

In the United States Court of Federal Claims

No. 97-573 V

(Filed: October 12, 1999)

PAULINE FADELALLA,
Plaintiff,
v.
THE UNITED STATES,
Defendant.

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) National Childhood Vaccine Injury
) Compensation Program; Guillain-
) Barre Syndrome; rubella vaccination;
) arbitrary and capricious
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OPINION AND ORDER

Petitioner seeks review in the United States Court of Federal Claims of a special master's decision that denied her compensation under the National Childhood Vaccine Injury Compensation Program ("Vaccine Act"). 42 U.S.C. § 300aa-10(a) (1994). The special master concluded that petitioner failed to present a prima facie case that a rubella vaccine caused her Guillain-Barre Syndrome ("GBS").⁽¹⁾ Pursuant to 42 U.S.C. § 300aa-12(e) (1994), petitioner filed a motion in this court seeking review of the special master's decision. For the reasons set forth below, the special master's decision is sustained. Petitioner's motion for review is denied.

I. Background

Petitioner received a rubella vaccination on August 22, 1994. Fadelalla v. Secretary of Health and Human Services, 1999 WL 270423, at *1 (Fed. Cl. Apr. 15, 1999); Petitioner's Motion and Memorandum in Support of Motion for Review ("Petitioner's Motion") at 2; Memorandum in Response to Petitioner's Motion for Review ("Response") at 1. Following the vaccination, Ms. Fadelalla developed a rash. Fadelalla, 1999 WL 270423, at *1; Petitioner's Motion at 2. Her hands and arms began to itch. Id. She also felt a burning sensation in her hands, tingling in her palms, fingertips, and toes, and suffered from weakness. Id. From September 12th to 23rd, 1994, Ms. Fadelalla was hospitalized at Lenox Hill Hospital in New York City and diagnosed with GBS. Fadelalla, 1999 WL 270423, at *1; Response at 1.

Petitioner filed a Petition for Vaccine Compensation on August 18, 1997. Ms. Fadelalla's petition was denied by a decision of the special master on April 15, 1999. Fadelalla, 1999 WL 270423, at *7.

Petitioner's Motion was filed on May 14, 1999. Respondent filed its Response on June 14, 1999. Based on a review of the record in this matter, including the transcript from oral argument before the special master, the parties' pleadings, exhibits, and the decision of the special master, the court upholds the findings of fact and conclusions of law of the special master. The court finds that the special master's decision which denied Ms. Fadelalla's requested relief was neither "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. §§ 300aa-12(e)(2)(B) (1994).

II. Discussion

A. Law Governing Special Master's Review

The Vaccine Injury Table lists vaccines covered by the Vaccine Act. 42 U.S.C. § 300aa-14(a) (1994). When a particular injury is listed under a vaccine on the Table, the petitioner is afforded a presumption that the vaccine caused the injury. GBS is not found on the Vaccine Injury Table. *Id.* When a particular injury is not found on the Vaccine Injury Table, the petitioner must prove by a preponderance of the evidence that a particular injury was caused by a vaccine listed on the Table.⁽²⁾ 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) (1994). The court of appeals has stated that "an action is the 'legal cause' of harm if that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action." *Shyface v. Secretary of Health and Human Services*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).⁽³⁾ See also *Sword v. United States*, 44 Fed. Cl. 183, 189 (1999). Under the Vaccine Act, the special master determines whether or not a petitioner is due compensation based on the merits of his or her case. 42 U.S.C. § 300aa-12(d)(3) (1994). The special master's decision is based on the "record as a whole" including "relevant medical and scientific evidence." 42 U.S.C. §§ 300aa-13(a)(1) and (b)(1) (1994).

B. Review by the Court of Federal Claims

Review by the Court of Federal Claims of a special master's decision is quite limited. See *Lampe v. Secretary of Health and Human Services*, 42 Fed. Cl. 632, 636-37 (1998); *Carraggio v. Secretary of Health and Human Services*, 38 Fed. Cl. 211, 217 (1997). When reviewing a special master's decision, a judge on the United States Court of Federal Claims may:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. §§ 300aa-12(e)(2)(A)-(C) (1994). It is not up to the court to substitute its own judgment for that of the special master in the absence of "clear error" on the part of the special master. *Misasi v. Secretary of Health and Human Services*, 23 Cl. Ct. 322, 325 (1991) (citing *Hyundai Electronics Indus. Co. v. International Trade Comm'n*, 899 F.2d 1204, 1209 (Fed. Cir. 1990)).

A decision of a special master will be found to be arbitrary and capricious only if the special master "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence . . . or is so implausible that it could not be ascribed to a difference in view. . . ." *Hines v.*

Secretary of Health and Human Services, 940 F.2d 1518, 1527 (Fed. Cir. 1991) (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)). See also Lampe, 42 Fed. Cl. at 637. "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." Burns v. Secretary of Health and Human Services, 3 F.3d 415, 416 (Fed. Cir. 1993).

C. Allegations of Petitioner's Motion for Review

The special master determined that petitioner failed to meet her burden of establishing that the rubella vaccination was the cause of her GBS. The special master stated that "other than temporal association and the absence of known other causes, [petitioner] has not submitted anything to prove a causal association between rubella vaccine and her GBS except [her expert's] firm belief that there is one."⁽⁴⁾ Fadelalla, 1999 WL 270423, at *5.

Petitioner asserts that she made out a prima facie case that the rubella vaccine caused her GBS, but the special master failed to shift the burden to respondent to prove otherwise. Id. at 7. Petitioner alleges that the special master failed to find a prima facie case because the special master failed to consider relevant evidence and failed to follow applicable law. Id. at 6. Petitioner asserts that, in addition to the temporal relationship between the vaccination and the onset of her GBS, as well as the absence of a known alternative cause, petitioner provided a significant amount of evidence in support of her claim. Petitioner's Motion at 16.

With respect to the evidence provided by petitioner in support of her prima facie case, petitioner asserts the following:

[Petitioner] supplied her medical records, in which Dr. Goodgold [petitioner's expert] diagnosed her GBS as caused by rubella vaccine, a diagnosis unquestioned by any treating doctor. She supplied the expert testimony of Dr. Goodgold, a neurologist and Professor of Neurology at NYU Medical School with 40 years of experience. She submitted the PDR, wherein the manufacturer of the rubella vaccine administered to [petitioner] admits reports, albeit rare, associating its rubella vaccine with GBS. [Petitioner] submitted scientific literature showing an association between the wild rubella virus and GBS and between the rubella vaccine and GBS. Finally, [petitioner] submitted the supportive testimony of Dr. Arnason.

Id. Because most of the evidence cited by petitioner relates to the testimony provided by her expert, Dr. Albert Goodgold, the court first examines Dr. Goodgold's testimony with respect to his diagnosis of petitioner.⁽⁵⁾ The court will then examine the special master's determination concerning Dr. Goodgold's credibility as an expert in the area of neurology involved in this petition.

Petitioner was first seen by Dr. Goodgold on September 12, 1994. Transcript of Proceedings Before the Special Master on January 25, 1999 ("Trans.") at 5. Dr. Goodgold testified that upon conducting a physical examination of petitioner he found "that she was somewhat unsteady, she had questionable weakness of her hip flexor muscles. There was questionable weakness of her eyelids and her stretch reflexes [were absent] . . . [His] impression was that she had . . . a form of Guillain-Barre syndrome." Id. at 6-7. Dr. Goodgold gave two principal reasons for his diagnosis. The first reason was based upon other vaccine-related GBS cases he had seen. Id. at 85-90. The other reason stemmed from his conclusion that there was an absence of any other cause. Id. at 85-86, 90.

The other vaccine-related cases to which Dr. Goodgold referred were not rubella cases. The GBS patients he observed had received tetanus and flu vaccines. Id. at 86. Dr. Goodgold testified that he had

two patients who had GBS following a tetanus vaccine and four or five following the flu vaccine. Id.; Fadelalla, 1999 WL 470423, at *2, 5. Dr. Goodgold's statement that there must be a relationship between the rubella vaccine and petitioner's GBS "because of lack of any other evidence and [because he] really just can't accept [petitioner's GBS] as a pure coincidence" appears from his testimony to be based entirely on his view that there was a lack of any other cause. Trans. at 85. The court determines that the special master did not act arbitrarily or capriciously in determining that Dr. Goodgold's testimony, as it relates to his diagnosis of petitioner's GBS, failed to "prove that more likely than not the vaccine caused her illness." Fadelalla, 1999 WL 270423, at *6.

With respect to Dr. Goodgold's credibility as an expert in the area of neurology involved in this petition, the special master determined that Dr. Goodgold was unfamiliar even with the medical literature submitted by petitioner. Id. In addition, the special master found that the literature Dr. Goodgold did rely on did not directly address the causal connection between the rubella vaccine and GBS. Id. Not only was Dr. Goodgold unfamiliar with much of the literature, Trans. at 46-49, but he frequently refused to answer questions posed to him during cross-examination. Id. at 74-82. In her decision, the special master provided a thorough comparison of the testimony of Dr. Goodgold with the testimony of respondent's expert, Dr. Arnason. See Fadelalla, 1999 WL 270423, at *2-6.

The special master has broad discretion to determine the credibility of each expert's testimony. See Bradley v. Secretary of Health and Human Services, 991 F.2d 1570, 1575 (Fed. Cir. 1993); Lampe, 42 Fed. Cl. at 640-41. Unless proven by the parties to be arbitrary and capricious, this court will not second-guess the special master's discretion in this regard. See Lampe, 42 Fed. Cl. at 640-41. It is apparent to the court, upon review of the special master's decision, as well as the transcript in this matter, that the special master did not act in an arbitrary or capricious manner when she determined that Dr. Arnason's testimony was more credible than Dr. Goodgold's.

Notwithstanding the lack of assistance from petitioner's expert, the special master independently examined the literature upon which petitioner relies and determined that it did not establish a causal connection between the rubella vaccination and GBS because the literature was anecdotal and did not directly address the issue of causal connection. Fadelalla, 1999 WL 270423, at *5. The special master relied instead on detailed testimony of Dr. Arnason concerning the distinction between cause and coincidence in determining whether petitioner's GBS was caused by the rubella vaccine. Id. at *3. The special master also found credible specific analyses of what Dr. Arnason believed to be shortcomings in Dr. Goodgold's testimony. Id. at *3-4.

Petitioner asserts the special master failed to consider the expert testimony of Dr. Arnason himself as it "supports" petitioner's theory of causation with respect to the onset of petitioner's GBS. In her motion, petitioner states:

"Dr. Arnason . . . has no opinion as to an alternate cause (other than the rubella vaccine) for Pauline's GBS; [Dr. Arnason] agrees; (sic) that the timing of Pauline's symptomatology is appropriate for a vaccine reaction, agrees that it's plausible for rubella vaccine to cause GBS; and believes that a plausible biological mechanism exists by which rubella vaccine can cause GBS. In these circumstances, and in light of the repeated diagnoses of Pauline's treating doctor, Dr. Arnason's . . . testimony . . . supports Pauline's theory.

Petitioner's Motion at 15-16. Petitioner's assumes that Dr. Arnason's "testi[mony] that he does not know what caused [petitioner's] GBS," strengthens her assertion that the rubella vaccine caused her GBS. Id. at 5 (citing Trans. at 118). However, petitioner's assumption is false. The absence of an alternative cause does not relieve petitioner of her duty affirmatively to demonstrate by a preponderance of the evidence that the rubella vaccine more likely than not caused her injury. See 42 U.S.C. § 300aa-13(a)(1). See also

Grant, 956 F.2d at 1144; Housand v. Secretary of Health and Human Services, 1996 WL 282882, at *4 (Fed. Cl. May 13, 1996), aff'd, 114 F.3d 1206 (Fed. Cir. 1997). Petitioner cannot rely on the fact that respondent's expert failed to prove the cause of petitioner's GBS as a substitute for petitioner's own failure of proof of causation-in-fact. See Housand, 1996 WL 282882, at *7.

With respect to petitioner's assertion that the special master committed an error of law by failing to consider relevant evidence, the court finds that the special master did consider the relevant evidence in arriving at her decision. In addition, because plaintiff failed to establish her prima facie case, the special master did not commit an error of law in failing to shift the burden to respondent to prove that there was no other cause for petitioner's GBS.

III. Conclusion

The special master's findings were not arbitrary and capricious. For the reasons set forth above, the court upholds the findings of fact and conclusions of law in the special master's April 15, 1999, decision. The decision of the special master is SUSTAINED. The clerk of the court shall enter judgment accordingly.

IT IS SO ORDERED.

EMILY C. HEWITT

Judge

1. Guillain-Barre Syndrome, which is also known as acute idiopathic polyneuritis, is defined as "a neurologic syndrome, usually following certain virus infections, marked by paresthesia of the limbs and by muscular weakness or a flaccid paralysis." Stedman's Medical Dictionary 15 (1995).

2. 42 U.S.C. § 300aa-13(b)(1) (1994) lists the matters to be considered in determining eligibility and compensation under the Vaccine Act. The special master shall consider the following:

[A]ll . . . relevant medical and scientific evidence contained in the record - (A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and (B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

42 U.S.C. § 300aa-13(b)(1) (1994).

3. Because the Vaccine Act is not specific with regard to the causation requirements in a non-Table case, the court of appeals in Shyface employed the approach of the Restatement (Second) of Torts §§ 430 - 433. The court found that this method of analysis provides both a uniform approach to vaccine cases and is in accord with the legislative history of the Vaccine Act. Shyface, 165 F.3d at 1351. The Restatement

provides:

§ 430. Necessity of Adequate Causal Relation

In order that a negligent actor shall be liable for another's harm, it is necessary not only that the actor's conduct be negligent toward the other, but also that the negligence of the actor be a legal cause of the other's harm.

§ 431. What Constitutes Legal Cause

The actor's negligent conduct is a legal cause of harm to another if

- (a) his conduct is a substantial factor in bringing about the harm, and
- (b) there is no rule of law relieving the actor from liability because of the manner in which his negligence has resulted in the harm.

§ 432. Negligent Conduct as Necessary Antecedent of Harm

- (1) Except as stated in Subsection (2), the actor's negligent conduct is not a substantial factor in bringing about harm to another if the harm would have been sustained even if the actor had not been negligent.
- (2) If two forces are actively operating, one because of the actor's negligence, the other not because of any misconduct on his part, and each of itself is sufficient to bring about harm to another, the actor's negligence may be found to be a substantial factor in bringing it about.

§ 433. Considerations Important in Determining Whether Negligent Conduct is Substantial Factor in Producing Harm

The following considerations are in themselves or in combination with one another important in determining whether the actor's conduct is a substantial factor in bringing about harm to another:

- (a) the number of other factors which contribute in producing the harm and the extent of the effect which they have in producing it;
- (b) whether the actor's conduct has created a force or series of forces which are in continuous and active operation up to the time of the harm, or has created a situation harmless unless acted upon by other forces for which the actor is not responsible;
- (c) lapse of time. Restatement (Second) of Torts §§ 430 - 433 (1963-1964). The Restatement clarifies the meaning of "substantial factor" by stating that a particular factor does not have to be the sole or predominant cause of harm in order to be a "substantial factor." *Id.* at § 430 cmt. d.

4. Although temporal association between an injury and a vaccination is sufficient to establish legal causation in *Table* cases, it is not sufficient to establish causation-in-fact. *Grant v. Secretary of Health and Human Services*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Evidence in the form of expert medical testimony or scientific studies is necessary. *Shyface*, 165 F.3d at 1351. Moreover, the Vaccine Act requires two separate inquiries under the statute. The first is whether a causal connection between the vaccine and the injury has been demonstrated. 42 U.S.C. § 300aa-13(a)(1)(A) (1994). The second is whether the injury involved was due to factors unrelated to the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B)

(1994). The Grant court stated that "evidence showing an absence of other causes [alone] does not meet petitioner's affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149.

5. The Supreme Court has provided a framework within which to evaluate scientific evidence in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). The Court determined that scientific expert testimony is admissible only if it is both relevant and reliable. Id. at 597. See also Kumho Tire Co. v. Carmichael, 143 L.Ed.2d 238, 246 (1999). In order for a scientific theory to have scientific reliability, the Court noted the traditional requirement of subjecting a particular theory to testing, peer review and publication. Daubert, 509 U.S. at 593-94. While Daubert broadened the scope of admissibility for scientific evidence in certain cases, the Court also recognized the continued importance of general acceptance within the scientific community as a means of determining the reliability of scientific evidence. Id. at 594.