

No. 90-2208V
(Filed: January 6, 1997)

DONNA WAGNER,

Petitioners,

v.

SECRETARY OF THE
DEPARTMENT OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Vaccine Act; Respondent's
burden of proving alternative
factors; Idiopathic causes.

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Ronald C. Homer, Boston, Massachusetts, for petitioner.

David L. Terzian, Department of Justice, with whom were Frank W. Hunger, Assistant Attorney General, Helene M. Goldberg, Director, John Lodge Euler, Deputy Director, and Gerard W. Fischer, Assistant Director, all of Washington, D.C., for respondent.

OPINION

BRUGGINK, Judge.

This National Vaccine Injury Compensation Program case is before the court on petitioner's motion for review of the decision of the Special Master denying compensation. The National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to -34 (1994) (the "Vaccine Act"), is designed to compensate individuals who suffer injuries as a result of certain statutorily designated vaccines. Such compensation may be sought by filing a claim against the Government in the United States Court of Federal Claims. By statute, these Vaccine Act claims are first submitted to the Office of Special Masters, which determines entitlement to and the amounts, if any, of compensation. 42 U.S.C. § 300aa-12(c), (d). Upon petitioner's motion, this court may then review the decision of the Special Master under a deferential standard of review. Because the court finds that the Special Master's decision was not in

accordance with law, that decision is reversed and remanded for further proceedings consistent with this opinion.

Background

The petitioner, Donna Wagner, received a rubella vaccination on December 3, 1987. On that date she was 39 years old. Approximately six days after this vaccination, she began to experience aching pain in her thighs and knees. The day after those symptoms appeared she also developed fever, and the next day developed a rash. After about five days the rash disappeared. However, on December 20, 1987, Ms. Wagner developed a new rash and began to experience some aching in her joints. Since that time, she has experienced intermittent episodes of pain and swelling in both her hand and wrist joints.

In 1990, Ms. Wagner filed a claim with this court seeking compensation for her injuries allegedly suffered as a result of her rubella vaccination. Special Master Hastings determined, based upon the testimony of the experts presented by both petitioner and respondent, and upon the results of the Omnibus Proceeding,⁽¹⁾ that the petitioner could not prove by a preponderance of the evidence that her injuries were caused by the rubella vaccination she received, and thus denied her claim for compensation.

Ms. Wagner now files this motion for review of the Special Master's decision denying compensation. She claims that the Special Master applied an incorrect legal standard in denying her claim by requiring that she prove the absence of another good explanation for her injuries, when the burden to prove an alternative cause should have been on the Government. Ms. Wagner asserts that she was entitled to a legal presumption that her injuries were caused by the rubella vaccination she received. She further argues that, under 42 U.S.C. § 300aa-13(a)(1)(B) & (a)(2)(A), the Government could not meet its resulting burden to show that some other unrelated factor caused her injuries because the "other factor" it relied upon had no known cause.

Discussion

This court reviews decisions by the Special Master under a highly deferential standard. "Factual findings are reviewed under the arbitrary and capricious standard; legal conclusions are reviewed under the 'not in accordance with law' standard; and discretionary rulings are examined for abuse of discretion." Johnson v. Secretary of Dep't of Health and Human Servs., 33 Fed. Cl. 712, 720 (1995), *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996). Thus, this court may not simply substitute its judgment for that of the Special Master. See Carter v. Secretary of Dep't of Health and Human Servs., 21 Cl. Ct. 651, 653 (1990) (citing Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416, 91 S.Ct. 814, 823-24, 28 L. Ed. 2d 136 (1971)). However, when the Special Master misinterprets or misapplies the applicable law, this court must reverse that decision unless the error would not affect the outcome.

Under the Vaccine Act, a petitioner may prove entitlement to compensation through one of two statutory avenues. First, the Vaccine Act lists specific injuries resulting from certain vaccines that, if suffered by the petitioner within a specified time period, entitle the petitioner to a presumption that the injuries were caused by the vaccine. Such injuries are called "on-table injuries." Once such a presumption attaches, the burden shifts to the Government to prove, if it can, by a preponderance of the evidence, that the injuries suffered were caused by some other unrelated factor. If, however, a petitioner does not have an on-table injury, then she may nevertheless receive compensation if she can prove by a preponderance of the evidence that her injuries were in fact caused by the vaccine. See Munn v. Secretary of Dep't of Health and Human Servs., 970 F.2d 863, 865 (Fed. Cir. 1992).

In this case, the Special Master found that the petitioner's injuries--described as arthropathy⁽²⁾--were not on-table injuries for the rubella vaccine.⁽³⁾ Thus, the proper standard in this case is whether the petitioner was able to show, based upon the record as whole, that it was more likely than not that her injuries were caused by the rubella vaccine. See Hines v. Secretary of Dep't of Health and Human Servs., 940 F.2d 1518, 1524-25 (Fed. Cir. 1991).

To meet her burden to prove it more likely than not that the rubella vaccination caused her arthropathy, the Special Master imposed a six-part test, which required Ms. Wagner to demonstrate that:

1. The petitioner in fact had a rubella vaccination, at a time when the petitioner was 18 years of age or older.
2. The petitioner had a history, over a period of at least three years prior to the vaccination, of freedom from any sort of persistent or recurring polyarticular joint symptoms.
3. The petitioner has developed an antibody response to the rubella virus.
4. The petitioner experienced the onset of polyarticular arthropathic symptoms during the period between one and six weeks after the vaccination.
5. Polyarticular arthropathic symptoms continued for at least six months after the onset; or, if symptoms remitted after the acute stage, polyarticular arthropathic symptoms recurred within one year of such remission.
6. There is an absence of another good explanation for the arthropathy; the petitioner has not received a confirmed diagnosis of rheumatoid arthritis, nor a diagnosis of . . . [Sjogren's Syndrome].

This test was developed by the Special Master in another proceeding, referred to as the Omnibus Proceeding. That proceeding combined and examined seventy cases pending before the Special Master that addressed similar issues--namely, that each petitioner complained of arthropathic injuries resulting from a rubella vaccination. The Special Master heard testimony from medical experts submitted by both the petitioners and the Government. Following this proceeding, the Special Master found that the medical connection between the rubella vaccine and arthropathy was tenuous, but that there was some connection. It was determined that if a petitioner could meet each and every element of the six-part test, then, and only then, could it be said that it was more likely than not that the rubella vaccine had caused the arthropathy.⁽⁴⁾

The Special Master found that Ms. Wagner could meet the first five elements of the test, but that she could not meet the sixth element because there was another reasonable explanation for her arthropathy. Based upon the expert testimony, the Special Master found that the petitioner suffers from Sjogren's Syndrome, an immunological disorder with an unknown etiology. The testimony indicated that arthropathy is present in somewhere between forty and sixty percent of patients with Sjogren's. Similar findings regarding Sjogren's Syndrome were made in the Omnibus Proceeding. Accordingly, the sixth element of the test specifically lists Sjogren's Syndrome as a disqualifying factor. Thus, if a petitioner has Sjogren's Syndrome, then under the Omnibus Proceeding's test, she cannot recover under the Vaccine Act for arthropathy allegedly resulting from a rubella vaccination.

Ms. Wagner claims that the first five elements of the test developed in the Omnibus Proceeding essentially act to create a new on-table injury, and that the sixth element is actually a burden that must be imposed on the Government to show that the injury was caused by some other unrelated factor. There

is merit to this assertion.

The Vaccine Act provides that for the Special Master to determine entitlement to compensation, he must find, based on the record as a whole, that:

(A) . . . the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition . . . , and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

42 U.S.C. § 300aa-13(a)(1).

It has recently been said that these two provisions of the statute are essentially "collapsed" into a single inquiry. See Johnson, 33 Fed. Cl. at 721. Johnson involved facts similar to the present case. There, the petitioner developed joint problems allegedly as a result of a rubella vaccination. The Special Master determined, however, that the petitioner's prior condition of fibromyalgia syndrome was more likely the cause of the injuries at issue and denied compensation. In reviewing the decision of the Special Master, the court stated that the essential inquiry in a non-table injury case is whether "on the record as a whole" the petitioner has shown it to be more likely than not that her injuries were caused by the vaccine. Id. at 721. However, the court took the analysis further and stated that the petitioner was also required to show the absence of some other cause for her injuries. Thus, Johnson "collapsed" the requirements of 42 U.S.C. § 300aa-13(a)(1) into a burden on the petitioner to show that it is more likely than not that the vaccine caused the injury, and also that there is not a preponderance of evidence that "some other superseding intervening" factor caused the injuries. Id. at 721 (citing Munn, 970 F.2d at 865).

However, the fact of a single inquiry "on the record as a whole" by the Special Master does not mean that the burden is on the petitioner to prove both part (A) and part (B) of section 300aa-13(a)(1). Once the petitioner puts on a prima facie case of causation, the burden shifts to the Government to put on evidence, under part (B), of an "unrelated factor." Part (B) thus acts essentially as a defense for the Government in these cases. See O'Connor v. Secretary of Dep't of Health and Human Servs., 24 Cl. Ct. 428, 429-30 n.2 (1991), aff'd, 975 F.2d 868 (Fed. Cir. 1992) (respondent has the burden under 42 U.S.C. § 300aa-13(a)(1)(B) to show "an actual alternative cause."); McClendon v. Secretary of Dep't of Health and Human Servs., 24 Cl. Ct. 329, 333 (1991), aff'd, 41 F.3d 1521 (1994) (the Vaccine Act "implicitly places the onus of proving the existence of an alleged alternative cause squarely on the shoulders of the respondent.") (citing Matthews v. Secretary of Dep't of Health and Human Servs., 18 Cl. Ct. 514, 518-19 (1989)). Placing that burden on the petitioner would require the petitioner to affirmatively prove that an infinite number of potential causes were not at work causing the injuries suffered. There is no foreseeable end to the burden that would be placed on the petitioners under such a statutory interpretation. The statutory language and the purpose of the Vaccine Act do not anticipate or support such a construction.

More important to this case, however, is the fact that the Vaccine Act specifically limits the "unrelated factors" which may be considered by the Special Master when considering "the record as a whole." They do not include "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition" 42 U.S.C. § 300aa-13(a)(2)(A).⁽⁵⁾ At the evidentiary hearing before the Special Master, both parties' experts testified that Sjogren's Syndrome has no known cause. A condition is idiopathic where there is no known etiology, which means simply that there is no known cause.

If the alternative cause here had not been idiopathic, the procedure followed may have been harmless. However, placing the burden on the petitioner in this case forced her to disprove the causal effects of a condition--Sjogren's Syndrome--that the Government could not rely on as a defense. The Vaccine Act does not permit such a barrier to recovery.

Conclusion

To the extent that the Omnibus Proceeding's test operated in this case to place the burden of disproving every alleged alternative cause on the petitioner, and to the extent it allows consideration of factors precluded by 42 U.S.C. § 300aa-13(a)(2)(A), it is not in accordance with the requirements of the Vaccine Act. Under the terms of the Vaccine Act, such alternative factors of causation should be both offered and proven by the Government, and are subject to the statutorily imposed limitations on such evidence. Accordingly, this case is remanded for further proceedings not inconsistent with this opinion.

ERIC G. BRUGGINK

Judge

1. The Omnibus Proceeding is the term used to describe the results of a separate inquiry undertaken in 1993 by the Office of Special Masters regarding the general association between arthropathic injuries and the rubella vaccination. The specifics of this inquiry are discussed infra.
2. The term "arthropathy" was used to describe both arthritis and arthralgia. Arthritis consists of joint pain or stiffness that is accompanied by objective indications such as redness or swelling. Arthralgia, on the other hand, is used to describe joint pain or stiffness where there is no objective criteria present.
3. The Special Master correctly noted that although the current statutory provisions list arthropathic injuries as on-table injuries, Ms. Wagner's claim was filed under a previous version of the Vaccine Act, which did not list arthropathy as a table injury for the rubella vaccine. The current version of the on-table injuries applies only to claims filed after March 10, 1995. See 42 C.F.R. § 100 (1996).
4. Ms. Wagner's case was not one of the seventy cases made a part of the Omnibus Proceeding. Nevertheless, the Special Master applied that proceeding's evidentiary findings to her claim, and required her to meet the criteria set out by that proceeding. Ms. Wagner did not raise any objection to the application of the Omnibus Proceeding to her claim before the Special Master, and has not raised any such objection before this court. Accordingly, the court does not examine the propriety of applying the Omnibus Proceeding to cases that were not directly involved in that proceeding. See generally Johnson, 33 Fed. Cl. at 730 n.10 (indicating concern over the ex parte nature of the Omnibus Proceeding).
5. In Johnson, the petitioner argued that, in view of the limitations imposed by 42 U.S.C. § 300aa-13(a)(2)(A), the Special Master erred in considering her fibromyalgia syndrome because of its unknown

etiology. However, the Johnson court stated that there was no need to address the merits of this provision because it found that the "first" step of the inquiry--whether petitioner could prove causation--was not established. Johnson, 33 Fed. Cl. at 721-22. The court did not recognize that the "second" step under the statute was already implicated by the last factor of the Omnibus Proceeding's test for actual causation. To the extent Johnson is inconsistent with this opinion, the court respectfully disagrees with that decision.