In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 03-2820V
Filed: March 29, 2010

HARRY TEMBENIS and GINA TEMBENIS, administrators of the estate of ELIAS TEMBENIS,	)	
Petitioners,	)	TO BE PUBLISHED
v.	)	Post-hearing evidence;
	)	Materiality of proffered evidence;
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	New evidence presented at hearing; Opportunity to rebut
Respondent.	)	

ORDER[1]

This matter comes before the Special Master on Respondent's Motion For Miscellaneous Relief, filed on February 19, 2010. Respondent maintains that Petitioners's expert, Dr. Marcel Kinsbourne, raised an alternative theory of causation ("alternative theory") for the first time at the October 23, 2009 hearing, and that fundamental fairness requires that she be given an opportunity to respond to that theory. Resp't Mot. For Miscellaneous Relief at 1-2 [hereinafter "Respt.'s Mot."].

Respondent requests that the Special Master require Petitioners to file the referenced medical literature regarding the alternative theory mentioned at the hearing. Id. at 1-2. Respondent further requests that Dr. Kinsbourne be required to submit a supplemental expert report addressing the "probative aspects" of that literature, and that Respondent be given an opportunity to respond to Dr. Kinsbourne's report. Id. In the alternative, Respondent requests only the opportunity to respond to the alternative theory proffered by Dr. Kinsbourne. Id.

[1] This Order will be published and posted to the Court of Federal Claims website. As provided by Vaccine Rule 18(b), each party has fourteen days within which to request the redaction "of any information furnished by that party (1) that is trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rule 18(b). In the absence of timely objection, the entire document will be made publicly available.

Petitioners filed an objection to Respondent's motion on February 26, 2010. Petitioners maintain that Respondent was not prejudiced for three reasons. First, Respondent cannot be prejudiced by the lack of medical literature because applicable precedent establishes that medical literature is not required to support an expert's causation theory. Pet'r Resp. To Resp't Mot. For Miscellaneous Relief at 3 [hereinafter "Petr.'s Resp."]. Second, Respondent is not prejudiced because Dr. Kinsbourne's alternative theory is well-known and consistent with the vaccinee's clinical course. Id. Third, Respondent is not prejudiced because it is clear that Respondent's expert will conclude that the alternative theory is not biologically plausible. Id. at 5-6. Petitioners believe that this case is ready for decision, but will submit a post-hearing brief if the Special Master requests. Id. at 6.

For the reasons set forth below, the Special Master **GRANTS** Respondent's motion.

I. Background

The relevant facts are as follows. Petitioners have alleged that vaccinee Elias Tembenis's December 26, 2000 Diphtheria-Tetanus-acellular-Pertussis ("DTaP") vaccination caused a seizure disorder that ultimately led to the vaccinee's death. Amended Pet. at 1. To support their claim, they submitted the expert report of Dr. Kinsbourne and supporting medical literature.[2]

In his expert report, Dr. Kinsbourne opined that:

> It is my opinion that, to a reasonable degree of medical probability, Elias Tembenis' two prolonged seizures within 24 hours of DTaP vaccination were caused or triggered by the vaccination. They led to an incompletely controllable seizure disorder. In the course of this seizure disorder, when Elias was seven years old, he had status epilepticus, which caused his death. Thus Elias' death was a sequela of his vaccine injury.

Pet'r Ex. 29 at 2-4. Dr. Kinsbourne attributed the severity of onset to the cause of the fever, the acellular pertussis vaccine. Id. at 2. The initial literature submitted and referenced by Dr. Kinsbourne discusses the relationship between DTaP and its predecessor, DTP, and the two vaccines' abilities to cause seizures. One reference discusses the pertussis toxin attaching itself to G-protein receptors in the brain.

An entitlement hearing was scheduled for October 23, 2009. Four days before the hearing, Petitioners submitted nine medical articles about the pertussis toxin and how the toxin can cause seizures. Respondent objected to the late filing. Petitioners responded to the objection, stating that:

[2] Petitioners also submitted a supplemental expert report regarding Soto Syndrome from Dr. Kinsbourne, which is not relevant here.

> [T]he petitioners recognize that the respondent will in all probability seek to file additional post-hearing literature. Indeed, in this literature-based forum, special masters typically request **post-hearing** filings of medical literature that supports the parties' relative positions. In these circumstances, the petitioners are not opposed to any such filings in this case, but reserve the right to comment on any article that sets forth new information not previously brought to the attention of Dr. Kinsbourne by Dr. Wiznitzer.

Petr.'s Resp. To Resp't Objection, Oct. 20, 2009, at 5 (emphasis in original). The Special Master did not exclude the nine articles.

At the hearing, Dr. Kinsbourne testified about his opinion as to causation in this case. The first part of Dr. Kinsbourne's direct testimony related to the pertussis toxin, "which is a known neurotoxin and it is known to have epileptogenic properties," and how it can cause epilepsy. Trial Tr. 19:7-12 , Oct. 23, 2009. The remainder of his direct testimony focused on comparing DTP to DTaP and on Soto Syndrome. During direct examination, the following line of questioning revealed Dr. Kinsbourne's alternative theory:

> Q: Could you please explain to the Court what, if any, significance there is to the duration of the seizures?
>
> A: Yes. The -- the duration of the seizures put them in a category called complex febrile seizures.
> . . .
> Now, the literature reflects that complex febrile seizures are more associated with subsequent neurological deficits than simple ones. [Elias's seizure was complex,] [s]o, this seizure was not a harmless event.
> Q: And Doctor, you believe these initial seizures are responsible for the subsequent seizures he experienced from the time of his December vaccination until his death in November?
>
> A: Yes. Well, the seizure initiated a sequence of seizures which turned out to be an epilepsy and one of some -- some magnitude. In fact, yes.

Trial Tr. 36-38.

After the hearing, the Special Master informed the parties that she thought Simon v. Secretary of Department of Health & Human Services, No. 05-941V, 2007 WL 1772062 (Fed. Cl. Spec. Mstr. June 1, 2007), might be determinative of this case. At a status conference on February 12, 2010, Respondent stated that Simon was distinguishable and that the theory in

Simon was not in the record of this case.[3] Respondent requested that the Simon theory be made part of the record, and that she have a chance to respond as to both that theory's validity and why that theory is not applicable in this case. Respondent then filed the motion at issue.

II. Discussion

Special masters have wide discretion in conducting proceedings. Hovey v. Sec'y of Dep't of Health & Human Servs., 38 Fed. Cl. 397, 400 (1997). Such discretion is guided, however, by the requirement that a special master consider all relevant and reliable evidence, consistent with fundamental fairness. Vaccine Rule 8(b)(1); see Hovey, 38 Fed. Cl. at 400.

Special masters "have often been lenient in allowing new items of evidence to be filed just prior to, or even during the course of, evidentiary hearings." Cedillo v. Sec'y of Dep't of Health & Human Servs., No. 98-916, 2009 WL 331968, *62 (Fed. Cl. Spec. Mstr. February 12, 2009), aff'd, 89 Fed. Cl. 158 (2009), appeal docketed, No. 2009-5004 (Fed. Cir. Oct. 7, 2009). When one party files evidence belatedly, the typical remedy is "to give the opposing party additional time, after the hearing, to obtain and file any new evidence to rebut the late-filed item." Id.[4] Because the decision to admit evidence is a discretionary determination which is

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[3] Respondent essentially argues that it is Dr. Kinsbourne's alternative theory, not his original theory, that is similar to the theory in Simon. Because the Special Master stated that she viewed Simon as relevant to this case, Respondent argues that it is a matter of fundamental fairness that she be given a chance to respond to the alternative theory.

In Simon, the vaccinee suffered a complex febrile seizure following a DTaP vaccination. The vaccinee subsequently developed epilepsy, which ultimately led to the vaccinee's death. The experts in that case agreed that vaccines can cause fevers and that fevers can cause seizures. Simon, 2007 WL 1772062 at *4. The experts further agreed that the vaccinee's initial seizure was connected to his subsequent seizures. Id. The special master found that the vaccinee's initial complex seizure caused his epilepsy. Id. Summarizing the rationale for his holding, the special master in Simon stated that "on a probability scale, it is reasonable to conclude that where the vaccine is associated with fever and seizure and the seizure is of a complex nature, in the absence of proof of an alternative cause, it is the vaccine that is legally responsible for a subsequent epilepsy and residual sequelae." Id. at *6.

[4] More fully, the special master in Cedillo stated:

> Further, throughout the history of the Vaccine Act, the special masters, including myself, have often been lenient in allowing new items of evidence to be filed just prior to, or even during the course of, evidentiary hearings. . . . The special masters' reasoning in these situations has been that it is generally better to hear all of the relevant evidence than to decide a case based on incomplete evidence. The remedy for the late filing in such situations has been to give the opposing party additional time, after the hearing, to obtain and file any new evidence to rebut the late-filed item. On some occasions this practice has resulted in the need for a second evidentiary hearing in the case, but the special master on those occasions generally has been willing to conduct such a second

usually made without a written ruling, the case law in this area is relatively sparse. See id. at *62 n.100. However, two Court of Federal Claims cases apply to the motion now before the Special Master.

In Kaminski v. Secretary of Department of Health & Human Services, 39 Fed. Cl. 253 (1997), the Court of Federal Claims reversed the special master's entitlement decision for the petitioner because the special master did not permit the respondent to present the testimony of a witness respondent first learned of at the hearing. In reaching its decision, the court stated that the special master's evidentiary ruling could be invalidated if it likely had a material effect on the outcome. Id. at 258. The court vacated and remanded, finding that exclusion of the witness's testimony "necessarily deprived respondent of the opportunity to challenge the fundamental factual assertions on which the case was based." Id. at 259.

In Vant Erve v. Secretary of Department of Health & Human Services, 39 Fed. Cl. 607 (1997), aff'd after remand, 232 F.3d 914 (Fed. Cir. 2000) (unpublished table decision), the special master used a four-part test to decide whether to reopen the record after he issued an entitlement decision in favor of the petitioners. The special master denied the respondent's motion to reopen the entitlement issue when new evidence came to light during the damages phase of the proceeding. Vant Erve, 39 Fed. Cl. at 610. The four factors the special master considered were: "(1) the nature of the proffered new evidence; (2) the prejudice to the parties; (3) the length of the delay; and (4) the reason for the delay." Id. at 610-11. The Court of Federal Claims reversed the special master, but approved the four-factor test. Id. at 611.[5] The Federal Circuit held that the Court of Federal Claims "properly concluded that [the special master] abuse[d] [his] discretion because the new 'information offered was highly probative; the delay, while extensive[,] was not prejudicial to petitioners; and the delay was not the fault of the respondent.'" Vant Erve, 232 F.3d 914 (quoting and upholding the Court of Federal Claims's decision).

In this case, no entitlement decision has issued and the record is not clearly "closed." Although the facts in this case are more like those in Kaminski than Vant Erve, the four-factor Vant Erve test is consistent with the analysis in Kaminski, and it provides a useful framework for evaluating the issues relevant to admitting evidence post-hearing.[6] In light of the traditional

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> hearing when necessary, in the interest of reaching a decision based upon all of the relevant evidence.

Cedillo, 2009 WL 331968, *62.

[5] Vant Erve cites to several multi-factorial analyses in decisions about other discretionary evidentiary issues, and notes that the factors of materiality and effect on outcome seem to be a common part of the analysis. 39 Fed. Cl. at 610-13.

[6] The analysis in Kaminski focuses on the materiality of the excluded evidence, but does not discuss any countervailing factors. However, the court seems to recognize that other factors could be

leniency in admitting evidence and the requirement to consider all relevant evidence, a special master should admit post-hearing evidence with a lesser showing than if the record were closed. Here, weighing the Vant Erve factors makes it clear that Respondent's motion should be granted.

A. The Nature of Petitioners' Alternative Theory

The "nature of the proffered new evidence" refers to the extent to which the evidence is "relevant and affective of outcome." Vant Erve, 39 Fed. Cl. at 612. The materiality of the evidence to the outcome is the most important factor; when the proffered evidence is highly probative or outcome determinative, the importance of the other factors is diminished. Id. If the proffered evidence likely would be outcome determinative, that evidence ordinarily should be admitted. See Kaminski, 39 Fed. Cl. at 258-59.

This factor weighs in Respondent's favor because it is material to the outcome of this case. Respondent requests three things: (1) the medical literature mentioned by Dr. Kinsbourne, (2) a supplemental expert report, and (3) an opportunity to respond to the alternative theory and to any literature or expert report. If the special master does not credit Petitioners' original theory of causation, Petitioners cannot prevail without showing the plausibility of the alternative theory. Additionally, without the alternative theory, Petitioners cannot establish that Simon is persuasive to this case. Consequently, each element of relief goes directly to a fundamental aspect of the case.

The medical literature is relevant to establishing the plausibility of the alternative theory. Unlike Simon, Respondent's expert in this case has not conceded the plausibility of the theory that an initial complex febrile seizure alone could lead to epilepsy. Thus, the alternative theory is still a contested issue. Although medical literature is not required to support an expert's opinion, it does go to the weight to be given to a contested opinion. In addition, Dr. Kinsbourne stated that he relied on the medical literature in forming his opinion, thereby placing the medical literature in issue.

The supplemental expert report is relevant for the same reason as the medical literature. The record must contain sufficient evidence to allow a special master to make factual findings and "articulate a reasoned basis for the judgment entered." Kaminski, 39 Fed. Cl. at 256. The report would allow the Special Master to weigh the plausibility of the contested alternative theory.

Further, Respondent has not had a full opportunity to challenge the alternative theory. At

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relevant to the decision whether to admit evidence. The court recognizes delay as a potential concern by stating that "[t]he special master's decision to disallow Ms. Gonzales' testimony, not for its untimeliness (a concern apparently never at issue), but for its expected failure to offer [relevant] facts . . . runs counter to the [traditional] policy of evidentiary flexibility and informality." Kaminski, 39 Fed. Cl. at 258 (emphasis added).

the hearing, Respondent was able to question her expert as to the plausibility of the alternative theory, but did so with no prior notice of the theory. Respondent also was unable to question the basis of Dr. Kinsbourne's opinion or to present counter-evidence. Even if, as Petitioners argue, Respondent's expert will deny the plausibility of the alternative theory, a response would contain the specific factors on which Respondent's expert relies. Allowing Respondent to submit evidence on the alternative theory would provide the special master with a more complete record to consider.

In opposition to Respondent's motion, Petitioners allege that the vaccinee's clinical course is consistent with the alternative theory. Petr.'s Resp. at 3. Assuming this is correct, it would not diminish Respondent's right to an opportunity to challenge a fundamental element of Petitioners' case. See Kaminski, 39 Fed. Cl. at 259.

B. Granting the Motion Would Not Prejudice Petitioners.

A party is prejudiced if its ability to prove its case is harmed. A party suffers prejudice if, for example, its ability to call a witness is harmed, evidence has been destroyed, or tests cannot be performed or duplicated. Vant Erve, 39 Fed. Cl. at 614. A party likely suffers prejudice if, shortly before or during trial, a party raises a new legal theory that requires additional research and analysis. See id.

None of these factors prejudices Petitioners in this case. Requiring Petitioners to produce medical articles does not affect Petitioners' ability to prove their case. The delay and expense likely would not be great, as Dr. Kinsbourne should be able to locate the literature he already referenced without great effort or expense. This is especially true if the literature describes a "well-accepted principle," as asserted by Petitioners. Petr.'s Resp. at 3 n.3. Petitioners already were prepared to submit post-hearing medical literature and an expert report in response to evidence revealed during the hearing. Petr.'s Resp. To Resp't Objection at 5 (stating that Petitioners "reserve the right to comment on any article that sets forth new information not previously brought to the attention of Dr. Kinsbourne by Dr. Wiznitzer"). Petitioners would not be prejudiced by submitting the referenced medical literature.

Whether Petitioners would suffer any prejudice by being required to submit a supplemental expert report is a closer question. The expense of paying Dr. Kinsbourne to prepare another expert report is greater than that for having him supply the citations to the literature he referenced. It would also take more time to have Dr. Kinsbourne prepare a report. However, given that it seems that Petitioners already contemplated commenting on new medical literature—and actually reserved the right to do so—it does not seem that the expense and delay are undue or so great as to prejudice Petitioners. And although Petitioners are free to present their case in the manner of their choosing, Petitioners must make a prima facie case of entitlement. Therefore requiring submission of a supplemental expert report would not cause prejudice.

Moreover, Respondent will be prejudiced without an opportunity to respond to the alternative theory. Having had no pre-hearing notice of the alternative theory, Respondent has not had the chance to contest it. The Special Master must consider all relevant and reliable evidence consistent with fundamental fairness. Vaccine Rule 8(b)(1). Petitioners' alternative theory is material to the outcome of this case; fundamental fairness and the Vaccine Rules require that Respondent have an opportunity to present evidence and contest that theory. See id.; Kaminski, 39 Fed. Cl. at 259.

C. The Length of the Delay Was Reasonable And Was Caused By Petitioners.

"When there is no final judgment, the real inquires should be whether the delay has prejudiced the nonmoving party and the identity of the party that caused the delay." Vant Erve, 39 Fed. Cl. at 614. Again, this factor weighs in favor of granting Respondent's motion.

Petitioners' development of the alternative theory was insufficient before the hearing to place Respondent on notice that she would be required to defend the claim on that ground.[7] Petitioners' strongest argument that the alternative theory was revealed before the hearing is an excerpt from Dr. Kinsbourne's expert report. Dr. Kinsbourne summarizes that "[i]t is my opinion that . . . Elias Tembenis' two prolonged seizures within 24 hours of DTaP vaccination were caused or triggered by the vaccination. They led to an incompletely controllable seizure disorder." Pet'r Ex. 29 at 2-4. This passage appears to say that the initial seizures led to epilepsy. However, the rest of Dr. Kinsbourne's report and the submitted medical literature all focus on the pertussis toxin and its ability to cause seizures. Read in the context of the report and filings, the above excerpt arguably refers to the original theory, not the alternative theory.

It cannot be viewed as Respondent's fault that she did not present evidence on the alternative theory before now. None of Petitioners' filings clearly sets forth the alternative theory; the filings focused on the pertussis toxin's epileptogenic properties. Respondent did not have clear notice until the hearing that the alternative theory would be an issue. At the post-hearing status conference, Respondent stated her intent to contest the alternative theory. Given the lack of pre-hearing notice, such a timing cannot be considered undue delay.

[7] In the Amended Petition, Petitioners cite two cases that were decided on a theory the same as or similar to the alternative theory. Simon, 2007 WL 1772062; Paulmino v. Sec'y of Dep't of Health & Human Servs., No. 03-2190V, Entitlement Ruling on Remand (Fed. Cl. Spec. Mstr. Mar. 18, 2006). Petitioners never developed the theory of those cases and did not cite those cases in their Pre-Hearing Brief. Petitioners' reliance on those cases was limited to the propositions that the DTaP vaccine can cause seizures, (Amended Pet. at 22), and that an onset within 12-24 hours after vaccination is acceptable, (Id. at 24-25).

III. Conclusion

The balance of equities favors admitting the evidence requested by Respondent. Therefore, the undersigned **GRANTS** Respondent's Motion For Relief. Accordingly,

(1) **on or before Friday, April 30, 2010,** Petitioner shall file the medical literature referenced at hearing by Dr. Kinsbourne, and a supplemental expert report addressing the theory that an initial complex seizure can cause epilepsy; and

(2) **on or before Tuesday, June 1, 2010,** Respondent shall file any responsive evidence.

Any questions regarding this Order shall be directed to Tom Broughan, at (202) 357-6353.

IT IS SO ORDERED.

s/ Dee Lord
Dee Lord
Special Master