

## OFFICE OF SPECIAL MASTERS

(Filed: July 29, 2005)

PATRICIA ANN D. WALTHER, D.V.M.,	)	
	)	
Petitioner,	)	
	)	
v.	)	No. 00-0426V
	)	DO NOT PUBLISH
SECRETARY OF	)	
HEALTH AND HUMAN SERVICES,	)	
	)	
Respondent.	)	
	)	

### DECISION<sup>1</sup>

Petitioner, Patricia Ann D. Walther, D.V.M. (Dr. Walther), seeks compensation under the National Vaccine Injury Compensation Program (Program).<sup>2</sup> Dr. Walther's medical records reflect that since late 1997, a number of physicians have concluded that Dr. Walther suffers "[p]ost vaccinal encephalomyelitis." Petitioner's exhibit (Pet. ex.) 41 at 83-86; *see also* Pet. ex. 18 at 1-2; Pet. ex. 40; Pet. ex. 49. Although Dr. Walther received an array of vaccinations while serving on active duty as a Captain in the United States Army during Summer 1997, *see* Pet. ex. 3 at 4-5; Pet. ex. 5 at 1,<sup>3</sup> Dr. Walther attributes her condition to diphtheria-tetanus (DT or Td) vaccine. *See* Petitioner's Pretrial Memorandum (P. Memo), filed May 11, 2005, at 3.

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<sup>1</sup> As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" will be available to the public. *Id.*

<sup>2</sup> The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

<sup>3</sup> The special master does not possess jurisdiction to consider claims related to vaccines that are not listed on the Vaccine Injury Table (Table), 42 C.F.R. § 100.3(a). *See, e.g., Charette v. Secretary of HHS*, 33 Fed. Cl. 488 (1995). Most of the vaccines that Dr. Walther received in Summer 1997 are not listed on the Table.

Respondent denies that Dr. Walther is entitled to Program compensation. Respondent presents three defenses. First, respondent disputes that Dr. Walther exhibits an encephalomyelitis. *See* Respondent's Witness List and Prehearing Memorandum (R. Memo), filed May 9, 2005, at 7. Second, respondent contends that Dr. Walther has not adduced sufficient evidence demonstrating that DT vaccine causes encephalomyelitis. *Id.* Third, respondent asserts that Dr. Walther "has not adequately eliminated the other" vaccines that she received in Summer 1997 as "causative agents" for her condition. R. Memo at 10.

The special master convened a hearing. Vera Byers, M.D., Ph.D. (Dr. Byers),<sup>4</sup> testified during Dr. Walther's case-in-chief. Arthur Safran, M.D. (Dr. Safran),<sup>5</sup> and Gregory Shoukimas, M.D., Ph.D. (Dr. Shoukimas),<sup>6</sup> testified during respondent's rebuttal case. Marcel Kinsbourne, M.D. (Dr. Kinsbourne),<sup>7</sup> and Margaret Montana, M.D. (Dr. Montana),<sup>8</sup> testified during Dr. Walther's surrebuttal case.

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<sup>4</sup> Dr. Byers received her medical degree from the University of California at San Francisco. Pet. ex. 48 at 5. She is certified by the American Board of Internal Medicine. *Id.* at 6. She completed a Fellowship in Clinical Immunology at the Department of Medicine, University of California at San Francisco. *Id.* at 5. She is a Fellow of the American Academy of Allergy and a member of the American Association of Immunologists. *Id.* at 6.

<sup>5</sup> Dr. Safran received his medical degree from New York University. Respondent's exhibit (R. ex.) C at 1. He is certified by the American Board of Internal Medicine and by the American Board of Psychiatry and Neurology. *Id.* He is a Fellow of the American Academy of Neurology. *Id.*

<sup>6</sup> Dr. Shoukimas received his medical degree from Tufts University. R. ex. F at 1. He is certified by the American Board of Radiology. *Id.* He is a senior member of the American Society of Neuroradiology. *Id.* at 2.

<sup>7</sup> Dr. Kinsbourne received his medical degree from Oxford University in England. Pet. ex. 54 at 1. He is a Member of the Royal College of Physicians. *Id.* In addition, he is certified by the American Board of Pediatrics. *Id.* He belongs to the American Neurological Association and to the Child Neurology Society. *Id.* at 4.

<sup>8</sup> Dr. Montana received her medical degree from Washington University, St. Louis. Pet. ex. 46 at 1. She is certified by the American Board of Radiology. *Id.* at 2. She is a member of the American College of Radiology. *Id.* at 5.

## THE LEGAL STANDARD

Dr. Walther acknowledges that she pursues necessarily an actual causation theory. *See* P. Memo at 6. Thus, to prevail, Dr. Walther must demonstrate by the preponderance of the evidence that (1) “but for” the administration of a July 31, 1997 DT vaccination, she would not have been injured, and (2) the July 31, 1997 DT vaccination “was a substantial factor in bringing about” her injury. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).<sup>9</sup> The United States Court of Appeals for the Federal Circuit (Federal Circuit) has described Dr. Walther’s burden as “heavy.” *Whitcotton v. Secretary of HHS*, 81 F.3d 1099, 1102 (Fed. Cir. 1996). The mere temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove legal cause. *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992). Rather, Dr. Walther must present “a medical theory,” supported by “[a] reliable medical or scientific explanation,” establishing “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” *Id.* at 1148; *see also Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994)(citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993)). “The analysis undergirding” the medical or scientific explanation must “fall within the range of accepted standards governing” medical or scientific research. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995). Dr. Walther’s medical or scientific explanation need not be “medically or scientifically certain.” *Knudsen*, 35 F.3d at 549. But, Dr. Walther’s medical or scientific explanation must be “logical” and “probable,” given “the circumstances of the particular case.” *Id.* at 548-49.

According to the Federal Circuit, “causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the [injured party] without detailed medical and scientific exposition on the biological mechanisms.” *Knudsen*, 35 F.3d at 549. However, in most actual causation cases in the Program, petitioners are not able to adduce epidemiological evidence regarding a vaccination and an injury. As a result, many special masters have struggled over the years to articulate the proper method of analyzing actual causation cases that lack epidemiological evidence regarding a vaccination and an injury. *See e.g., Stevens v. Secretary of HHS*, No. 99-0594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001); *see also Pafford v. Secretary of HHS*, 64 Fed. Cl. 19 (2005), *appeal docketed* No. 05-5105 (Fed. Cir. Apr. 12, 2005). A judge of the United States Court of Federal Claims has advanced recently a “rule of reason.” *Pafford*, 64 Fed. Cl. at 31. The judge posits that in appropriate circumstances, proof of biologic plausibility between a vaccine and an injury; proof that an injury occurred within a medically-

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<sup>9</sup> The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See, e.g., Thornton v. Secretary of HHS*, 35 Fed. Cl. 432, 440 (1996); *see also In re Winship*, 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring), *quoting* F. James, CIVIL PROCEDURE 250-51 (1965). Mere conjecture or speculation will not meet the preponderance of the evidence standard. *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984); *Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612 (1995), *aff’d*, 73 F.3d 381 (Fed. Cir. 1995).

acceptable time period following vaccination; and proof eliminating other potential causes for the injury may satisfy a petitioner's burden. *See id.*

## DISCUSSION

Congress prohibited special masters from awarding compensation “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 300aa-13(a). Numerous cases construe § 300aa-13(a). The cases reason uniformly that “special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone.” *Raley v. Secretary of HHS*, No. 91-0732V, 1998 WL 681467, at \*9 (Fed. Cl. Spec. Mstr. Aug. 31, 1998); *see also Camery v. Secretary of HHS*, 42 Fed. Cl. 381, 389 (1998). The special master has canvassed thoroughly the record. He determines that Dr. Walther's medical records alone do not reflect an independent basis for him to conclude more likely than not that Dr. Walther's July 31, 1997 DT vaccination caused actually Dr. Walther's condition. Indeed, in her records, Dr. Walther suggests that “multiple vaccinations coupled with immunosuppressives” sparked her condition. Pet. ex. 34 at 1; *see also* Pet. ex. 35 at 11 (Dr. Walther “plans to consult w/ Neurologist at Mayo Clinic this Summer to attempt to more specifically clarify the basis for her current condition, and, in particular, whether the Rabies vaccine is the most likely culprit.”) Thus, Dr. Walther depends predominantly upon Dr. Byers's opinion to establish her claim.

The special master engages usually in a comprehensive, critical, intellectual analysis of the facts, the medical evidence and the medical testimony under the actual causation standard. *See, e.g., Malloy v. Secretary of HHS*, No. 99-0193V, 2003 WL 22424968 (Fed. Cl. Spec. Mstr. Aug. 6, 2003). However, the special master harbors significant concerns regarding the quality and the substance of Dr. Byers's testimony. As a consequence, the special master rejects Dr. Byers's opinion. The special master explains briefly his decision.

Dr. Byers is a seemingly engaging, delightful person. But, in her role as an expert witness in this proceeding, Dr. Byers was ill-prepared. Dr. Byers stated numerous times that she did not remember aspects of her report and of the medical literature that she cited in her report. *See, e.g.,* Transcript (Tr.), filed June 22, 2005, at 69 (Dr. Byers could not recall a detail of a case report); 82 (Dr. Byers “forgot” whether a study involved the pertussis vaccine); 88-91 (Dr. Byers could not “comment” on details of a study that she cited); 97 (Dr. Byers misidentified the type of animal model for experimental allergic encephalomyelitis); 103-05 (Although Dr. Byers asserted that a concept called “epitope spreading” has been shown “in response to a vaccination,” Dr. Byers did “not know what the organism was”); 110-14 (Dr. Byers could not recall fundamental details of a medical study). The special master appreciates that Dr. Byers drafted her report some time before the hearing in this case. Nevertheless, the special master expects an expert witness who anticipates payment for participating in a case to be fully conversant with the expert's report and with the medical literature that the expert cited in the report at the time of hearing.

Likewise, the special master is not satisfied that Dr. Byers explained appropriately the relevance of the National Childhood Encephalopathy Study (NCES)<sup>10</sup> to her opinion that DT vaccine causes encephalomyelitis. *See* Tr. at 108-115. According to Dr. Byers, the NCES contains “a concise description of the lines of evidence indicating that tetanus” vaccine has “a causal role in acute encephalitis.” Tr. at 114. The special master has entertained in two cases medical expert testimony regarding the NCES. *See generally* *Eiss v. Secretary of HHS*, No. 97-0529V, Decision on Entitlement and Damages (Fed. Cl. Spec. Mstr. Mar. 9, 2005); *Moberly v. Secretary of HHS*, No. 98-0910V, Decision (Fed. Cl. Spec. Mstr. June 30, 2005). The special master understands that the NCES is “one study, among others” developed in Great Britain during 1976 to address “widespread public and professional concern over the safety of *pertussis* immunization.” NCES at 80 (emphasis added). The special master understands also that NCES authors found that “significantly more cases than controls were immunized with D[iphtheria]T[etanus]P[ertussis] within the 72 hours prior to” the onset of serious acute neurologic illnesses. NCES at 118; *see also* NCES at 142. The special master understands further that NCES found “no statistically significant association (at the 5 per cent level) between” the onset of serious acute neurological illnesses “and DT immunization in the cases when compared with controls.” NCES at 118. Thus, from the special master’s lay perspective, the NCES is completely inapposite to Dr. Byers’s opinion.

Dr. Byers indicated that any vaccine “can cause a range of demyelinating conditions.” Pet. ex. 47 at 5; *see also* Tr. at 116. Indeed, Dr. Byers conceded that other vaccines that Dr. Walther received concurrently with the DT vaccination on July 31, 1997, were “candidates for the cause of” Dr. Walther’s condition. Pet. ex. 47 at 7; *see also id.* at 3-4, 9; Tr. at 117, 122. Dr. Byers stated essentially that she implicated DT vaccine as the cause of Dr. Walther’s condition simply because of the greater number of case reports associating a component of DT vaccine with demyelinating disorders. Tr. at 122; *see also* Pet. ex. 47 at 7-9. In the special master’s view, Dr. Byers’s attempt to differentiate Dr. Walther’s DT vaccination--the only Table vaccine that Dr. Walther received--from Dr. Walther’s other vaccinations as the cause for Dr. Walther’s condition based solely upon a greater number of case reports associating a component of DT vaccine with demyelinating disorders expresses in no way a viable proposition that Dr. Walther’s DT vaccination, rather than one of Dr. Walther’s other vaccinations, caused more likely than not Dr. Walther’s condition. Therefore, the special master determines that Dr. Byers’s premise is not persuasive. Thus, the special master decides that the evidence does not demonstrate affirmatively that DT vaccine caused actually Dr. Walther’s condition. *See Grant*, 956 F.2d at 1147-8 (quoting H.R. REP. NO. 908, 99th Cong., 2nd Sess., pt. 1, at 15 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6356)(emphasis omitted); *see also Munn v. Secretary of HHS*, 970 F.2d 863, 865 (Fed. Cir. 1992) (Petitioner “must prove by the preponderance of the evidence that the vaccine, *and not some other agent*, was the actual cause of the injury.”)(emphasis added).

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<sup>10</sup> *See* R. Alderslade, *et al.*, *The National Childhood Encephalopathy Study: A Report on 1000 Cases of Serious Neurological Disorders in Infants and Young Children from the NCES Research Team*, in UNITED KINGDOM DEPARTMENT OF HEALTH AND SOCIAL SECURITY, WHOOPING COUGH: REPORTS FROM THE COMMITTEE ON SAFETY OF MEDICINES AND THE JOINT COMMITTEE ON VACCINE AND IMMUNIZATION 79-184 (Her Majesty’s Stationery Office 1981).

The special master recognizes certainly that one of his colleagues has ruled that a Td vaccine caused actually a child's encephalomyelitis, *see Johnson v. Secretary of HHS*, No. 99-0219V, 2000 WL 1141582 (Fed. Cl. Spec. Mstr. July 27, 2000), and another of his colleagues has ruled that a diphtheria-tetanus-acellular pertussis (DTaP) vaccine caused actually a child's encephalomyelitis. *See Kuperus v. Secretary of HHS*, No. 01-0060V, 2003 WL 22912885 (Fed. Cl. Spec. Mstr. Oct. 23, 2003). However, each case is distinguished easily on the facts. In each case, the child received just one vaccination preceding the onset of encephalomyelitis. *See Johnson v. Secretary of HHS*, No. 99-0219V, 2000 WL 1141582, at \*1; *Kuperus v. Secretary of HHS*, No. 01-0060V, 2003 WL 22912885, at \*2. And, in each case, the special master determined that the child's single vaccination represented the only immunologic challenge preceding the onset of encephalomyelitis. *See Johnson v. Secretary of HHS*, No. 99-0219V, 2000 WL 1141582, at \*10; *Kuperus v. Secretary of HHS*, No. 01-0060V, 2003 WL 22912885, at \*10-11. In contrast, Dr. Walther received concurrently one Table vaccine and many non-Table vaccines, every one of which represented a biologically-plausible explanation for her condition.

### CONCLUSION

The special master is exceedingly sympathetic to Dr. Walther's circumstances. Nevertheless, on the record before him, the special master rules that Dr. Walther is not entitled to Program compensation. Therefore, in the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

The clerk of court shall send Dr. Walther's copy of this decision to Dr. Walther by overnight express delivery.

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John F. Edwards  
Special Master