

In the United States Court of Federal Claims

**No. 00-426V
(Filed: December 8, 2005)**

**PATRICIA ANN WALTHER,
D.V.M.,**

Petitioner,

v.

**SECRETARY OF HEALTH
and HUMAN SERVICES,**

Respondent.

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* **National Childhood Vaccine Injury**
* **Act; Non-Table Injury; Multiple**
* **Vaccinations; Causation; Expert**
* **Credibility**
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Richard Gage, Cheyenne, WY, for petitioner.

Mark Curtis Raby, U.S. Department of Justice, Washington, DC, with whom were Peter D. Keisler, Assistant Attorney General and Director Timothy P. Garren for respondent.

OPINION

FIRESTONE, Judge.

This National Childhood Vaccine Injury Act (“Vaccine Act” or “Act”), 42 U.S.C. §§ 300aa-10 to -34 (2000), matter is before the court on the petitioner’s, Patricia Ann D.

Walther (“petitioner”), Motion for Review of the July 29, 2005 decision by Special Master John F. Edwards. The special master denied relief on the grounds that the petitioner had failed to satisfy her burden of proof that a diphtheria-tetanus (“Td”) vaccination she received on July 31, 1997 caused her to develop a “post vaccinal encephalomyelitis,” in the form of acute disseminate encephalomyelitis (“ADEM”). The petitioner argues that under the Federal Circuit’s recent ruling in Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005), the special master applied the wrong legal standard for causation. The petitioner asks the court to find that she satisfied her burden of proof and is entitled to relief.

ADEM is not an injury listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14a, in connection with the Td vaccine. Thus, the petitioner was required to prove by a preponderance of the evidence that the Td vaccine actually caused the petitioner’s alleged ADEM. 42 U.S.C. §§ 300aa-13a(1) and 300aa-11(c)(1)(C)(ii)(I). Under the Federal Circuit’s recent ruling in Althen, the 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 the vaccination and the injury.” 418 F.3d at 1278. Once the petitioner satisfies this burden, she is entitled to recover unless the government (“the respondent”) shows, also by a “preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.” Id. (quoting Knudsen v.

Sec'y of Health & Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994)) (alteration in the original). As discussed below, the court finds that Althen did not change the burden of proof for this petitioner and therefore it does not mandate reversal of the special master's decision. The special master's decision was not arbitrary or capricious and therefore it must be affirmed.

BACKGROUND

The undisputed facts show that the petitioner, a doctor of veterinary medicine, received several vaccinations while she was serving as a Captain in the United States Army during the summer of 1997. On July 31, 1997, the petitioner received a Td vaccination, as well as vaccinations for yellow fever, typhoid, and meningitis. A week later, she received a rabies vaccination. Of the five vaccinations petitioner received in July and August 1997, only the Td vaccine is a "listed" vaccine under the Vaccine Injury Table, and thus it is the only vaccine subject to a claim under the Act.

At a hearing held by the special master, the petitioner and the respondent both presented opinion testimony as to (1) the causation of the petitioner's ADEM by the Td vaccine, and (2) the diagnosis of ADEM.

In order to establish causation under the Act, the petitioner presented the opinion testimony of Vera Byers, M.D., Ph.D. Dr. Byers received her medical degree from the University of California at San Francisco. She is certified by the American Board of Internal Medicine. She completed a Fellowship in Clinical Immunology at the Department of Medicine, University of California at San Francisco. She is a Fellow of

the American Academy of Allergy and a member of the American Association of Immunologists.

Dr. Byers testified that, accepting the diagnosis that the petitioner had ADEM, she believed to a medical certainty that the petitioner's ADEM was caused by the Td vaccination that the petitioner received in July 1997. Tr. 57. She focused her opinion on the tetanus component of the vaccine, which Dr. Byers stated can cause destruction of nerve tissue, which could lead to ADEM. Tr. 57-59. Dr. Byers explained that the petitioner's symptoms began seven days after the Td vaccination, which is within the four to seven day window expected for secondary responses to Td vaccinations. Tr. 63-64. Dr. Byers stated that the petitioner suffered from a secondary response because she had previously received a Td vaccination. Tr. 64. Dr. Byers testified that she did not believe that the rabies vaccine could have caused the ADEM because the rabies vaccine was administered only one day before the petitioner started to show symptoms. Tr. 65. Dr. Byers also testified that she did not believe that the yellow fever vaccine was the cause because the petitioner did not show any other signs of an adverse response to the yellow fever vaccine, which she said would have been expected. Tr. 68-69.

On cross-examination, the respondent focused on Dr. Byers' report and in particular on the conclusions she had drawn from the various studies and case reports she had identified therein. On cross-examination, Dr. Byers could not recall whether a study she relied upon involved the Td vaccine or the DPT vaccine, which includes a vaccine for pertussis. Tr. 89. She was also unable to recall the specifics of other studies she relied

upon. Tr. 88, 90, 100. In addition, Dr. Byers could not explain her reliance on the British National Childhood Encephalopathy Study (“NCES”), which she stated contained “a concise description of the lines of evidence indicating that [the] tetanus [vaccine has a] causal role in acute encephalitis.” Tr. 114. In response to questioning by the special master, Dr. Byers failed to explain how the study supported her opinion. She could not explain how the study’s focus on the DPT vaccine, which includes a vaccine for pertussis, supported her opinion. She also failed to explain how the study’s conclusion that most neurological injury occurred within 72 hours – and not within seven days as Dr. Byers’ testified – supported her opinion. Finally, she could not explain the study’s conclusion that the Td vaccine, as opposed to the DPT vaccine, did not show any statistically significant increase in acute neurological injury. Tr. 108-115. Decision at 5.

In response to other questions from the special master, Dr. Byers conceded that any vaccine “is capable of producing a demyelinating condition.” Tr. 116. She further conceded that the other vaccines the petitioner received concurrently with the Td vaccination “were candidates for the cause of” the petitioner’s condition. Tr. 117, 122. Dr. Byers stated that she focused on the Td vaccine as the cause because of the greater number of case reports associating the tetanus vaccine with demyelinating disorders. Tr. 122.

In addition to providing testimony on causation, the petitioner presented testimony on the nature of her condition. The petitioner presented testimony from Marcel

Kinsbourne, M.D., and Margaret Montana, M.D. Dr. Kinsbourne is certified by the American Board of Pediatrics. He is a member of the Royal College of Physicians, of the American Neurological Association, and of the Child Neurology Society. Dr. Montana is a certified radiologist and a member of the American College of Radiology. Dr. Kinsbourne testified that the petitioner has ADEM. Tr. 243. Dr. Montana testified about her review of MRI scans of the petitioner. Tr. 263.

The respondent presented testimony from Arthur Safran, M.D., and Gregory Shoukimas, M.D., Ph.D. Dr. Safran is certified by the American Board of Internal Medicine and by the American Board of Psychiatry and Neurology. He is a Fellow of the American Academy of Neurology. Dr. Shoukimas is a certified radiologist and is a member of the American Society of Neuroradiology. Both Dr. Shoukimas and Dr. Safran testified that they did not believe the petitioner had ADEM. Tr. 145, 200. Dr. Safran also testified that, even if one assumed that the petitioner had ADEM, there is no evidence to show that the Td vaccine caused her ADEM. Tr. 200. Dr. Safran stated that he had not found a single study which suggested that the Td vaccine can cause ADEM. In such circumstances, Dr. Safran concluded that it was impossible to tell which of the vaccines the petitioner received in July and August 1997 was responsible for her condition. Tr. 200-201.

In his July 2005 decision, the special master focused his findings exclusively on the issue of causation. After reviewing Dr. Byers' testimony in detail, the special master rejected Dr. Byers' testimony. Following a recitation of the errors in Dr. Byers'

testimony and her failure to adequately explain her reliance on the NCES study, the special master concluded that Dr. Byer had failed to demonstrate affirmatively that the Td vaccine actually caused the petitioner's condition. The special master found that Dr. Byer had failed to convincingly demonstrate that the petitioner's condition was more likely caused by the Td vaccine than by one of the other vaccines the petitioner received. The special master found that Dr. Byer's reliance on case reports associating a component of the Td vaccine with demyelinating disorders was not enough to prove specific causation. He concluded that Dr. Byer's opinion was not persuasive. Decision at 5. Consequently, the special master denied relief to the petitioner. Decision at 6.

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, where the legal conclusions are not in accordance with law, or its discretionary rulings are an abuse of discretion. Turner v. Sec'y of Health & Human Servs., 268 F.3d 1334, 1337 (Fed. Cir. 2001). In this connection, special masters are accorded great deference in determining the credibility and reliability of expert witnesses. Hanlon v. Sec'y of Health & Human Servs., 191 F.3d 1344, 1349 (Fed. Cir. 1999).

With regard to the level of proof needed to establish causation, the court is bound by the standard recently stated by the Federal Circuit in Althen. As noted above, under that standard, the petitioner bears the burden in a causation-in-fact case of proving both

general and specific causation. The petitioner must establish that the vaccine at issue is capable of causing the injury and must also establish that the vaccine caused the injury in the subject case. Althen clarifies that a petitioner does not need to produce “medical documentation of plausibility” to support general causation. 418 F.3d at 1281. Under Althen, a petitioner may rely on reliable medical testimony to establish the necessary link between a vaccine and an injury even if there are no documented cases. Id. at 1280. However, Althen affirmed that a petitioner must still demonstrate that the vaccine was the “reason for the injury.” Id. at 1278 (citation omitted). In this connection, the petitioner must provide proof of “a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes.” Id. at 1281 (emphasis added). Only after a petitioner has met her burden does the burden shift to the respondent to prove by a preponderance of the evidence that a “factor unrelated” to the vaccine caused the injury. 42 U.S.C. § 300aa-13(a)(1).

B. The Special Master Was Not Arbitrary or Capricious in Rejecting Dr. Byers' Opinion

At the core of the petitioner's motion for review is her assertion that the special master applied the wrong causation standard by requiring the petitioner to rule out a "hypothetical alternate cause." The petitioner contends that she met her burden when Dr. Byers gave her reasons for ruling out the other vaccines. The petitioner argues that Althen clarifies that the purpose of the Vaccine Act's preponderance of the evidence standard is to allow a finding of causation "in a field bereft of complete and direct proof of how the vaccines affect the human body." 418 F.3d at 1280. The petitioner concludes that under Althen the special master placed too heavy of a burden on the petitioner.¹

The respondent argues, in response, that the special master applied the correct legal standard for causation. The respondent contends that the petitioner was denied relief because the special master did not find the petitioner's causation expert, Dr. Byers, to be credible.

The court agrees with respondent that the special master denied the petitioner relief because he rejected Dr. Byers' opinion testimony and not because he applied the wrong legal standard. In particular, the special master rejected Dr. Byers' causation theory because her attempt to link the Td vaccine to petitioner's ADEM was not sufficiently supported to be credible. Dr. Byers claimed that she based her opinion that the

¹ The petitioner also challenges the special master's failure to address her claim that she suffers from ADEM. However, that issue is relevant only if the petitioner establishes that the Td vaccine can cause and did in fact cause her condition in this case.

petitioner's ADEM was caused by the Td vaccine on the greater number of studies and case reports that indicated an association between the tetanus vaccine and ADEM. Tr. 122. However, as discussed below, the special master found that some of those studies failed to support Dr. Byers' opinion. In addition, the special master found Dr. Byers' premise unpersuasive in that Dr. Byers had conceded that any of the vaccines that the petitioner received could have caused her condition. Decision at 5.

For example, Dr. Byers stated that she included the NCES study in her opinion because it contains "a concise description of the lines of evidence indicating that [the] tetanus [vaccine has a] causal role in acute encephalitis." Tr. 114. However, the NCES study involved the DPT vaccine, not the Td vaccine. Decision at 5. Dr. Byers failed to account for the impact of the pertussis vaccine. Indeed, she was not aware that the NCES study found no statistically significant increase in acute neurologic injury following Td vaccinations alone without pertussis. Tr. 112-114. At one point, Dr. Byers stated that she had read the NCES study two years earlier, but then later she confessed that she had not actually read the details of the study. Tr. 114. In addition, findings from the NCES study did not support Dr. Byers' opinion. Dr. Byers stated that the petitioner's ADEM began seven days after receipt of the Td vaccination. Tr. 64. She also testified that the petitioner's secondary reaction would occur around a week later. Tr. 71. Yet the NCES study indicated that most adverse reactions to the DPT vaccine occur within 72 hours. Decision at 5.

The NCES study was not the only study or case report that Dr. Bryer relied on that

did not necessarily support her opinion. She included another study that involved the DPT vaccine without accounting for the pertussis. Tr. 88. She failed to account for the fact that the same study involved children and did not involve adults. Tr. 89-90.

It is well-settled that “an expert opinion is no better than the soundness of the reasons supporting it.” Perreira v. Sec’y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (citations omitted). Here, the expert’s opinion that the petitioner’s ADEM was caused by her Td vaccination was based on the medical literature, and not on her independent study of either the vaccine or the injury. In such circumstances, Dr. Byers’ inability to recall the details of the studies she relied upon or to explain their relevance to her conclusions gave rise to concerns about the credibility of her opinion. Concern over her credibility was heightened when she testified about the NCES study, which plainly did not support her conclusion. A special master may properly reject expert opinion, where the expert opinion is based, in part, on studies that do not support the expert’s opinion. Waleryszak v. Sec’y of Health & Human Servs., 45 Fed. Cl. 573, 578-79 (1999), aff’d 250 F.3d 753 (Fed. Cir. 2000).

In view of the foregoing, the court cannot conclude on this record that the special master’s decision to reject Dr. Byers’ opinion was arbitrary and capricious. Dr. Byers failed to persuade the special master that the tetanus component of the Td vaccine was any more likely to have caused the petitioner’s ADEM than were any of the other vaccines that she received at or around the same time. The special master’s conclusion that Dr. Byers’ opinion was not persuasive is supported by the record and is therefore

affirmed.

CONCLUSION

For the reasons discussed above, the court finds that the petitioner has failed to demonstrate that the denial of her claim was arbitrary and capricious or otherwise not in accordance with law. As a result, the petitioner's Motion for Review is **DENIED**.

IT IS SO ORDERED.

NANCY B. FIRESTONE
Judge