In the United States Court of Federal Claims

No. 01-707VC
(Filed: March 17, 2010)[1]

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MICHAEL STEPHEN SHAW,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Vaccine Act; off-table claim; Hepatitis B vaccine; transverse myelitis; chronic inflammatory demyelinating polyneuropathy; small fiber neuropathy; request for reconsideration; new evidence

Sylvia Chin-Caplan and *Ronald Homer*, Boston, MA, for petitioner.

Voris E. Johnson, United States Department of Justice, Civil Division, Torts Branch, Washington, D.C., with whom were *Gabrielle Fielding*, Assistant Director, *Mark Rogers*, Deputy Director, *Timothy P. Garren*, Director, and *Tony West*, Assistant Attorney General for respondent.

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OPINION

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BRUGGINK, *Judge*.

Petitioner, Michael Shaw, seeks review of a decision entered by the special master denying compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-1 to -34 (2006). Mr. Shaw brought this claim alleging the Hepatitis B vaccine caused him to suffer a neuropathy.

[1] In accord with the Rules of the Court of Federal Claims, App. B, Rule 18(b), this opinion was initially filed under seal on February 26, 2010. The parties were afforded fourteen days in which to propose redactions. Neither party proposed any redactions.

The special master considered the parties' submissions and heard testimony from one of Mr. Shaw's treating physicians and from defendant's medical expert, ultimately concluding that Mr. Shaw failed to establish that any vaccine he received brought about his injury. Accordingly, she denied his petition for compensation.

In her decision, the special master found that Mr. Shaw did not suffer from either of the injuries he alleged but rather from another condition: small fiber neuropathy. Because the evidence did not support vaccine causation for this separate condition, the special master denied Mr. Shaw's petition. He subsequently filed a motion for reconsideration, seeking to introduce additional evidence regarding the condition diagnosed by the special master. When the special master denied his motion, Mr. Shaw filed this motion for review of the special master's ruling, alleging her decision was not in accordance with law. The matter has been briefed and this court heard oral argument on February 3, 2010. For the reasons set forth below, petitioner's motion for review is granted in part, and the case is remanded to the special master for proceedings in accordance with this opinion.

BACKGROUND[2]

Mr. Shaw was born in 1959. Over the years leading up to the vaccination at issue, he enjoyed a variety of athletic endeavors including traditional and extreme sports such as motocross, parachuting, rafting, and mountain climbing. As a result of these activities, his medical history includes several concussions, a cracked pelvis, a chipped tailbone, a fractured nose, and broken bones in his hands and feet.

In May of 1999, Mr. Shaw received a Hepatitis B vaccination in anticipation of international business travel. He experienced no immediate ill effects. A month later, on June 11, 1999, he received his second Hepatitis B vaccination as well as a polio vaccination. Within a week, he experienced tingling and numbness in his big toe.[3] Ten days after receiving his second

[2] The facts are drawn from the parties' filings and the special master's decision and are undisputed, unless otherwise noted.

[3] The parties dispute the timing of the onset of this condition. Mr. Shaw contends it began within 48 hours after the vaccination but contemporaneous medical records indicate it occurred six days after the vaccination.

Hepatitis B vaccination, Mr. Shaw visited his primary care physician, complaining of numbness in his lower right leg. His physician diagnosed him with a lumbar strain and right-leg radiculopathy,[4] prescribed prednisone, and encouraged him to have x-rays and an MRI.

On June 23, 1999, about two weeks after his second vaccination, Mr. Shaw departed on a two-week international business trip. During the course of this trip, he experienced continued tingling and numbness in his legs as well as sharp, burning pain in his arms and problems with his memory, speech, and coordination. Shortly after his return, Mr. Shaw underwent an MRI of his back and visited his doctor again, complaining of flu-like symptoms and continued tingling and numbness in his extremities. The doctor diagnosed him with a back strain and sinus inflammation.

Over the next five years, Mr. Shaw was examined by more than a dozen doctors, including neurologists and other specialists, who had limited success in diagnosing and treating his condition. Several commented on the difficulty of diagnosing Mr. Shaw's ailment and noted that various procedures and tests had failed to produce any objective results. Although there was no uniformity among these physicians regarding the nature or cause of Mr. Shaw's condition, many believed he suffered from small fiber neuropathy. Others suggested his condition was chronic fatigue syndrome, fibromyalgia, chronic Epstein Barr virus, or psychiatric issues. A number of these specialists mentioned the possible role of Mr. Shaw's vaccinations, though few went so far as to allege vaccine causation. Other of his treating physicians considered, but expressly rejected, the possibility of vaccine causation.

In 2001, Mr. Shaw filed a workers' compensation claim with his employer, ultimately entering into a set-aside agreement and receiving workers' compensation payments. In December of 2001, he filed his vaccine claim. During the pendency of his vaccine claim, and in addition to treatment by numerous medical doctors, Mr. Shaw received treatment in 2003 from Dr. Sherri Tenpenny, a doctor of osteopathic medicine. Dr. Tenpenny initially treated Mr. Shaw for mercury toxicity, a procedure later deemed unnecessary and which left him quite ill for several weeks. The severity of Mr. Shaw's symptoms have waxed and waned over the years, but continue to this day.

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[4] Radiculopathy is a "[d]isorder of the spinal nerve roots." *Stedman's Medical Dictionary* 1503 (27th ed. 2000).

PROCEDURAL HISTORY

Mr. Shaw filed this case on December 20, 2001. It was promptly stayed at his request pending the outcome of an omnibus proceeding involving other Hepatitis B cases. The stay was lifted in 2006 and progress in the case resumed. Mr. Shaw filed the report of Dr. Tenpenny as one of his treating physicians, in which she opined that he suffered from either transverse myelitis ("TM") or chronic inflammatory demyelinating polyneuropathy ("CIDP"). The government filed the expert report of Dr. Thomas Leist, a neuro-immunologist, stating there was no evidence that any vaccine caused Mr. Shaw's condition and that there was no evidence he suffered from a demyelinating process. The special master conducted an evidentiary hearing on March 12, 2008.

The special master issued a thorough decision, carefully detailing Mr. Shaw's medical history, the testimony, and her analysis.[5] She concluded that Mr. Shaw failed to satisfy his evidentiary burden and denied compensation. The special master noted that Mr. Shaw's testifying physician, Dr. Tenpenny, was neither a neurologist nor an immunologist and had no experience treating TM or CIDP, the conditions about which she testified. The special master also detailed Dr. Tenpenny's training and experience as an osteopathic physician. Dr. Tenpenny, who was offered as a treating physician and not an expert, testified regarding her belief that Mr. Shaw had TM or CIDP, including discussion of the etiology and characteristics of those conditions.

The special master's decision also reviewed the qualifications, experience, and testimony of Dr. Leist, the government's expert witness, who testified that there was no evidence Mr. Shaw suffered a neurological injury caused by a vaccination. The decision also summarized Dr. Leist's testimony regarding the difference between TM, which involves an inflamation or lesion on the spinal cord, and CIDP, which involves inflamation of the nerve roots out in the peripheral nerves. He further testified of his doubt that Mr. Shaw had either TM or CIDP and noted that none of the treating neurologists had treated him as if he had either condition. Dr. Leist also noted the lack of any objective evidence to verify Mr. Shaw's reported symptoms.

The special master noted that the government's expert did not contest the plausibility of Mr. Shaw's proposed medical theory, namely that the

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[5] *Shaw v. Sec'y of HHS*, No. 01-707V, 2009 WL 3007729 (August 31, 2009) [hereinafter "*Shaw"*].

Hepatitis B vaccine can induce an autoimmune response attacking the nerves' myelin sheaths and leading to TM or CIDP. Likewise, the government did not contest the appropriateness of the timing and onset of Mr. Shaw's symptoms. She found, however, that he failed to establish "a logical sequence of cause and effect between the received vaccine and his *actual* injury." *Shaw* at *25 (emphasis added). Specifically, based on Mr. Shaw's medical records, including the diagnoses of his many treating physicians, she found that his condition was not TM or CIDP but rather a small fiber neuropathy. Based on Dr. Leist's unrebutted testimony that the small nerve fibers are not coated in a myelin sheath, the special master concluded that Mr. Shaw's theory of demyelination could not possibly cause small fiber neuropathy. Accordingly, she denied his petition for compensation.

Mr. Shaw subsequently moved for reconsideration of the special master's decision, claiming it was based on a mistake of material fact and offering to submit textbook evidence indicating that at least some small nerve fibers have myelin sheaths. The government opposed this motion, noting that this evidence was not new and thus did not satisfy the legal standard for reconsideration. The special master agreed that the proffered evidence was previously available and noted that even if this newly offered evidence were correct, other findings supported her decision.[6] She also noted that Mr. Shaw's failure to immediately rebut Dr. Leist's testimony at the hearing "may be attributed directly to Dr. Tenpenny's acknowledged lack of expertise in neurological matters." *Id.* at *32.[7] The special master denied the motion for reconsideration.

ARGUMENT

This court has jurisdiction to review the special master's decision. *See* 42 U.S.C. § 300aa-12(e)(1)–(2). On review, we may sustain the decision, set aside the decision and issue our own findings of fact and conclusions of law, or remand to the special master. 42 U.S.C. § 300aa-12(e)(2). We may set aside only those findings of fact and conclusions of law that are "arbitrary,

[6] *See infra* page 10 discussing the effect of these other findings in light of our remand to consider the evidence that some small fibers may be myelinated.

[7] In the Westlaw citation, the special master's ruling on the motion for reconsideration is appended to her decision on entitlement.

capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). This standard of review applies differently to different aspects of the special master's decision: findings of fact are reviewed under the deferential "arbitrary and capricious" standard, legal conclusions under the "not in accordance with law" standard, and discretionary rulings for an "abuse of discretion." *Munn v. Sec'y of HHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

In the memorandum in support of his motion for review, Mr. Shaw alleges the special master's decision ignores "numerous treating physicians [who] overwhelmingly concluded that he suffered a small fiber neuropathy as a result of the hep B vaccine" and is "based on a mistake of material fact." *See* Ptr.'s Mem. in Supp. of Mot. for Rev. [hereinafter "Ptr.'s Mem."] at 17. He concedes that the "new" evidence was previously available but argues that he could not have anticipated the special master would place any significance on the small nerve fibers' myelination or lack thereof. *Id.* at 22. Finally, he argues that other special masters have ruled that Hepatitis B vaccines have caused various neurological injuries including small fiber neuropathies. *Id.* at 24.

I. General overview of the Vaccine Act

Congress enacted the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act") as a simpler alternative to traditional tort litigation for those injured by an immunization. *See* H.R. Rep. No. 99-908, at 3–4 (1986). The Vaccine Act provides two routes for a petitioner to obtain compensation. Under the easier of the routes, known as a "table injury," the claimant need only show he received a vaccination listed on the Vaccine Injury Table and suffered one of the listed corresponding injuries within the prescribed time after the vaccination. *Pafford v. Sec'y of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citing *Capizzano v. Sec'y of HHS*, 440 F.3d 1317, 1319 (Fed. Cir. 2006)). Upon this showing, the vaccine is presumed to have caused the injury. *Id.*

The other route, which is used in this case, is called an "off-table" case and does not carry with it the presumption of causation. Instead, the petitioner must prove that the vaccination caused or significantly aggravated an illness, disease, disability or condition.[8] *See* 42 U.S.C. § 300aa-11(c). In *Althen v.*

[8] The claimant must also show that the allegedly injurious vaccine is listed on the Vaccine Injury Table, was received while within the United

Sec'y of HHS, the Federal Circuit set out a three-prong test for establishing causation in an off-table claim:

> Concisely stated, [petitioner's] 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.

418 F.3d 1274, 1278 (2005). The first prong asks whether the vaccine in question *can* cause the injury alleged. *Pafford*, 451 F.3d at 1356. The second prong applies the medical theory and asks whether the vaccine *did* cause the petitioner's injury. *Id.* The third prong asks whether symptoms occurred within a time frame that is neither too late nor too soon after the allegedly causal vaccination. *See De Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1352 (2008). These three prongs "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford*, 451 F.3d at 1355.

II. The new evidence is admissible but not dispositive

Both the statutory scheme and case law make clear that the Vaccine Act is tilted in favor of compensating injured claimants. Congress intended for the Act to compensate "vaccine-injured persons quickly, easily , and with certainty and generosity." H.R. Rep. No. 99-908, at 3 (1986). In recognition of this aim, the Federal Circuit has consistently reiterated the relaxed standard of proof in such cases. *See Knudson v. Sec'y of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994) ("[T]o require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program."). Likewise, "close calls" are to be resolved in favor of the claimant. *Capizzano*, 440 F.3d at 1324.

In light of the Vaccine Act's bias toward compensation, we find it in the interest of justice to remand this case to the special master to consider the new

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States, and that the effects of that injury lasted more than six months or resulted in surgery or death. 42 U.S.C. § 300aa-11(c). Litigation rarely concerns these requirement.

evidence and to permit Dr. Leist to expand or clarify his earlier testimony. We leave it to the special master to determine whether to reopen the record beyond that extent. We intend no slight to the special master, whose decision was thorough and well reasoned,[9] and we confidently leave it to her discretion to determine the appropriate weight and the effect of this new evidence.

A. The special master appropriately considered Mr. Shaw's diagnosis

Arguably the crux of the special master's decision was her finding that Mr. Shaw suffered not from TM or CIDP, as Dr. Tenpenny alleged, but rather from a small fiber neuropathy. Unrebutted testimony indicated that Mr. Shaw's medical theory, demyelination, was incapable of causing this condition. Because the diagnostic finding was essentially dispositive of the case, we address it first, and conclude it was not arbitrary or capricious.

As previously noted, the Vaccine Act's relaxed "preponderant evidence" standard reflects the inherent uncertainty of vaccine causation—"a field bereft of complete and direct proof of how vaccines affect the human body." *Althen,* 418 F.3d at 1280. This uncertainty encompasses the difficulty that frequently accompanies diagnosing a claimant's condition. A petitioner is not required to "categorize [his] injury," *Kelley v. Sec'y of HHS*, 68 Fed. Cl. 84, 100 (2005), and it is not the role of the special masters to diagnose vaccine-related injuries. *Knudsen*, 35 F.3d at 549.

In some cases, however, the diagnosis of the alleged injury is quite significant because it bears directly on the plausibility of the claimant's theory.[10] When, as here, it is necessary for a special master to determine from what condition a claimant suffers, it is not error to do so. *See Broekelschen v. Sec'y of HHS*, 89 Fed. Cl. 336, 344 (2009) ("[I]t was appropriate in this case—where virtually all of the evidence on causation was dependent on the

[9] In contrast, we note this situation is in largely of Mr. Shaw's own making, specifically his decision not to present an expert witness and choosing instead to offer a treating osteopathic physician with no training or experience in treating the neurological conditions he ostensibly has.

[10] We note that in *Kelley*, a case frequently cited by disappointed claimants, the two possible diagnoses were "hopelessly blurred," 68 Fed. Cl. at 102, and their underlying processes were the same. *Id.* at 86 n.1–2, 97.

diagnosis of petitioner's condition—for the special master to determine the proper diagnosis before applying the *Althen* test.").

Here, the special master heard unrebutted testimony from Dr. Leist, the government's expert, indicating that demyelination, the medical theory propounded by Mr. Shaw, could not culminate in the injuries he claimed to have. Confronted with such testimony, it was incumbent upon the special master to determine the precise nature of Mr. Shaw's condition. Based on the extensive medical records, she found that "the consensus diagnosis is that petitioner suffers from a small fiber neuropathy." *Shaw* at *25. We cannot say this is error, and note that Mr. Shaw does not challenge this aspect of the special master's finding.

B. The effect of the newly offered evidence on the Althen *test*

After the special master issued her decision rejecting Mr. Shaw's claim to entitlement, Mr. Shaw moved for reconsideration, simultaneously submitting a new exhibit. The exhibit is a two-page excerpt from *Adams and Victor's Principles of Neurology*, Ropper and Brown, eds. (8th ed. 2005). Included in this exhibit is a table classifying various types of nerve fibers and noting that the "A-delta" type are "[s]mall, thinly myelinated" fibers. Mr. Shaw believes this evidence shows that the special master's decision, which relied on testimony that small fibers are not myelinated and thus not subject to demyelination, was based on a mistake of fact. Ptr's Mem. at 21.

As already noted, in light of the Vaccine Act's bias toward compensation, we find it in the interest of justice to remand with instruction for the special master to consider the effect of this new evidence. We do not, however, mandate any particular result but leave the outcome to the special master's discretion. After considering the weight and probative value of this new evidence, the special master may very well determine that it does not merit reliance. Even if she decides to accept and rely on this evidence, this is by no means requires a reversal of the special master's previous conclusion; other evidence may undercut Mr. Shaw's entitlement to compensation.

Although the special master framed her decision solely in terms of *Althen's* second prong, we note that *Althen's* first prong is also in play. Specifically, Mr. Shaw has presented no evidence or testimony of a theory connecting the Hepatitis B vaccine to the condition he actually has: small fiber neuropathy. Although the special master accepted as plausible his medical

theory linking the vaccine to TM and CIDP, this theory is of no significance in light of the determination that Mr. Shaw does not actually suffer from either of those conditions. It may be that the new evidence is sufficient to provide this medical theory, but that determination is for the special master.

Additionally, it remains an open question whether Mr. Shaw has satisfied *Althen's* second prong: a logical sequence of cause and effect between the vaccination and the alleged injury. Therefore, even if the new evidence supports a medical theory explaining that this vaccine *can* cause small fiber neuropathy, Mr. Shaw must also present evidence that it *did* cause his condition. In both the entitlement decision and the motion for reconsideration, the special master noted that her decision to deny compensation was supported by reasons other than the small fibers' alleged lack of myelin sheaths.

Specifically, the special master noted the absence of any evidence tending to show a logical sequence linking the Hepatitis B vaccine to Mr. Shaw's condition. In particular, the special master noted the lack of any objective test results diagnostic of TM or CIDP or, for that matter, any other neurological injury. She also noted that, save Dr. Tenpenny, none of Mr. Shaw's treating physicians had diagnosed or treated him for TM or CIDP. The special master also relied on Dr. Leist's testimony that Mr. Shaw lacked any immune reactivity to the Hepatitis B surface antigen,[11] a response that should be present in someone suffering from a progressive vaccine-related autoimmune disorder.

It appears, however, that some of these apparent weaknesses in Mr. Shaw's case relate primarily to a diagnosis of TM or CIDP. It may well be that these findings apply with equal force to the diagnosis of small fiber neuropathy, though we leave this determination to the special master. We simply note that the admission of the new evidence does not automatically satisfy the demands of *Althen's* second prong.

III. Conclusion

In light of the purposes and structure of the Vaccine Act, we find it in the interest of justice for the special master to consider the effect of the newly

[11] A surface antigen is a molecular sequence contained on the exterior of a pathogen and is the component "recognized" by the immune system.

offered evidence. Accordingly, we remand the case and direct the special master to consider the new evidence and to allow Dr. Leist the opportunity to rebut the evidence or clarify his earlier testimony. We leave it to the special master's discretion whether to reopen the record beyond that extent.

s/Eric G. Bruggink
Eric G. Bruggink
Judge