In the United States Court of Federal Claims

No. 03-87 V (Filed August 8, 2005)

Leland F. Dempsey, Kansas City, Missouri, for petitioner.

James A. Reistrup, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for respondent, with whom where Peter D. Keisler, Assistant Attorney General, Timothy P. Garren, Director, Gabrielle M. Fielding, Assistant Director, and Catherine E. Reeves, Senior Trial Counsel.

OPINION

Merow, Senior Judge

This National Childhood Vaccine Injury Act matter is before the court on Petitioner's Motion for Review of the Opinion, filed May 13, 2005, in this case by the chief special master. The opinion in question denied relief concluding that petitioner had failed to satisfy her burden of proof that the measles-mumps-rubella ("MMR") vaccination administered to her son, Mario Arturo Rodriguez ("Mario") on January 25, 2000, caused the transverse myelitis/quadriparesis ("TM") he manifested shortly thereafter.

Upon review of the record evidence together with the briefs of the parties and the recent ruling in *Althen v. Sec'y of Health and Human Servs.*, __ F.3d __ (Fed. Cir. No. 04-5146, July 29, 2005) it is concluded that petitioner satisfied her burden of proof and is entitled to relief.

TM is not an injury listed on the Vaccine Injury Table. 42 U.S.C. § 300aa-14(a). Therefore petitioner must prove by a preponderance of the evidence that the MMR vaccination caused Mario's TM. 42 U.S.C. § 300aa-13(a)(1), -11(c)(1)(C)(ii)(I). That is, as ruled in *Althen* at slip op. p. 5, 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 vaccination and injury. If Althen satisfies this burden, she is 'entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.' Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994) (alteration in original) (citation omitted).

With respect to the first "medical theory" element the expert testimony in this matter differed, but the chief special master determined (Chief Special Master Opinion "CSMO" p. 15) that,

Dr. Sladky's [respondent's expert] arguments aside, there is a wealth of persuasive support from IOM [Institute of Medicine of the National Academy of Sciences] <u>Huston</u> [*Huston v. Secretary of HHS*, 39 Fed. Cl. 632 (1997)] and <u>Harris</u> [*Harris v. Secretary of HHS*, No. 93-333 V, 2001 WL 530644] for the proposition that the MMR vaccine can cause TM. Accordingly, it is so found here.

The record evidence supports this finding.

As for the second "logical sequence" element and the third "proximate temporal relationship" element the record evidence together with findings by the chief special master demonstrate that the requisite burden of proof has been satisfied. The chief

special master, in reliance on *Harris, supra*, determined that the petitioner was required to demonstrate that the onset of Mario's TM occurred between one and four weeks after vaccination and that the TM was monophasic in course as contrasted with "bi" or "multi-phasic" TM, where there is a relapse and remission of the illness. The onset of Mario's TM occurred eleven days after vaccination, and the experts agreed that the TM was monophasic. CSMO, p. 16.

The chief special master also determined that the petitioner has the burden of demonstrating that no better explanation for the TM exists. *Id.* In *Pafford v. Secy. of the Dep't of Health and Human Servs.*, 64 Fed. Cl. 19, 35 (2005) it is concluded that this requirement does not mean "that the petitioner must discount every potential cause that exists within the entire realm of possibility, or 'prove that an infinite number of potential causes were not at work causing the injuries suffered,' *Wagner*, Fed. Cl. at 139, but rather the petitioner must confront the range of potential causes that are evidenced in the record." In the instant case respondent's expert offered no alternative explanation for the cause of Mario's TM other than coincidence. CSMO, p. 17. The chief special master found at p. 18 of his opinion, that, "A review of the record and the experts' testimony shows that 'no better explanation for the TM exists' in the context of *Pafford's* legal guidance."

Accordingly, with the findings discussed above, it is concluded that petitioner satisfied the required burden of proof as set forth in *Althen*. The record proof establishes a medical theory causally connecting the MMR vaccination with Mario's TM. A logical sequence of cause and effect has been established showing, by a preponderance of the evidence, that the vaccination was the reason for Mario's TM. Proximate temporal relationship between vaccination and injury is established.

¹/ The chief special master, at pp. 16-17, 19 of his opinion, does question the level of certainty expressed by petitioner's expert, Dr. Marcel Kinsbourne, with respect to MMR causation of Mario's TM. However a review of the somewhat confusing transcript exchange (Kinsbourne Tr. 51) shows his testimony was that he was reasonably certain to a level of medical certainty ". . . that the MMR did do it." Dr. Kinsbourne's testimony together with his expert report (Petitioner's Exh. 18) fully satisfies the requirement for medical opinion supporting the MMR vaccination as the relevant cause for Mario's TM. 42 U.S.C. 300 aa-13(a)(1); *Althen* at slip op. pp. 7-8. As the chief special master found (slip op. pp. 17-18) with respect to MMR vaccination causation for Mario's TM "no better explanation for the TM exists." *See Knudsen v. Sec'y of Health and Human Servs.*, *supra.* at pp. 548-49.

Respondent has not submitted any evidence that Mario's TM was caused by factors unrelated to the vaccine. Petitioner is thus entitled to relief under the Vaccine Act.

Notwithstanding, the chief special master denied relief on the basis that "there is no direct evidence linking Mario's TM to the MMR vaccination" CSMO, p. 19. The absence of an organism-specific antibody index ("OSAI") test which, had one been timely conducted, could have provided direct evidence of vaccine linkage to the central nervous system and therefore verified the cause for Mario's TM, is the basis for the determination that the burden of proof was not satisfied. *Id*.

However, similar to the special master's added requirement for medical literature which was rejected in *Althen* at Slip. Op. p. 8, the added requirement for an OSAI test to provide "direct" evidence also "prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id.* Deleting the erroneously added OSAI "direct evidence" requirement, the chief special master's findings are otherwise sufficient to establish petitioner's entitlement to recovery under the applicable burden of proof standard.

For the reasons discussed above, it is **ORDERED**:

- (1) The determination of the chief special master that petitioner is not entitled to compensation under the Vaccine Act is **REVERSED** and the matter is **REMANDED** for a compensation determination;
- (2) Petitioner's Motion for Leave for Oral Argument, filed July 18, 2005, and Respondent's Motion to Strike, filed July 22, 2005 are **DENIED** as moot.

James F. Merow Senior Judge