subsequent opportunity to rebut the evidence). The petitioners, however, chose not to seek relevant reports from the UK litigation or to recall Dr. Bustin for further questioning.

The Hazlehursts also contend that the special master's admission of Dr. Bustin's testimony and reports violated the purpose of the Vaccine Act to resolve cases through simplified procedures without the trappings of "full blown tort litigation." In keeping with that purpose, they assert that the special master should have excluded evidence such as Dr. Bustin's elaborate and costly review of Unigenetics.

It is correct that "[t]he Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994). Rather, Congress intended for the Vaccine Act to establish a compensation system that is "fair, simple, and easy to administer." Id., citing H.R. Rep. No. 99-908, at 7, as reprinted in 1986 U.S.C.C.A.N. 6344, 6348. In furtherance of that

purpose, Congress eliminated the usual requirement of proving fault and simplified the process of establishing causation. For Table injuries, causation is presumed, and even for off-Table injuries, proof of causation is simpler in certain respects than in tort litigation. See, e.g., id. ("[T]o require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program."); Moberly, 592 F.3d at 1325 ("Nor is a petitioner required to point to epidemiological studies or 'general acceptance in the scientific or medical communities' to prove causation, as the legal standard is a preponderance of the evidence, not scientific certainty.").

Nothing in those underlying principles suggests that the special master's consideration of Dr. Bustin's evidence contravened the purposes of the Vaccine Act. The special master did not expect or require the Hazlehursts to replicate Dr. Bustin's review of the Unigenetics laboratory procedures; rather, she offered the petitioners the opportunity to seek reports and exhibits that had been prepared for the UK litigation, just as the government had done. As the Court of Federal Claims observed, "given the fact that [the government] neither commissioned nor paid for [Dr. Bustin's] reports, it is difficult to distinguish them conceptually from any information existing in the public domain." Hazlehurst, 88 Fed. Cl. at 483 n.17. We therefore discern no legal error in the special master's consideration of Dr. Bustin's testimony and reports.

In any event, we agree with the Court of Federal Claims that the special master would have reached the same conclusion regarding the reliability of the Unigenetics data even in the absence of Dr. Bustin's evidence. The special master stated that she "d[id] not rely solely on [Dr. Bustin's] testimony in evaluating the reliability of the test

results obtained by Unigenetics," but also "consider[ed] the testimony of other witnesses and the filed scientific literature addressing Unigenetics' testing techniques." Hazlehurst, 2009 WL 332306, at *93. She discussed the testimony of the government's witnesses Dr. Brian J. Ward (an infectious disease specialist), Dr. Diane Griffin (an immunologist), and Dr. Bertrus Rima (a virologist), and found it to be more persuasive than that of petitioners' expert Dr. Ronald Kennedy on the subject of vaccine-strain measles virus persistence. Id. at *7, *128-32.

The special master also identified at least two key flaws in the Unigenetics data and related articles (such as the 2002 Uhlmann article) that would have been evident even without Dr. Bustin's analysis. First, the positive findings of measles virus persistence have not been successfully replicated by laboratories independent of Dr. Wakefield or Unigenetics, despite several efforts to do so. Second, the articles "do not include sufficient laboratory data to evaluate the conducted testing procedures and the validity of the test results." Hazlehurst, 2009 WL 332306, at *124. Given the abundance of other evidence undermining the reliability of the Unigenetics test results, the special master's consideration of Dr. Bustin's evidence, even if erroneous, would not justify reversal of the special master's decision. See Hines, 940 F.2d at 1526.

B

The Hazlehursts also argue that the special master disregarded critical evidence regarding the reliability of the Walker group's test results, in violation of the Vaccine Act's requirement to consider "all . . . relevant medical and scientific evidence." 42 U.S.C. § 300aa-13(b)(1). They assert that the special master ignored evidence—including testimony from Dr. Hepner and exhibits from the Walker group's 2006 IMFAR

poster presentation—showing that the Walker group used genetic sequencing to verify its test results. If the special master had given that evidence proper consideration, the Hazlehursts argue, she would have found that the Walker study reliably detected persistent vaccine-strain measles virus in the bowels of autistic children. The Hazlehursts therefore assert that the special master's decision to accord little weight to the Walker group's test results was arbitrary and capricious. We disagree.

As an initial matter, even if the special master had made no explicit reference to the evidence that the Walker group used genetic sequencing, we would presume that she considered that evidence. See Medtronic, Inc. v. Daig Corp., 789 F.2d 903, 906 (Fed. Cir. 1986) ("We presume that a fact finder reviews all the evidence presented unless he explicitly expresses otherwise."). In this case, however, it is not necessary to rely on that presumption, as the special master's opinion specifically refers to that evidence. Discussing Dr. Krigsman's testimony, the special master explained:

> Dr. Krigsman stated that the preliminary findings of that [Walker group] study show that based on the obtained PCR results, measles virus is present in the biopsied gastrointestinal tissue taken from patients with autism and bowel disease and examined by Dr. Krigsman. Dr. Krigsman acknowledged, however, as did Dr. Hepner, that not all of the samples had been sequenced for vaccine strain measles.

Hazlehurst, 2009 WL 332306, at *139 (citations to exhibits and testimony omitted). Thus, the special master clearly understood the testimony that some, though not all, of the Walker group's samples were sequenced to confirm vaccine-strain specificity. Moreover, the exhibits that the special master cited in her opinion included the June 2006 IMFAR abstract and IMFAR poster presentation—the very documents that the Hazlehursts contend were "ignored." We thus cannot conclude that the special master failed to consider the evidence in question, in violation of 42 U.S.C. § 300aa-13(b)(1).

In any event, an examination of the cited exhibits and testimony reveals inconsistent and preliminary data that provides only minimal support for the petitioners' claim that the Walker group confirmed the presence of vaccine-strain measles virus, as opposed to wild-type measles virus. While the abstract states that "PCR analysis on . . . tissue from an initial 82 patients showed that 70 (85%) were positive" for measles virus, the poster presentation states that "PCR analysis on . . . tissue from an initial 86 patients showed that 57 (66%) were positive" for measles virus. With respect to sequencing, the abstract observes that "[f]ourteen [samples] have been verified by DNA sequence," but it does not state whether the sequencing was vaccine-strain specific. The poster presentation, on the other hand, states: "Thirty five [samples] have currently been verified by DNA sequence. Six of the thirty five MV [measles virus] positive [samples] bear sequence that is specific to vaccine strain MV." That information, which suggests that only a small number of samples were successfully sequenced for vaccine-strain measles virus, is confirmed by Dr. Krigsman's testimony: "All we could say at the time of this poster is that, as far as vaccine-strain-specific sequencing positivity, a total of six specimens [] were positive . . . . So genetic material that was specific for vaccine-strain measles virus was positive in six."[2] Given that the Walker group's data reflects only a small amount of vaccine-strain-specific sequencing, it was not inappropriate for the special master to include only a brief discussion of the Walker group's sequencing efforts in her opinion.

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[2] The Hazlehursts cite portions of Dr. Hepner's testimony and expert report for the proposition that the Walker group verified that the material it amplified by PCR was vaccine-strain measles virus. However, the cited material concerning sequencing discusses only "measles virus (MV)" generally and is therefore ambiguous regarding the number of samples successfully sequenced for the vaccine strain of the virus.

The special master's decision to accord little weight to the Walker group's data was largely based on the study's other shortcomings and was thus well within her discretion in weighing the evidence. Most significantly, the special master found that the Walker group's research was unpublished, preliminary, and incomplete. Hazlehurst, 2009 WL 332306, at *124-25, *139, *150. Embodied only in a poster presentation, the Walker study was not subject to peer review and therefore has not been subjected to scrutiny from the greater scientific community. See id. at *16, quoting Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 594 (1993) ("The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology."). In fact, Dr. Krigsman and Dr. Hepner repeatedly described the Walker group's data as "partial" and "preliminary." As the special master observed, Dr. Hepner testified that she "certainly wouldn't draw any conclusions about the biological significance" of the Walker group's test results at that early stage. In particular, Dr. Hepner noted the lack of a "proper control source" of tissue samples from children without autism spectrum disorders. She explained that the Walker group's current data does "not give us any information yet about this cohort of patients relative to a different cohort of patients."

The special master also expressed misgivings about the Walker group's use of controls in its study. The special master noted that "while positive controls (specifically 'an artificial laboratory construct' of wild-type measles virus) have been run in each experimental run in the study, no negative controls have been run to date because the investigators are still looking for suitable negative controls." Hazlehurst, 2009 WL 332306, at *125. In their reply brief, the Hazlehursts dispute the special master's

statement that "no negative controls have been run." They argue that negative "technical" controls were run with every sample to check for contamination and to assure the reliability of the PCR testing, even though the Walker group lacked certain "experimental" controls, namely, control samples of tissue from children who tested negative for autism.

The record is unclear as to precisely what negative controls were run. Although Dr. Hepner testified that "no-template negative controls" were run "as a control for contamination," she also stated that the Walker group was still "in the process of procuring samples that would be appropriate negative controls." She further noted that "the negative control at this point generally has been a no-template control because we don't have access to the right material." The confusion is compounded by Dr. Bustin's testimony that he could not rule out the possibility of contamination—suggested by several indicators of unidentified genetic material in the Walker group's poster presentation—because "there's no negative control there."

What is clear from the record is that, at the time of the omnibus autism hearings, certain key controls used by the Walker group were incomplete and in flux. Most critical is the undisputed lack of a sufficient control group of non-autistic children with which to compare the positive findings in autistic children. If the Walker group were to find persistent measles virus at comparable rates in both autistic and non-autistic children, for example, such a finding would significantly undermine the petitioners' theory that persistent measles virus contributes to the causation of autism spectrum disorders. Moreover, Dr. Hepner's testimony suggests that the Walker group was also seeking a different type of positive control to rule out the possibility of cross-contamination. That

evidence further underscores the preliminary and unconfirmed nature of the Walker group's results.

Like the Court of Federal Claims, we do not believe that the Walker group's small amount of vaccine-strain-specific genetic sequencing "carries enough weight to overcome the special master's conclusion that the Walker group's results were preliminary, unpublished, and not entitled to substantial weight." Hazlehurst, 88 Fed. Cl. at 488. We therefore find no error in the special master's determination that she could not "place much weight on the preliminary findings of Walker study . . . specifically the alleged findings of vaccine-strain measles virus in some of the bowel biopsies that were tested." Hazlehurst, 2009 WL 332306, at *125.

III

Because we find no error in the special master's consideration of the evidence, we also find no error in her decision to discount Dr. Corbier's opinion that the MMR vaccine caused Yates's autism. By Dr. Corbier's own admission, his opinion depended heavily on the reliability of the scientific studies purporting to show measles virus persistence in autistic children.

Compensation under the Vaccine Act is limited to those individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or by a preponderance of "causation-in-fact" evidence, to a listed vaccine. The special master concluded that the Hazlehursts' evidence failed to demonstrate the necessary causal link, and the petitioners have not identified any reversible error in the special master's decision reaching that conclusion.

AFFIRMED.