

In the United States Court of Federal Claims

No. 01-234V
(Filed: May 26, 2005)

RICHARD PISCOPO,

Petitioner,

v.

**SECRETARY OF HEALTH
and HUMAN SERVICES,**

Respondent.

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* **Vaccine Act; Non-Table Injury;**
* **Multiple Vaccinations; Causation;**
* **Expert Testimony; Due Process.**

Rev. Dr. Richard Piscopo, Brooksville, FL, pro se plaintiff.

Catherine E. Reeves, U.S. Department of Justice, Washington, DC, with whom were Peter D. Keisler, Assistant Attorney General and Director Timothy P. Garren for defendant.

OPINION

FIRESTONE, Judge.

The petitioner, Richard Piscopo (“petitioner”), has moved to review the entitlement decision of Special Master John F. Edwards denying him compensation under the National Vaccine Injury Act of 1986, as amended, 42 U.S.C. §§ 300aa-10 – 300aa-34 (“Vaccine Act” or “Act”), and directing that judgment be entered dismissing his petition. The petitioner raises two objections to the Special Master’s dismissal of his petition. First, the petitioner objects to the Special Master’s rejection of his expert, Dr. Mark R. Geier. The

petitioner had relied upon Dr. Geier to establish that his present condition, which involves an immune disorder, was caused by the Hepatitis B vaccine he had received. The petitioner claims that had he known that the Special Master had intended to reject Dr. Geier's opinion, the petitioner would have looked for another expert. In this connection, the petitioner argues that the Special Master's rejection of his expert without prior notice denied him due process. Second, the petitioner objects to the Special Master's substantive conclusion that the petitioner failed to prove that he suffers from a vaccine-related injury. The petitioner argues that his medical records establish a causal connection between the vaccines he received and his immunological illness. The Special Master concluded that the petitioner's medical records were not sufficient to establish the petitioner's claim. For the reasons set forth below, the decision of the Special Master denying compensation is **AFFIRMED**.

BACKGROUND

On April 20, 2001, the petitioner filed the present petition for vaccine compensation, claiming that he was injured as a result of receiving a Hepatitis B vaccination on April 24, 1998. At the time the petition was filed, the petitioner was represented by counsel. The case was originally assigned to the Chief Special Master Gary Golkiewicz. On June 22, 2001, counsel for the respondent wrote to the petitioner's counsel requesting that he file the medical documentation necessary to make a claim under the Vaccine Act. Thereafter, the case, along with twenty-five other cases involving claims that the Hepatitis B vaccine had caused an immunological illness, was re-assigned to

Special Master George Hastings. All of the cases were handled by the same counsel as a group, while the petitioners' counsel developed a causation theory for this group of cases.

After the petitioner filed additional documentation to support his petition on March 1, 2002, there was no further activity on the case until January 14, 2003. On that date Special Master Hastings ordered the case continued until the conclusion of five of the twenty-six cases, unless a party requested him to take separate action. Thereafter, on November 24, 2003, the case was re-assigned to Special Master John Edwards.

On December 11, 2003, the petitioner's counsel filed a motion to withdraw as attorney of record in the case. The motion indicated that the petitioner wished to proceed pro se. On December 30, 2003 Special Master Edwards granted the petitioner's counsel's motion.

On February 13, 2004, the respondent filed a report pursuant to Rule 4(b) of Appendix B of the Rules of the United States Court of Federal Claims ("RCFC") asserting that the petitioner had failed to prove that he was entitled to compensation under the Act and moving for dismissal of the petition. In particular, the government noted that the petitioner had failed to provide a qualified expert medical opinion to support his contention that the petitioner's Hepatitis B vaccinations had caused his alleged injury. Resp't Rule 4(b) Report at 13-14. In addition, the respondent noted that the petitioner had received numerous vaccinations in April, May, and June 1998 and that most of the vaccines were not covered by the Vaccine Act. Id. at 14. Apparently, the petitioner received four vaccinations on April 24, 1998, including: oral typhoid; Hepatitis B; rabies; and Japanese encephalitis.

Decision at 2 n.3. On May 5, 1998, the petitioner received a second round of vaccinations including: tetanus; inactivated polio-virus; his second Japanese encephalitis and his second for rabies. Id. On May 20, 1998, he received a third Japanese encephalitis vaccination and on May 27, 1998, he was vaccinated for Hepatitis A. Id. Thereafter, on June 2, 1998, he received his second Hepatitis B vaccination. Id.

In response to the respondent's report, Special Master Edwards issued an order on February 19, 2004, indicating the deficiencies in the petitioner's filings and ordering the petitioner to file a medical expert opinion by no later than April 30, 2004. On April 15, 2004, the Special Master accepted the petitioner's request to substitute William Paul Glass, Jr. as counsel. On May 6, 2004, the petitioner identified Dr. Mark Geier as his medical expert. Thereafter, on June 14, 2004, the Special Master issued an order giving the petitioner until July 9, 2004 to file a medical expert opinion. The petitioner filed an expert report by Dr. Mark Geier. Dr. Geier noted on his curriculum vitae that he had medical training and professional experience in the areas of genetics and obstetrics and gynecology. Pet'r Ex. 21AA. Dr. Geier also noted that he had testified as an expert in vaccine injury cases. Id. at 3.

Following a status conference in July 2004, the Special Master ordered the respondent to file a response to Dr. Geier's opinion by October 8, 2004. The respondent filed its response on October 7, 2004. At the same time, the respondent filed a motion to exclude Dr. Geier's testimony on the grounds that Dr. Geier was not qualified to offer an

opinion regarding the cause of the petitioner's immunological illness. In addition, the respondent filed the report of Dr. Burton Zweiman, a board-certified allergist and immunologist. Dr. Zweiman noted the scientific and medical deficiencies that he found in Dr. Geier's opinion. Resp't Ex. A. Relying upon Dr. Zweiman's opinion, the respondent argued that Dr. Geier's expert report did not meet the standards for admissibility of expert testimony, which were established by the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589-92 (1993), and which the Special Masters have looked to for guidance in evaluating the credibility and reliability of expert opinions under the Vaccine Act.

After receiving the respondent's response and motion, the Special Master ordered the petitioner to file a reply to the respondent's motion. He also proposed that a hearing be held on the admissibility of the medical expert testimony. Thereafter, the petitioner's second attorney, William Glass, filed a motion to withdraw from the case. He indicated that the petitioner wished to proceed pro se. The motion was granted on December 1, 2004.

On December 7, 2004, the petitioner filed a Notice attaching additional documents for the Special Master's consideration. In that December 7, 2004 filing the petitioner made plain that he understood that his case presented "legal issues as it relates to the HBV [Hepatitis B vaccine] and my Claim. I realize that I received multiple vaccines and that multiple vaccines played a part in the mix of the Immune mediated disease which is robing

[sic] me of my life” Pet’r December 7, 2004 Notice at 4. He went on to state, “had I been able to file a Claim for a Vaccine Injury from Multiple Vaccines, I would have.” Id. at 5. He explained that he could not face the “stress of paying out thousands of dollars for expert witnesses”. Id. at 1. He identified several alleged errors in the respondent’s expert’s report. He further contended that his illness is consistent with an illness described in a “medical insert” prepared by a Hepatitis B vaccine manufacturer. Id. at 4. He concluded that the “HBV Vaccine and Multiple vaccines,” have caused his injury and he asked the Special Master to “Rule on my case.” Id. at 5.

On January 3, 2005, the respondent filed a response to the December 7, 2004 filing and on February 4, 2005, the Special Master issued his decision denying the petitioner’s claim. In his opinion the Special Master provided numerous reasons for rejecting the petition. First, the Special Master found that Dr. Geier, the petitioner’s expert, was not qualified to render an opinion regarding the cause of the petitioner’s illness in this case. In particular, the Special Master noted that Dr. Geier is a geneticist and not an immunologist and therefore did not have the requisite knowledge to offer an expert opinion regarding the relationship between the petitioner’s immunological illness and the Hepatitis B vaccine. Decision at 4-5. The Special Master also noted that Dr. Geier’s opinions have been increasingly criticized in other vaccine cases. See Decision at 5. The Special Master identified seven cases in which Special Masters had rejected the expert opinion offered by Dr. Geier because the opinion related to areas outside Dr. Geier’s areas of education, training and experience. Id. The Special Master further noted that under the American

Medical Association guidelines for expert witnesses, doctors are to testify only with respect to areas in which they have education, training, and experience. See Decision at 4-5 (citing American Medical Association, Policy Compendium 416 (1999)).

Second, the Special Master found that Dr. Geier's opinion did not provide a legally sufficient basis to conclude that the petitioner's Hepatitis B vaccinations were a "substantial factor" in bringing about the petitioner's illness. In particular, the Special Master noted that while Dr. Geier recognized that other vaccinations that the petitioner received - such as typhoid, rabies, and Japanese encephalitis (which are not covered by the Vaccine Act) - might have also played a part in causing petitioner's immune problems, he failed to explain why those vaccines and not the Hepatitis B vaccine were not the substantial cause of petitioner's illness. The Special Master stated, "Dr. Geier's medical report is devoid of any discussion eliminating as a cause of Rev. Piscopo's condition the host of other vaccines that Rev. Piscopo received concurrently with his hepatitis B vaccinations in 1998." Decision at 6. Because Dr. Geier did not address the other vaccinations that the petitioner received at the same time as he received the Hepatitis B vaccinations, the Special Master concluded that Dr. Geier failed to establish that the Hepatitis B vaccine was a substantial factor in bringing about the petitioner's injury. Id.

Third, the Special Master held that the petitioner's medical records alone were not sufficient to establish the petitioner's claim. The Special Master held that the petitioner's medical records reflected that the petitioner's doctors held a variety of opinions as to what had caused the petitioner's illness. For example, one of the petitioner's doctors thought

that the Japanese encephalitis vaccinations were the “culprit”. Pet’r Ex. 1 at 151. Another doctor, Dr. Robert Good, acknowledged that he could not determine which vaccination caused the petitioner’s “autoimmune phenomenon”. Pet’r Ex. 18 ¶ 10.

The Special Master also rejected the petitioner’s contention that the package insert for the Hepatitis B vaccine prepared by Merck & Company, Inc. proved that the Hepatitis B vaccine caused petitioner’s illness. The insert apparently identified various immune illnesses as possible adverse responses to the vaccine. The Special Master determined that a package insert was not sufficient to establish specific causation in any individual case and thus did not prove that the Hepatitis B vaccine caused the petitioner’s illness in this case. Decision at 7. It was for all of these reasons that the Special Master determined that the petitioner was not entitled to compensation.

DISCUSSION

A. Standard of Review

The Vaccine Act provides that this court may set aside a Special Master’s decision only if the Special Master’s fact finding is arbitrary and capricious or where the legal conclusions are not in accordance with law; discretionary rulings of the Special Master are tested on the abuse of discretion standard. 42 U.S.C. § 300aa-12(e)(2); Turner v. Sec’y of Health and Human Servs., 268 F.3d 1334, 1337 (Fed. Cir. 2001). In this connection, Special Masters are accorded deference in determining credibility and weighing evidence regarding causation and their determinations will be upheld unless they are shown to be arbitrary and capricious. Lampe v. Sec’y of Health and Human Servs., 219 F.3d 1357, 1360

(Fed. Cir. 2000). Determinations as to the qualification of experts and the admissibility of their testimony, including an evaluation of whether the opinion is reliable and relevant, are generally within the discretion of a trial judge, and are reviewed for an abuse of discretion, only overturned if manifestly erroneous. See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999) (holding that a trial court’s decision on the admissibility of expert testimony is reviewed for an abuse of discretion); Milmark Servs., Inc. v. United States, 731 F.2d 855, 860 (Fed. Cir. 1984) (holding that the admissibility of expert testimony is within the discretion of the trial court, and its action will be sustained unless “manifestly erroneous”); see also Terran v. Sec’y of Health and Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 2000) (applying the abuse of discretion standard to a Special Master’s determination on the reliability of an expert opinion in a case under the Vaccine Act).

The Vaccine Act provides two methods for establishing causation. Munn v. Sec’y of Health and Human Servs., 970 F.2d 863, 865 (Fed. Cir. 1992). A petitioner may demonstrate that he or she sustained an injury that is listed on the Vaccine Table, 42 U.S.C. § 300aa-14, and that the injury occurred within the time provided on the Vaccine Table. Munn, 970 F.2d at 865. In these “Table Injury” cases causation is presumed. Id. If the injury or timing does not comport with the requirements of the Vaccine Table, a petitioner may, in the alternative, establish a claim upon proving that a vaccine covered under the Vaccine Act was the “actual cause” of the injury. Id.; 42 U.S.C. § 300aa-11(c)(1).

The level of proof needed to establish entitlement in a causation-in-fact case, such as this one, has been discussed by the Federal Circuit in several cases. In brief, a petitioner

must to satisfy two tests. First, the petitioner must present credible evidence of general causation, namely evidence that the vaccine, here the Hepatitis B vaccine, is capable of causing autoimmune disorders, including the type responsible for the petitioner's condition. Second, the petitioner must present credible evidence of specific causation, namely that the Hepatitis B vaccine was the cause of the petitioner's illness in his particular case. The Federal Circuit has explained that a petitioner must demonstrate that "but for" the vaccination the injury would not have occurred and that the vaccine was a "substantial factor" in bringing about the condition. Shyface v. Sec'y of Health and Human Servs., 165 F.3d 1344, 1351-52 (Fed. Cir. 1999). If a petitioner is able to establish actual causation, then the burden shifts to the government to establish that a factor unrelated to the vaccine was the actual cause of the injury or illness. 42 U.S.C. § 300aa-13(a)(1)(B); Jay v. Sec'y of Dep't of Health and Human Servs., 998 F.2d 979, 984 (Fed. Cir. 1993).

B. The Special Master Did Not Abuse His Discretion by Rejecting the Petitioner's Expert or by Failing to Provide the Petitioner with an Opportunity to Find Another Expert

At the core of the petitioner's motion for review is his assertion that the proceedings below were not fair because the petitioner believed that the Special Master was going to "use" Dr. Geier's opinion to make his decision. The petitioner claims that "had I . . . been told or informed, that Dr. Mark R. Geier's M.D. Report was not suitable, I would have secured and will yet, secure, another expert medical report, by one who meets the courts [sic] standard of expert witnesses." Mot. Review at 3. The petitioner argues that

he was somehow misled about the Special Master's consideration of Dr. Geier's testimony and that this resulted in a deprivation of "due process".

After carefully reviewing the case, the court finds that the Special Master did not abuse his discretion in rejecting Dr. Geier's expert opinion or in failing to provide the petitioner with an opportunity to obtain another expert before he rendered his decision.

Each issue will be examined in turn.

First, the Special Master did not abuse his discretion in determining that Dr. Geier did not have the education, training or experience to proffer a reliable opinion on the cause of the petitioner's immunological disorders. Although under RCFC Appendix B, Rule 8(c), "[t]he special master will consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties" and is not bound by rules of evidence, the special master also has discretion in determining what evidence is relevant and reliable, and may apply the principles articulated in Daubert. See Terran v. Sec'y of Health and Human Servs., 41 Fed. Cl. 330, 336 (1998) ("Although the Federal Rules of Evidence do not apply in vaccine cases, the court believes Daubert is useful in providing a framework for evaluating the reliability of scientific evidence."), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999).

Under Daubert, trial courts are charged with a "gatekeeping" function to "ensure that any and all scientific testimony . . . is not only relevant but reliable" because experts are given latitude to give opinions that are not based on firsthand knowledge on the "assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline." 509 U.S. at 589, 592. The Supreme Court has also recognized that in some

cases, “the relevant reliability concerns may focus upon personal knowledge or experience.” Kumho, 526 U.S. at 150.

Dr. Geier’s curriculum vitae reveals that his medical training and professional experience relate to the areas of genetics and obstetrics and gynecology. Pet’r Ex. 21AA. This experience and training is largely irrelevant to the expertise needed to establish a causal relationship between the Hepatitis B vaccine and the petitioner’s autoimmune disorder. Dr. Geier does not have a background in immunology. The Special Master therefore did not abuse his discretion in concluding that Dr. Geier’s conclusions about the specific cause of the petitioner’s illness were not reliable. The fact that Dr. Geier had testified in other vaccine cases does not alter this conclusion. The Special Master correctly noted that Dr. Geier had been previously criticized for offering expert opinions outside his areas of training, education, and experience. Decision at 5. For all of these reasons, the Special Master did not abuse his discretion when he decided to reject Dr. Geier’s expert opinion on the ground that he was not qualified to offer an opinion regarding the petitioner’s Hepatitis B vaccination and his alleged autoimmune illness.

Second, the Special Master did not err in failing to provide the petitioner with an opportunity to secure and submit another expert opinion after the Special Master rejected Dr. Geier’s opinion. The record reveals that the Special Master provided the petitioner with ample time to secure a medical expert. In addition, the petitioner knew about, and was given an opportunity to respond to, the respondent’s criticism of Dr. Geier’s testimony. In this connection, the petitioner informed the Special Master that he had no intention of

securing additional experts, even though he understood that his case was vulnerable on the issue of causation. See Pet'r December 7, 2004 Notice at 1, 4.

This court has not had occasion to address whether principles of fundamental fairness dictate that petitioners should be given the opportunity to remedy deficiencies in their proffered testimony after an expert's opinion has been rejected by a Special Master. Courts have held in similar circumstances that trial judges are not required to provide parties with an opportunity to cure their case after their expert has been rejected. See Nelson v. Tennessee Gas Pipeline Co., 243 F.3d 244, 249 (6th Cir. 2001); Pride v. BIC Corp., 218 F.3d 566, 578-79 (6th Cir. 2000) ("District courts have broad discretion to exclude untimely disclosed expert-witness testimony."). In Nelson, the Sixth Circuit explained that where a plaintiff has an adequate opportunity to develop his expert testimony and to respond to the challenges raised to the testimony, "fairness does not require that a plaintiff . . . be afforded a second chance to marshal other expert opinions . . ." Id. at 250. The Nelson court was guided by the Supreme Court's decision in Weisgram v. Marley Co., 528 U.S. 440 (2000), in which the Supreme Court held that after Daubert, parties are expected to put their best case forward in the first instance and are not entitled under fairness principles to "shore up their cases by other means [as they would have] had they known their expert testimony would be found inadmissible." Id. at 455-56.

In light of these decisions and the circumstances present in this case, this court finds that principles of fundamental fairness did not dictate that this petitioner be given a second chance to find an expert after his first expert was rejected. The petitioner was given

ample opportunity to find an expert and to address the respondent's objections to his expert's opinion. In his response, the petitioner indicated that he was not interested in providing the Special Master with another expert opinion. Pet'r December 7, 2004 Notice at 1. In such circumstances, fundamental fairness did not dictate that the petitioner be given another opportunity to present a new expert opinion to shore up his case.

C. The Special Master's Conclusion that the Petitioner Failed to Prove A Non-Table Injury Was Not Arbitrary or Capricious

The petitioner also argues that he established a vaccine-related injury based on the medical records presented to the Special Master.¹ The petitioner contends that "[e]very doctor within the record of fact, states that the present disease which I suffer with, is a direct result of the vaccines." Mot. Review at 2. In particular, he notes that Dr. Robert Good stated that he "suffered serum sickness from the vaccines." *Id.* In this connection, the petitioner does not dispute that Dr. Good stated that he could not determine which vaccine caused his "autoimmune phenomenon." *See* Pet'r Ex. 18 ¶ 10. The petitioner states that he knows that "the vaccines I received in April May [sic] and June of 1998 have caused my present disease." Mot. Review at 2. He does not claim specifically that his illness was actually caused by the Hepatitis B vaccine.

As discussed above, the Special Master concluded that the petitioner had failed to

¹ In his decision, Special Master Edwards did, apparently in the alternative, evaluate Dr. Geier's expert opinion as part of the petitioner's case and found it insufficient to prove causation as a matter of law. However, in his Motion to Review, the petitioner does not challenge this holding, but instead argues that he established causation through his medical records alone.

prove causation because the petitioner failed to present evidence to rule out the effect of his other vaccinations on his illness. The Special Master noted that Dr. Geier never eliminated the other vaccines that the petitioner received, such as the rabies and Japanese encephalitis vaccines, as the primary cause of the petitioner's condition. The Special Master further noted that petitioner's medical records indicated that the other non-Vaccine Act vaccines the petitioner had received were the possible causes of his condition. Decision at 6-7. For example, one of the petitioner's doctors identified the Japanese encephalitis vaccine as the likely "culprit" for his present illness. Pet'r Ex. 1 at 151. Another identified the rabies vaccine as the cause of the petitioner's health problems after being vaccinated. Pet'r Ex. 3 at 3. Even Dr. Good, whom the petitioner relies upon, noted that it was not possible to determine which of the vaccines caused the petitioner's illness. See Mot. Review at 2; Pet'r Ex. 18 ¶ 10.

In these circumstances, the Special Master was not arbitrary or capricious in concluding that the petitioner had failed to meet his burden of proof on causation. Where, as here, the petitioner received multiple vaccinations, the Special Master correctly concluded that the petitioner needed to rule out the role of the other non-Vaccine Act vaccines in causing the petitioner's illness. See Pafford v. Sec'y of Health and Human Servs., 64 Fed. Cl. 19, 35 (2005) ("the attendant burden of proof in an actual causation case subsumes the obligation to successfully eliminate potential alternative causes of the alleged injury that have been identified in the record." (citing Munn, 970 F.2d at 865)). Where evidence of causation is not plain from the medical records, an expert opinion is

needed to establish causation. See Rutigliano v. Valley Business Forms, 929 F. Supp. 779, 783, aff'd, 118 F.3d 1577 (3d Cir. 1997). Here, the medical records do not establish that the petitioner's condition was substantially caused by the Hepatitis B vaccine. None of the doctors who treated the petitioner identified the Hepatitis B vaccine as a substantial factor in causing his illness. The Special Master therefore did not err in concluding that the petitioner failed to prove by a preponderance of the evidence that the Hepatitis B vaccine, and not some other agent, was the actual cause of his injury.

CONCLUSION

The court sympathizes with the petitioner's circumstances. However, the court is bound by the requirements of the Vaccine Act and the law interpreting that statute. Under the Vaccine Act, a petitioner with a non-Table injury must establish that a vaccine listed in the Vaccine Act actually caused the illness for which the petitioner is seeking compensation. For all of the reasons set forth above, the Special Master correctly determined that the petitioner failed to meet his burden of proof. Accordingly, the decision of the Special Master is **AFFIRMED**.

IT IS SO ORDERED.

NANCY B. FIRESTONE
Judge