

In the United States Court of Federal Claims

No. 00-273V
(Filed: March 25, 2003)
TO BE PUBLISHED

***** *
DEBRA KAY KEITH, *
 Petitioner, *

 v. *

SECRETARY OF THE DEPARTMENT *
OF HEALTH AND HUMAN SERVICES, *
 Respondent. *

***** *

* National Vaccine Injury
* Compensation Program; Review
* of Order Granting Motion to
* Dismiss; Sufficiency of Evidence
* to Establish Causation; Absence
* of Expert Opinion Evidence.

Debra Kay Keith, Vine Grove, Kentucky, *pro se*.

Joan E. Coleman, Trial Attorney, Torts Branch, Civil Division, Department of Justice, Washington, D.C., attorney of record and argued for Respondent. With her on the briefs were *Gabrielle Manganiello*, Assistant Director; *Mark W. Rogers*, Assistant Director; *John Lodge Euler*, Deputy Director; *Helene M. Goldberg*, Director; and *Robert D. McCallum, Jr.*, Assistant Attorney General, Department of Justice.

OPINION

BASKIR, Judge.

Debra Kay Keith filed a petition in May 2000 seeking compensation under the National Vaccine Injury Compensation Program (Program), 42 U.S.C. §§ 300aa–10-34 (1994). She alleged that Tetanus shots she received in 1997 and 1998 caused her to contract Brachial Neuritis and aggravated her pre-existing brain stem defect, a Chiari I malformation. While Ms. Keith presented thorough records documenting her symptoms and doctors' evaluations, this evidence did not itself show that she had Brachial Neuritis or that the vaccination caused an aggravation of her brain stem defect. Ms. Keith lacked any medical expert opinion to substantiate her claims.

In late 2002, the Respondent filed a second Motion to Dismiss, alleging that the Petitioner had insufficient proof to make out a *prima facie* case of injury or causation in fact. The Respondent also alleged that the Petitioner had failed to comply with numerous orders requiring her to present an expert medical opinion, even after Special Master E. LaVon French granted her several extensions of time. Concluding there was insufficient evidence of causation and no medical expert opinion provided by the Petitioner to cure this defect, the Special Master found that the Petitioner had not met her burden of proof and was not entitled to compensation under the Program. Thus, the Special Master granted the Respondent's motion in October 2002.

The Petitioner filed her appeal of the Special Master's dismissal on October 30, 2002, alleging that she presented sufficient proof of causation in the form of medical records and her own opinions. However, unsubstantiated claims of a petitioner, without more, do not entitle a person to compensation. While the Court does not dispute the nature or severity of her symptoms, Ms. Keith has presented no basis for overturning the Special Master's decision. After examining the entire record before us and hearing the parties, we deny the petition and affirm the decision of the Special Master.

PROCEDURAL NOTE

Ms. Keith filed her petition below *pro se*. From September 2001 to November 2002, she was represented by counsel. After Ms. Keith filed her appeal, counsel withdrew from the case. Thus, because of Ms. Keith's *pro se* status, we will liberally interpret her petition for review. See *Forshey v. Principi*, 284 F.3d 1335, 1357-58 (Fed. Cir. 2002) (*en banc*).

FACTS

Ms. Keith first contends that her vaccinations caused Brachial Neuritis, one of the injuries listed in the Vaccine Injury Table. However, while her records indicate that she suffered symptoms similar to those associated with Brachial Neuritis, she has no medical evidence establishing the cause of these symptoms. Second, Ms. Keith contends that the vaccinations aggravated her pre-existing Chiari I malformation. However, a review of her medical records fails to establish that the vaccination was a cause in fact of the aggravation, or that an aggravation occurred at all. Thus, as we shall see, while Ms. Keith has a long history of suffering from troublesome symptoms, she has not presented sufficient evidence to establish the vaccinations as a cause of any of them.

The following facts derive from Ms. Keith's medical records and her personal interpretation of them, which are undisputed by the Respondent.

Ms. Keith received three Tuberculin (PPD) skin tests in 1977, 1985 and 1990. In May 1997, she received her first Tetanus (Td) vaccination. Two months later, Ms. Keith began to have chilling sensations in the back of her neck and head, swelling of the head, and muffled hearing. These symptoms lasted for nine or ten days and were accompanied by severe headaches, stiff neck, and sharp shooting pains in her neck and head. Petitioner contends that for the next two months, she experienced muscle spasms, severe body soreness, exhaustion, and various other problems.

By late 1997, these symptoms began to fade. However, shortly thereafter, new ones manifested including vision and hearing difficulties, bowel disturbances, and tingling sensations throughout the entire left side of the body.

Ms. Keith went through several medical tests to determine the cause of her illness. In early 1998, she visited a neurologist, Dr. Lovegildo Garcia, who took a series of blood tests for more than 15 illnesses. Dr. Garcia's initial impression was that the Petitioner had a right brain disorder, seizure disorder, or even some sort of psychophysiological condition. On a follow-up visit, Dr. Garcia noted that Petitioner's blood tests were essentially normal, except for certain slight elevations. He recommended that she see a rheumatologist to test for collagen disease or lupus, which can present tingling sensations on one side of the body. He also suggested that she obtain an MRI (Magnetic Resonance Imaging) of her brain and spine and a DopScan of her neck vessels, which the Petitioner indicated she would have to delay because of the expense of such tests.

During this period, Ms. Keith visited an ear doctor for a recurring hearing problem she believed was diagnosed and treated in 1990. Hearing tests and a CT (Computed Tomography) scan did not reveal anything abnormal, except a slight left-sided hearing loss. Around the same time, Ms. Keith was also being treated by a chiropractor for back problems.

In March 1998, Ms. Keith returned to Dr. Garcia and complained that she continued to experience numbness on the left side of her body and constant severe headaches. Ms. Keith mentioned having read that some of her symptoms, including muscle spasms and back/neck pain, could have been due to a tetanus infection. Dr. Garcia explained that even if she had a mild tetanus infection, it is very unusual to survive such an infection for so long without antibiotic treatments. He then spoke with Dr. Anna Wong of the Infectious Disease Center in Louisville, Kentucky, who felt it was possible that the Petitioner had an infection and had since recovered, but that a continuous infection is unusual without any other accompanying signs of infection. There was no evidence of an acute infection since her white blood cell count was normal. Dr. Wong recommended that the Petitioner complete the whole tetanus immunization and submit to more blood tests. Dr. Garcia again recommended an MRI of her brain and spine.

The Petitioner had her second tetanus vaccination in April 1998. Three weeks later, she had a similar reaction to the previous one, only not as intense or enduring. Her symptoms included swelling sensations in the head, aching muscles, and muffled hearing. Ms. Keith went to the emergency room, at which time she asked for a tetanus antibody test. The doctor on duty diagnosed the Petitioner with a muscle tension headache. According to the doctor's report, this condition is caused by tightness in the neck and head muscles resulting from neck or jaw joint problems, and more commonly, emotional stress. The doctor stated that he found no evidence of a serious health problem as a cause for the headache. He gave her a prescription for a benzodiazepine medication (examples include Valium, Xanax, and Librium) and told her to follow up with her neurologist.

Ms. Keith continued to suffer from the same symptoms of pain, numbness, and tingling down her left leg, and in December 1998 she saw Dr. Timothy Law, who then sent her to another neurologist. After nerve conduction tests and an EMG (electromyogram) study, the neurologist found that her symptoms could be related to a central nervous system cause, and he too encouraged her to have an MRI of her brain. He did not think a central nervous system cause was likely, however, and indicated that if the MRI was unremarkable, he would recommend for her to look into other possibilities such as rheumatological disease.

Under Dr. Law's instructions, Ms. Keith went for an MRI of her brain and neck, and a Chiari I malformation (defect of the brain stem) was discovered. In July 1999, the Petitioner saw yet another neurologist, Dr. John J. Guarnaschelli, who reviewed her medical records. He opined that although the Chiari I malformation was present radiographically, he did not believe it was surgically significant at that point and would not recommend surgery unless further signs of a definitive progressive brain stem dysfunction were to occur. More importantly, Dr. Guarnaschelli addressed a second issue: whether the malformation was in any way related to the immunologic response and/or the allergic reaction the Petitioner had suffered. Dr. Guarnaschelli wrote in his evaluation: "I think that it is unlikely that there is any relationship between the two."

Ms. Keith had follow-up blood tests conducted in July 1999. She contended in her Petition that the various levels recorded by these tests were the result of a high number of tetanus antibodies in her blood. However, after receiving a response from a doctor at the University of Kentucky Allergy Clinic who reviewed Ms. Keith's lab reports, Ms. Keith admitted that the antibody test does not show if the victim is having a reaction to the vaccine, but rather, whether the patient is protected against the virus and to what extent. Thus, these tests did not provide any evidence that the Petitioner's vaccinations had caused her reaction.

The Petitioner then considered filing a petition for compensation with the Program and requested an information packet. Ms. Keith felt that her symptoms matched those listed under “Brachial Neuritis,” and in her petition she stated: “I concluded that the strong reaction to the first Td shot resulted in a condition called Brachial Neuritis.” She also concluded that her chronic stress syndrome weakened her immune system, which was complicated by the strong reaction she had to the Td shots. In April 1999, before she saw the second neurologist, the Petitioner filed a report with the Vaccine Adverse Event Reporting System and, in May 2000, her petition for compensation.

Ms. Keith submitted supplemental materials to document her visit to a new doctor, Dr. Ayez Ahmed, on August 3, 2000. She had tested her blood pressure at home and was concerned with very large fluctuations she was encountering between readings. According to the Petitioner’s own statement, Dr. Ahmed said these fluctuations were due to nerves, and he suggested that she see a psychiatrist. He offered to write a prescription for a mild blood pressure drug and “something for her nerves,” both of which she refused. She showed him her medical records and vaccine petition and asked if her Chiari I malformation had anything to do with her symptoms, to which Dr. Ahmed replied: “Nothing whatsoever.”

Finally, the Petitioner submitted additional supplemental materials, relating to her analysis of her medical records and a pattern she saw of anemia and immune deficiency disorder. Ms. Keith supplemented her petition as such because she believed that the doctors never paid any attention to the results of the CBC (complete blood count) tests, but rather, they “looked only at the one set of tests they ordered and saw nothing unusual in them.”

PROCEEDINGS BELOW

The Special Master expressly recognized the extent of Ms. Keith’s pain and suffering. However, she ultimately found Petitioner’s evidence of causation insufficient to prove the *prima facie* elements required by § 300aa-11(c) of the Program.

From the beginning of her review, the Special Master was confronted with a dearth of evidence supporting the Petitioner’s case. Thus, in September 2000, she issued her first order to Ms. Keith to submit a medical expert report tying her illnesses to the vaccinations. In November, the Special Master suspended the case for five months. She again directed the Petitioner to file an expert report, giving her an extension until May 1, 2001, and warned Ms. Keith that her case was close to dismissal. Over the next year and a half, the Special Master granted three more extensions to the Petitioner.

In April 2001, the Petitioner submitted a "Conclusive Report on Vaccine Petition #00273." This report contained another analysis by the Petitioner regarding the causes of her symptoms, copies of medical records already presented in her petition, information from the Internet about Chiari malformations, pamphlets from the American Syringomyelia Alliance Project, her financial information including doctors' and hospital bills, and an addendum to her petition. This addendum documented the Petitioner's growing frustration with her inability to "find even one doctor who has the knowledge and/or the honesty and integrity to acknowledge the truth [she has] presented in [her] vaccine petition."

In July 2001, the Respondent filed a Rule 4 report and a Motion to Dismiss, arguing that the Petitioner had failed to establish the requisite causation between the vaccinations and her symptoms. The parties subsequently held a status conference, at which the Special Master explained to Petitioner that drawing her own opinions about her condition would be insufficient as a matter of law to prove a vaccination claim. The Special Master further explained that the only way Ms. Keith could establish her case was with a qualified, certified, and well-credentialed medical doctor who would investigate the medical records and the Petitioner's materials. Additionally, the Special Master asked the Respondent to share half the costs of a medical expert with the Court. The parties ultimately agreed to have the Special Master choose and pay for an independent expert wholly out of vaccine funds. (Later, however, Ms. Keith secured counsel, whose responsibility it then became to perfect her case.)

In sum, the Special Master explained that it was possible that the Petitioner suffered an adverse reaction to the vaccine, but that mere possibility was insufficient to win her case. Although Ms. Keith had done a meticulous job in presenting the facts, the Special Master required a medical expert opinion to substantiate the Petitioner's claims that it was the vaccine, and not some other agent or illness, that caused her symptoms.

The Petitioner promptly responded to every portion of the Respondent's Motion, but in general she alleged that she had already proved causation and that the doctors were wrong in dismissing her case as "all made up." In August 2001, the Special Master suspended the matter again, for 180 days.

The Special Master then granted another extension for the Petitioner to file her expert report. Failing to meet that deadline, the Petitioner submitted a status report a month later, indicating that she had contacted more doctors who declined to participate in her case. Incidentally, we note that the Petitioner's diligence in seeking a medical expert is not in question. Ms. Keith, with the help of counsel, contacted numerous doctors, including her former neurologist, but she was turned down by each one of them.

The Special Master granted another extension until February 2002, and then another one until May 2002. In September 2002, the Respondent submitted a second Motion to Dismiss based on Petitioner's insufficient evidence of causation and her failure to submit an expert report. Finally, in October 2002, two full years after Ms. Keith was first directed to provide expert evidence, the Special Master granted the Respondent's motion.

ORAL ARGUMENT ON THE PETITION

_____ On March 18, 2003, this Court held oral argument via telephone conference on Ms. Keith's petition. Two central issues arose during argument. First, Ms. Keith asserted that she should have claimed "encephalitis" as her Table injury, rather than Brachial Neuritis. Second, the Petitioner conceded that she had absolutely no medical evidence or expert opinion supporting the claim that her vaccinations caused, or aggravated, any of her illnesses. Unfortunately, while Ms. Keith had no choice but to state the truth, this concession was fatal to her case.

We note three problems regarding Ms. Keith's first argument. First, Ms. Keith did not claim she suffered from encephalitis in her proceedings before the Special Master, and it is too late for her to bring this claim on appeal. See Vaccine Rule 8(f). However, even if her claim was timely, encephalitis is not a Table injury for tetanus. See 42 C.F.R. § 100.3 (Vaccine Injury Table). Third, even if it was a Table injury for tetanus, Ms. Keith presented no documentation from a doctor or medical expert diagnosing her with encephalitis, nor do her original medical records point to such an illness as a potential cause for her symptoms. As we will discuss below, Ms. Keith cannot secure compensation for an unsubstantiated claim, regardless of its timeliness.

As to the second issue, Ms. Keith conceded that she had no medical evidence supporting her original claims. Ms. Keith further admitted that her doctors refused to acknowledge that her attacks even occurred. However, the existence of her symptoms has never been in dispute. Thus, the Court asked the Petitioner whether, assuming they did in fact occur, she had any medical evidence that the vaccinations were the cause. To this she answered no.

Finally, Ms. Keith claimed that her counsel did not do enough to help her find a doctor who would support her case. She had suggested he ask her immunologist to interpret her tetanus antibody tests; however, counsel did not follow through. Thus, Ms. Keith was forced to continue looking for a doctor on her own, which we know ended unsuccessfully. While we recognize the frustration Ms. Keith faced in her pursuit of a medical expert and in working with counsel, unfortunately she has no recourse in this Court. Dissatisfaction with counsel simply has no effect on the merits of a civil case, and that claim must be pursued elsewhere, if at all.

STANDARD OF REVIEW

This Court may set aside the Special Master's findings of fact and conclusions of law if they are found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. See 42 U.S.C. § 300aa-12(e)(2)(B); *Saunders v. Sec'y of Dep't of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994). "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 v. Sec'y of Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). The relevant arbitrary and capricious standard is "well understood to be the most deferential possible." *Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992).

Ms. Keith's Petition for Review did not state any legal basis for overturning the Special Master's findings. However, as noted above, allegations made in a *pro se* complaint are held to less strict standards than pleadings formally drafted by lawyers. Thus, we perceive Ms. Keith to be alleging that the Special Master acted arbitrarily and capriciously in dismissing her case. However, a careful review of the proceedings below reveals that the Special Master did not err in dismissing Ms. Keith's petition.

DISCUSSION

The Petitioner seeks compensation for an alleged Table injury, Brachial Neuritis, as well as the aggravation of her existing Chiari I malformation.

For the first claim, the Petitioner can secure compensation by showing that her injury or condition is listed in the Table; that her injury manifested itself within the time frame given by the Table; and that all other requirements of 42 U.S.C. § 300aa-13(a)(1) have been met. This path establishes a presumption of causation for the Petitioner, and shifts the burden to the Government to prove that a factor unrelated to the vaccine was the actual cause of injury.

For her second claim, aggravation of an off-Table injury, the Program still allows recovery but the Petitioner faces a tougher evidentiary burden. She must prove that the vaccine, and not some other agent, was the actual cause of her injury. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii). Thus, this path requires proof of actual causation before the burden can shift to the Government.

Table Injury

First, the Petitioner claims she suffered from a Table injury – Brachial Neuritis. As part of her case, she must prove that she sustained her first symptom or manifestation of Brachial Neuritis within two to twenty-eight days of her Td vaccination. See 42 U.S.C. § 300aa-11(c)(1)(C)(i); 42 C.F.R. § 100.3. While Ms. Keith’s petition presents Table injury claims for both her 1997 and 1998 vaccinations, in her Petition for Review and again during the hearing she concedes the 1997 claim because of the absence of medical verification of her symptoms. We note as well that the symptoms occurred two months after the shot, which is well beyond the 28-day statutory time limit.

To meet her burden as to the 1998 vaccination, Ms. Keith has offered medical records from doctors as well as her own written opinions. While the Petitioner’s medical records provide extensive documentation of her symptoms, which presumably occurred within the Table time frame, they do not establish that these symptoms were actually related to, or caused by, Brachial Neuritis. In fact, the Petitioner’s records point to many other illnesses as possible causes of her symptoms, including seizure disorder, rheumatological factors, and a psychophysiological condition. Moreover, the Petitioner was ultimately diagnosed with a brain stem defect that is known to produce the symptoms she suffered, including headache, fatigue, and tingling in the extremities.

Ms. Keith’s only evidence of a Table injury comes from her own analysis and opinion, which she formed after she received the Vaccine Program information packet and identified the injury most similar in symptoms to her own. While the Court acknowledges the similarity of the Petitioner’s symptoms to those occurring from Brachial Neuritis, “the special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1).

Thus, in the absence of clear, definitive medical records establishing this injury, a medical expert opinion was necessary to categorize the reactions described by Ms. Keith as actual manifestations of Brachial Neuritis. See *Dickerson v. Sec’y of Dep’t of Health & Human Servs.*, 35 Fed. Cl. 593, 599-600 (1996) (affirming in part the dismissal of a petition for compensation when mother failed to substantiate her on-Table claim of residual seizure disorder with medical expert opinion). For example, Ms. Keith alleged that her blood tests were indicative of high tetanus antibodies in her system. But this allegation on its own is not sufficient to establish that she suffered an on-Table injury. She needed a medical expert to diagnosis her with Brachial Neuritis before she could recover compensation for such a claim.

The Special Master asked the Petitioner on numerous occasions to produce a medical expert report, and explained to her the reasons why this was necessary. The Special Master even attempted to find a medical expert for the Petitioner. However, after encountering refusals by many doctors, Ms. Keith was unable to produce an

expert and thus she had no medical explanation to support her case of causation.

Because the Petitioner failed to meet the statutory requirement of providing a medical expert opinion in the face of an unsubstantiated claim, we cannot find that the Special Master acted arbitrarily or capriciously in dismissing this claim.

Off-Table Injury

Next, Ms. Keith alleges that she suffered aggravation of a pre-existing off-Table injury – the Chiari I malformation. In order to establish *prima facie* entitlement to compensation for an off-Table injury, the Petitioner must prove that the vaccine actually caused her injury. 42 U.S.C. § 300aa-13(a)(1)(A), 300aa-11(c)(1)(C)(ii). The Federal Circuit requires vaccine petitioners to “prove, by a preponderance of the evidence, 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 Dep’t of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Moreover, there must be a “logical sequence of cause and effect showing that the vaccination was the reason for the injury” and a “reputable medical or scientific explanation must support this ... sequence...” *Grant v. Sec’y of Dep’t of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

We face the same evidentiary problems as above. The Petitioner has presented thorough medical records documenting her symptoms and discussions with doctors; however, not one of these records establishes a causal link between the vaccines and her injury. What evidence we do have about the Chiari I defect, from the records of the Petitioner’s neurologist and physician, establishes that her doctors believed there was no connection at all.

Ms. Keith’s case for causation was based exclusively on her own opinions, unsupported by medical evidence. The Special Master stated in her dismissal order that she conducted an exhaustive review of the Petitioner’s medical records in order to find even the slightest evidence of actual causation, and we have done so as well. However, both efforts have failed to support a *prima facie* case for Ms. Keith.

Again, because of this defect, Ms. Keith needed a medical expert opinion to establish that the vaccines actually caused her Chiari I aggravation. Ms. Keith states in her “Conclusive Report” that she had some sort of “brain attack” three weeks after her second shot, and thus this proved that the tetanus shot also caused her first attack. Although the Petitioner’s symptoms did appear within two months of her first vaccination, and again within three weeks of her second vaccination, “a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury.” *Grant*, 956 F.2d at 1148. Were the Special Master to find that this coincidence alone established actual causation, her findings would indeed have been clearly erroneous.

Ms. Keith needed to do more than show a proximate temporal association. She needed medical evidence or a medical expert report to establish but-for causation, *Shyface*, 165 F.3d at 1352, and a “logical sequence of cause and effect,” *Grant*, 956 F.2d at 1148. Because she could not provide an expert opinion, the Petitioner failed to establish a *prima facie* case of causation. See, e.g., *Hodges v. Sec’y of Dep’t of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). Thus, on the record before us, we find that the Special Master did not act arbitrarily or capriciously in dismissing the Petitioner’s second claim.

CONCLUSION

In sum, Ms. Keith has been incredibly diligent about documenting her symptoms and doctors visits, researching possible causes, and presenting this evidence in a well-organized fashion to this Court. We are truly sympathetic to Ms. Keith’s years of suffering. Unfortunately, we are constrained by the National Vaccine Injury Compensation Program to ensure that its very specific requirements are met. We simply cannot award compensation under the Program without sufficient evidence to meet a *prima facie* case of causation, and Ms. Keith has not presented such evidence.

For the foregoing reasons, the **Petitioner’s Motion for Review is DENIED, and the decision of the Special Master, dated October 10, 2002, is hereby AFFIRMED.** The Clerk of the Court shall enter judgment accordingly. Each party to bear its own costs.

IT IS SO ORDERED.

/s/

LAWRENCE M. BASKIR
Judge