

In the United States Court of Federal Claims

No. 99-0160V

Filed: January 12, 2005

(Reissued for Publication: March 8, 2005)*

ELIZABETH O. SCHNEIDER, as natural mother and guardian of her son, JOHN R. SCHNEIDER,) Vaccine Act: The special master's) decision denying compensation is) upheld where: (i) the evidence failed to) support petitioner's assertions that she) was directed to proceed to a hearing) without the benefit of counsel and with) a hostile witness; (ii) the special master) properly rejected a discovery request) that required the initiation of a scientific) study to examine the relationship) between alleged neurological injuries) and a protease inhibitor used in the) manufacture of the Hepatitis B vaccine;) and (iii) the record offered no evidence) to support petitioner's claim of vaccine-) caused anaphylactic shock.
Petitioner,	
v.	
SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES,	
Respondent.	

Elizabeth O. Schneider, Hudson, Ohio, appearing pro se.

Althea Walker Davis, with whom were Assistant Attorney General Peter D. Keisler, Director Timothy P. Garren, Deputy Director John Lodge Euler, and Assistant Directors Mark W. Rogers and Vincent Matanoski, Torts Branch, Civil Division, United States Department of Justice, for respondent.

ORDER

WIESE, Judge.

This case comes before the court on petitioner's motion for review of the special master's September 3, 2004, decision denying compensation under the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34 (2000). Petitioner alleges that her son, John R. Schneider, suffered neurologic injuries as a result of receiving a Hepatitis B vaccine on September 25, 1993, the day following his birth. The issues have been briefed and the court heard

* Upon respondent's request, this order is being reissued for publication.

oral argument on December 20, 2004. For the reasons set forth below, we affirm the special master's decision.

I.

Petitioner's son is afflicted with a permanent and totally disabling neurological disorder for which no accepted medical diagnosis or biological cause has ever been determined. Petitioner, appearing before the special master without the assistance of counsel, offered three arguments in support of her claim of vaccine causation of her son's disabling condition. First, petitioner contended that her son experienced anaphylaxis or anaphylactic shock within four hours of receiving the Hepatitis B vaccine and thus suffered a so-called Vaccine Table injury, *i.e.*, an injury that is presumed to be vaccine related. In support of this contention, petitioner pointed to hospital records indicating that her infant son had exhibited an irregular heartbeat following administration of the vaccine. Second, petitioner asserted that as a result of the vaccination, her son suffered an encephalopathy characterized by demyelination, a progressive neurological condition involving the destruction of the myelin sheathing of the central nervous system, which first appeared symptomatically as developmental delay in January 1994. Third, and finally, petitioner attributed her son's condition to the alleged presence in the vaccine of the chemical agent phenylmethylsulphonyl flouride ("PMSF").

The special master rejected petitioner's arguments for lack of any supporting evidence either in the form of medical records or medical opinion. More particularly, as to petitioner's assertion that her son experienced anaphylactic shock following administration of the vaccine, the special master noted that the record contained no evidence to support this contention. To the contrary, on the basis of uncontradicted evidence, the special master found that: (i) the medical records showed an irregularity in the infant's heartbeat even before the vaccine had been administered and not, as petitioner claimed, only after the vaccine's administration; (ii) anaphylaxis requires prior exposure to an allergen and thus can occur only on a second or third administration of a vaccine but not, as was claimed here, in conjunction with the vaccine's first administration to a newborn; and (iii) anaphylaxis is a dramatic state associated with cardiovascular collapse, an event that would not have gone unrecorded or untreated by qualified medical personnel, yet nothing in the medical records affirms that such an event occurred. Based on these several considerations, then, the special master rejected petitioner's contention that her son experienced anaphylaxis following administration of the Hepatitis B vaccine.

As to petitioner's second contention, that her son suffered an acute demyelinating encephalopathy attributable to the Hepatitis B vaccine, although petitioner's expert originally offered such a medical assessment, he later retracted

that diagnosis when he became aware of additional facts suggesting that petitioner's son had exhibited signs of neurologic injury even earlier in time than the developmental delays first observed in January 1994—an observation chronologically inconsistent with the expected clinical progression of a demyelinating encephalopathy. Additionally, respondent's expert testified that the medical records show that petitioner's son had normal patterns of myelin. Based on these considerations, the special master concluded that petitioner had not demonstrated a vaccine-induced demyelinating encephalopathy.

Finally, as to petitioner's assertion that her son's condition had been caused by the presence in the vaccine of the chemical agent PMSF, the special master found that petitioner had not offered any medical or scientific evidence to support this theory. Rather, the special master noted, the theory rested solely on petitioner's own "unsubstantiated lay belief"—an evidentiary source that the Vaccine Act specifically declares may not provide the basis for an award of compensation. See 42 U.S.C. § 300aa-13(a)(1) ("The special master or court may not make . . . a finding [in favor of compensation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.") Accordingly, the special master rejected petitioner's claim that a vaccine containing PMSF caused the global encephalopathy afflicting her son.

In her challenge to the special master's ruling, petitioner asserts that the special master's decision is procedurally defective and, hence, not entitled to finality. Specifically, petitioner maintains that the special master required her to proceed to trial without the benefit of counsel and with a hostile expert witness. In addition, petitioner claims that the special master improperly denied her request for discovery and failed to rely on the evidence in the medical records. Upon consideration of the record, we cannot accept these arguments.

II.

This case was filed in March 1999 but did not proceed to a hearing until July 2004. Much of the intervening time was given over to petitioner's efforts to find an additional expert to support her causation argument. Ultimately, however, those efforts were not successful, and on December 26, 2002, petitioner advised the special master that she would proceed with Dr. John Tilelli (petitioner's initially retained expert) as petitioner's "sole expert." Thereafter, on January 23, 2003, the special master entered an order directing petitioner to file, no later than April 25, 2003, a supplemental report from Dr. Tilelli responding to the opposing views of respondent's expert, Dr. Mary Anne Guggenheim. Petitioner failed to file such a report.

On April 29, 2003, petitioner's counsel filed a motion to withdraw from the case explaining that petitioner had terminated counsel's services and was "now seeking other counsel . . . to take over this case." On May 19, 2003, the special master granted the motion to withdraw and directed petitioner to respond, no later than July 30, 2003, to the special master's order of January 23, 2003. Failure to respond timely, the order cautioned, would cause the special master to "close the documentary record and schedule at once an evidentiary hearing." The special master further explained:

Since March 1999, the chief special master, and this special master, have afforded Ms. Schneider a full, fair opportunity to adduce medical evidence that supports her claim. Regardless, Ms. Schneider has not advanced significantly the claim. Now, Ms. Schneider seeks yet more time in order to retain new counsel. However, given the case's long and particularly unproductive procedural history, the special master does not consider the mere withdrawal of counsel to be an adequate basis for an extended continuance of proceedings. Therefore, by no later than July 30, 2003, Ms. Schneider shall comply completely with the special master's January 23, 2003 order.

Petitioner filed her response on July 31, 2003. In her response, petitioner provided additional medical records and advised that "John Tilelli, M.D. is not Petitioner's expert witness. He was chosen by Petitioner's former attorney, and, like the attorney, is no longer involved with John's case." Confronted with this turn of events, the special master entered another order on October 27, 2003, pointing out that under the Vaccine Act, compensation could not be awarded to a claimant in the absence of substantiating medical records or medical opinion. In this connection, the special master noted that "John's medical records as a whole do not demonstrate that John's September 25, 1993 Hepatitis B vaccination caused actually John's current condition." The proof of petitioner's case, the special master continued, therefore demanded a "legally-sufficient medical expert's opinion." The order concluded as follows:

The chief special master, and this special master, have afforded Ms. Schneider a full, fair opportunity to adduce medical opinion evidence that supports her claim, including the ample opportunity to obtain Dr. Tilelli's reply to Dr. Guggenheim's opinion. But, Ms. Schneider has disavowed specifically Dr. Tilelli's opinion and Dr. Tilelli's continued participation in the case. Thus, in essence, after more than four years of development, Ms. Schneider has returned this case to its initial procedural posture. In the special master's view, the case has passed a critical juncture. By no later than January 15, 2004, Ms. Schneider shall file a medical expert's

opinion that supports fully her case or the special master will dismiss the petition.

Petitioner filed her response on January 21, 2004. The response included a letter to petitioner from Dr. Tilelli stating, in substance, that while he remained willing to testify to the views set out in his initial report, the broader issues raised by respondent's expert (distinguishing between peripheral and central nervous system demyelination) "would be best addressed by a pediatric neurologist."

On March 9, 2004, the special master entered an order anticipating the scheduling of a hearing on petitioner's claim and directing petitioner to file a status report "identifying three dates that petitioner has confirmed with John Tilelli, M.D., for a hearing." Thereafter, petitioner proposed three such dates and the special master entered an order scheduling a hearing for one of those days, July 20, 2004. The order noted, *inter alia*, that "[p]etitioner's medical expert, John Tilelli, M.D., . . . shall appear by telephone."

III.

As indicated at the outset of this discussion, the facts do not support petitioner's assertion that she was obligated to proceed without counsel and with a hostile witness. Under the rules of procedure applicable to proceedings before the Office of the Special Masters, "[a]ny fact or argument not raised specifically in the record before the special master shall be considered waived and cannot be raised by either party in proceedings on review of a special master's decision." Vaccine Rule 8(f), App. B., RCFC. Because petitioner never presented this argument to the special master, such an argument is not appropriate for consideration in this appeal.

But even if the court were to look beyond the limitations of its rules to address petitioner's contention on its merits, it is clear that this argument has no substance. First, the special master never directed petitioner to proceed without counsel; it was always open to petitioner to enlist the aid of new counsel. Second, petitioner cannot reasonably argue that she was compelled by circumstances to so proceed. The special master's May 19, 2003, order, while denying petitioner's request for an extension of time in which to find new counsel, simultaneously allowed petitioner until July 30, 2003—nearly two and a half months later—to file her expert's supplemental report responding to the views presented by respondent's expert. Similarly, under the special master's October 27, 2003, order, petitioner was given until January 15, 2004—another two and a half months—in which to file the report of any new expert. Significantly, at no point during this period did petitioner assert that she required the assistance of counsel. Nor did petitioner raise such a contention when the special master, acting with the consent of the parties, scheduled

the matter for hearing in July 2004. Thus, petitioner's claim that she was forced to proceed without the benefit of counsel cannot be sustained.

Nor can the court uphold petitioner's contention that she was required to proceed to trial with a hostile expert witness. While it is correct to say that the special master ruled that the substantiation of petitioner's case would require the testimony of a medical expert, it is not correct to assert that such a ruling obligated petitioner to rely on the testimony of Dr. Tilelli. Petitioner decided to rely on Dr. Tilelli's testimony. No doubt, that decision was prompted by the recognized need for the testimony of an expert. But the larger truth is that despite months of searching, petitioner was unable to find any other expert who was willing to support her claim of vaccine causation. Ultimately, then, it was petitioner's choice to rely on Dr. Tilelli's testimony and not any directive of the special master.

In addition to the above argument, petitioner attacks the validity of the special master's decision based on the contention that the special master improperly rejected the request for discovery petitioner had raised during the hearing. Specifically, during the hearing, petitioner requested the special master to direct the testing of all lots of the Hepatitis B vaccine to determine whether any contained phenylmethylsulphonyl flouride ("PMSF"), a protease inhibitor initially used in the vaccine manufacturing process, which she maintained had been the subject of a warning included in FDA guidelines relating to the recombinant DNA technology involved in the manufacture of the Hepatitis B vaccine. As the basis for this request, petitioner offered the argument that the failure to have eliminated PMSF from all lots of the Hepatitis B vaccine would explain what she further asserted were reported "incidents of injury" associated with the Hepatitis B vaccine.¹

The special master rejected petitioner's request, and properly so. At its most basic level, discovery is concerned with the search for relevant information among existing evidence. Petitioner's request, however, involved the special master initiating a scientific study to examine the relationship between PMSF and the safety of the Hepatitis B vaccine. Such a request is beyond the authority of the special master to grant. As the special master pointed out, the task of ensuring the safety of

¹ At oral argument, petitioner brought to the court's attention the various documents she had filed on the date of the hearing before the special master to support her assertion identifying PMSF as a likely cause of her son's injuries. It was these documents, or more particularly petitioner's interpretation of them, that petitioner maintains warranted the initiation of the global discovery effort requested of the special master. Although the special master's decision does not discuss these documents, the court sees no neglect of evidence in his not doing so. Without the benefit of expert testimony to guide the fact finder in an understanding of these documents, the claim petitioner makes about them is simply conjecture.

the nation's vaccine program rests not with the courts but rather with the Secretary of the Department of Health and Human Services and the advisory bodies that the Secretary is authorized to appoint, specifically, the National Vaccine Advisory Committee and the Advisory Commission on Childhood Vaccines. See, respectively, 42 U.S.C. §§ 300aa-5, -19.

Turning, finally, to the merits of the case, petitioner asserts that the special master's failure to find that her son had experienced an anaphylactic shock reflects his decision to rely exclusively on expert testimony without any regard for the evidence in the medical records. This criticism is not valid. The special master rejected a diagnosis of anaphylaxis not in spite of the medical records but because of them. As noted above, neither expert found any evidence even remotely suggestive of the claim that petitioner's son had experienced an anaphylactic shock following administration of the Hepatitis B vaccine. On the record before the special master, no other decision would have been reasonable.

CONCLUSION

For the reasons set forth above, the special master's September 3, 2004, decision is affirmed.