

**OFFICE OF SPECIAL MASTERS**

(Filed: February 28, 2006)

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| TERESA MOBERLY,                            | ) |              |
| as mother and next friend of her daughter, | ) |              |
| MOLLY MOBERLY,                             | ) |              |
|  | ) |              |
| Petitioner,                                | ) |              |
|  | ) |              |
| v.   | ) | No. 98-0910V |
|  | ) | PUBLISH      |
| SECRETARY OF                               | ) |              |
| HEALTH AND HUMAN SERVICES,                 | ) |              |
|  | ) |              |
| Respondent.                                | ) |              |

**DECISION ON REMAND<sup>1</sup>**

Petitioner, Teresa Moberly (Ms. Moberly), as next friend of her daughter, Molly Moberly (Molly), seeks compensation under the National Vaccine Injury Compensation Program (Program).<sup>2</sup> Molly suffered two brief seizures within 48 hours after she received a diphtheria-pertussis-tetanus (DPT) vaccination on September 17, 1996. *See, e.g.*, Petitioner’s exhibit (Pet. ex.) 5 at 1; Pet. ex. 9 at 3; Pet. ex. 12 at 14; Pet. ex. 16 at 1; Pet. ex. 17 at 10. The seizures did not require immediate medical attention. *See, e.g.*, Pet. ex. 12 at 14. Molly developed eventually an intractable seizure disorder accompanied by developmental delay. *See, e.g.*, Pet. ex. 44 at 34-35. Ms. Moberly attributes Molly’s current condition to Molly’s September 17, 1996 DTP vaccination. Petition (Pet.) at 1.<sup>3</sup>

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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> Ms. Moberly concedes that Molly’s condition does not qualify for the statutory  
(continued...)

The special master convened a hearing limited to medical issues. *See* Transcript (Tr.), filed April 2, 2003. Marcel Kinsbourne, M.D. (Dr. Kinsbourne),<sup>4</sup> testified for Ms. Moberly. Dr. Kinsbourne opined that Molly's September 17, 1996 DPT vaccination "caused" Molly's current condition, encompassing "epilepsy and impair[ed] mental function." Tr. at 20-21; *see also* Tr. at 9. Dr. Kinsbourne relied predominantly upon the National Childhood Encephalopathy Study (NCES) published in Great Britain in 1981.<sup>5</sup> According to Dr. Kinsbourne, the NCES is really "the only satisfactory epidemiological study" regarding DPT and neurological injury. Tr. at 11. Dr. Kinsbourne cited particularly an exception to the general rule that NCES authors used to determine the date of onset of the qualifying neurological illness for each case child accepted into the NCES. *See* Tr. at 12-17, 32-39, 42-43. In Dr. Kinsbourne's view, the presentation of Molly's condition "would have met inclusion criteria" of the NCES under the exception to the general rule that NCES authors used to determine the date of onset of the qualifying neurological illness for each case child accepted into the NCES. Tr. at 11-17. Dr. Kinsbourne asserted that because the NCES exposed "a positive outcome" between DPT and certain neurological injuries within a certain time frame following vaccination, the NCES "would validate" a correlation between Molly's September 17, 1996 DPT vaccination and Molly's current condition. Tr. at 11-13.

The special master considered exhaustively Dr. Kinsbourne's testimony about the NCES and about the exception to the general rule that NCES authors used to determine the date of onset of the qualifying neurological illness for each case child accepted into the NCES. *See Moberly v. Secretary of HHS*, No. 98-0910V, 2005 WL 1793416 (Fed. Cl. Spec. Mstr. June 30, 2005). The special master noted that Dr. Kinsbourne "expressed readily" that the NCES exception "'is not clear.'" *Moberly*

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<sup>3</sup>(...continued)

presumption of causation afforded by § 300aa-11(c)(1)(C)(i); § 300aa-13(a)(1)(A); the Vaccine Injury Table (Table), 42 C.F.R. § 100.3(a)(II) (2004); and the qualifications and aids to interpretation (QAI), 42 C.F.R. § 100.3(b)(2) (2004), that apply to the Table governing the petition. *See, e.g.*, Petitioner's Prehearing Memorandum (P. Prehearing Memo) at 1. Thus, Ms. Moberly acknowledges that she must prove that Molly's September 17, 1996 DPT vaccination caused actually Molly's condition. *See* P. Prehearing Memo at 1.

<sup>4</sup> Dr. Kinsbourne received his medical degree from Oxford University in England. Pet. ex. 33A 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. He holds a variety of academic and hospital appointments. *Id.* at 1. He is a full professor at New School University in New York, where he teaches "brain organization." Tr. at 8.

<sup>5</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).

*v. Secretary of HHS*, No. 98-0910V, 2005 WL 1793416, at \*26, citing Tr. at 13. In addition, the special master noted that Dr. Kinsbourne “acknowledged the ‘subjective’ character of the ‘criterion’ in NCES ‘text’ containing the exception.” *Id.*, citing Tr. at 17. Further, the special master noted that Dr. Kinsbourne “rejected initially specific language in the exception.” *Id.* The special master deemed ultimately Dr. Kinsbourne’s testimony about “the exception in the NCES” to be “contradictory and confusing.” *Id.* As a consequence, the special master held that the NCES exception “is not a suitable basis on which to ground an actual causation claim.” *Id.*

Likewise, the special master considered exhaustively other evidence regarding causation that Ms. Moberly adduced. *See Moberly v. Secretary of HHS*, No. 98-0910V, 2005 WL 1793416. The special master found that Dr. Kinsbourne had not “expressed credibly and rationally an opinion using the disparate elements of the evidence.” *Moberly v. Secretary of HHS*, No. 98-0910V, 2005 WL 1793416, at \*28. Therefore, the special master decided that Ms. Moberly was “not entitled to Program compensation.” *Id.*, at \*29.

Ms. Moberly moved for review. *See* Petitioner’s Memorandum in Support of Motion for Review (Motion for Review), filed *nunc pro tunc* July 29, 2005. The case is before the special master now on remand from the United States Court of Federal Claims. *See Moberly v. Secretary of HHS*, No. 98-0910V, Order of the Judge (Fed. Cl. Dec. 27, 2005). The Court recognizes certainly the special master’s dilemma in the case: Ms. Moberly’s primary theory, based upon an exception contained in the NCES, “does not call for the usual role of an expert to interpret data and determine how closely a child’s case fits within a particular study, but rather requires knowledge of exactly what NCES authors did.” *Moberly v. Secretary of HHS*, No. 98-0910V, Order of the Judge at 1-2 (Fed. Cl. Dec. 27, 2005). Therefore, the Court has instructed the special master to provide the parties “the opportunity to supplement the record with evidence demonstrating how the NCES authors” applied the exception to the general rule that the authors used to determine the date of onset of the qualifying neurological illness for each case child accepted into the NCES. *Id.* at 2. The Court has suggested that the evidence may consist of “the oral or written testimony of an author or authors of the NCES,”<sup>6</sup> or of “records reflecting the medical history of NCES patients” meeting the exception. *Id.*

## I.

On January 3, 2006, the special master convened an informal, yet substantive, status conference to discuss proceedings on remand. The special master and the parties reviewed types of

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<sup>6</sup> It is an unfortunate failing of the informal nature of Program proceedings that the record does not reflect completely that in 2001, the special master recommended—and Ms. Moberly pursued—the precise evidentiary development that the Court contemplates. *See, e.g.*, Petitioner’s Status Report, filed September 17, 2001; Petitioner’s Status Report, filed November 1, 2001. In 2001, Ms. Moberly described her efforts to obtain the assistance of an NCES author, or of NCES authors, as “a fruitless endeavor.” Petitioner’s Status Report, filed November 1, 2001, at 2, ¶ 4.

evidence that may satisfy the intent of the Court's remand order. Given her experience in 2001, *see, e.g.*, Petitioner's Status Report, filed November 1, 2001, Ms. Moberly expressed significant pessimism about the potential success of renewed efforts to enlist an NCES author, or NCES authors, to participate in the case. Likewise, Ms. Moberly expressed significant pessimism about the potential success of any effort to obtain NCES records without the cooperation of NCES authors. Instead, Ms. Moberly indicated that she intended to parse the record to identify any information that the parties and the special master may have overlooked during proceedings on the petition. The special master directed the parties to search also for articles or transcripts related to workshops that NCES authors conducted, or speeches that NCES authors gave, that may contain examples of subjects that NCES authors included in the NCES under the exception that is at issue in the case.

On January 9, 2006, the special master convened another informal, yet substantive, status conference to discuss proceedings on remand. The parties reported their progress in producing evidence consistent with the Court's remand order. The special master commanded the parties to submit by January 30, 2006, any additional evidence. *See Moberly v. Secretary of HHS*, No. 98-0910V, Order of the Special Master (Fed. Cl. Spec. Mstr. Jan. 9, 2006).

The parties did not offer any additional evidence by January 30, 2006. On February 13, 2006, the special master convened a formal status conference. The parties represented that they had not discovered any evidence that may satisfy the intent of the Court's remand order. Thus, the parties stated that they would not be supplementing the record.<sup>7</sup>

There is no "additional evidence" for the special master to review. *Moberly v. Secretary of HHS*, No. 98-0910V, Order of the Judge at 2 (Fed. Cl. Dec. 27, 2005). The special master has studied carefully his original decision. In the absence of additional evidence, the special master does not revise his original decision.

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<sup>7</sup> During the February 13, 2006 status conference, Ms. Moberly argued that the ten-year follow-up study to the NCES published in 1993, *see Nicola Madge, et al., The National Childhood Encephalopathy Study: A 10-year Follow-up: A Report on the Medical, Social, Behavioural and Educational Outcomes After Serious, Acute, Neurological Illness in Early Childhood, in DEVELOPMENTAL MEDICINE AND CHILD NEUROLOGY Vol. 35, No. 7, Supp. No. 68 at 1-117 (July 1993); see also David Miller, et al., Pertussis Immunisation and Serious Acute Neurological Illnesses in Children, 307 BRITISH MEDICAL JOURNAL 1171-1176 (1993)*, supports Dr. Kinsbourne's interpretation of the NCES exception. Argument is not evidence. Dr. Kinsbourne addressed the 1993 NCES follow-up study in his testimony in 2003. Dr. Kinsbourne said merely that the 1993 NCES follow-up study demonstrated that a proportion of NCES subjects in the statistically-significant class identified by the NCES exhibited "permanent brain damage." Tr. at 20-21. Dr. Kinsbourne did not assert in any way that the 1993 NCES follow-up study had any bearing on his interpretation of the NCES exception. And, Ms. Moberly has not filed a supplemental opinion from Dr. Kinsbourne attesting to the proposition that the 1993 NCES follow-up study illuminates NCES method, specifically the application of the NCES exception.

## II.

Ms. Moberly believes that the decision by the United States Court of Appeals for the Federal Circuit (Federal Circuit) in *Althen v. Secretary of HHS*, 418 F.3d 1274 (Fed. Cir. 2005), alters somehow the legal analysis of actual causation claims in the Program. Thus, Ms. Moberly requested during proceedings on remand that the special master examine *Althen* in his decision on remand. Respondent objected, maintaining that Ms. Moberly's request exceeded the scope of the Court's remand order. The special master agreed. However, upon further reflection, and in anticipation of a second remand, the special master presents his view regarding the impact of *Althen* on the instant case.

In *Althen*, the Federal Circuit iterated that under the "court's well-established precedent," *Althen*, 418 F.3d at 1281, the actual causation standard requires a petitioner to adduce "preponderant evidence" demonstrating: "(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." *Id.* at 1278. Thus, the Federal Circuit criticized sharply a *solitary* special master's endeavor "to craft a new legal" formula for the resolution of actual causation claims in the Program. *Id.* at 1281; *see also Stevens v. Secretary of HHS*, No. 99-0594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001). In particular, the Federal Circuit ruled that the *solitary* special master's mandate that a petitioner "provide confirmation from the relevant medical community that it is seeing, reporting (in peer-reviewed literature), and discussing a 'suspected or potential association' between *the vaccine received* and the alleged injury," *Althen v. Secretary of HHS (Althen I)*, No. 00-0170V, 2003 WL 21439669, at \*12 (Fed. Cl. Spec. Mstr. June 3, 2003), citing *Stevens v. Secretary of HHS*, No. 99-0594V, 2001 WL 387418, at \*24 (emphasis in original), contravened "clear" statutory "language" in § 300aa-13(a)(1) allowing a petitioner to substantiate a claim with "medical records *or* medical opinion." *Althen*, 418 F.3d at 1279-80 (emphasis in original).

The United States Court of Federal Claims has held that "[s]pecial masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand." *Hanlon v. Secretary of HHS*, 40 Fed. Cl. 625, 630 (1998). Thus, this special master never adopted *Stevens*, or its progeny, *Althen I*. Indeed, this special master is on record in August 2003—long before the Federal Circuit's decision in *Althen*—as rejecting soundly *Stevens* and *Althen I*. *See, e.g., Cusati v. Secretary of HHS*, No. 99-0492V, Transcript, filed August 25, 2003, at 16-21. This special master expressed firmly that the *Stevens* test, as "refined" by *Althen I*, requiring a petitioner to "produce objective, supportive medical literature recognizing a potential causative role of the vaccine," *Althen v. Secretary of HHS*, No. 00-0170V, 2003 WL 21439669, at \*12, n. 29, offends certainly the United States Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). While the Supreme Court endorses peer-reviewed literature as "relevant" in the assessment of the validity of a medical or scientific theory, the Supreme Court recognizes absolutely that "in some instances[,] well-grounded but innovative theories will not have been published" and that in other instances, certain theories may be "too particular, too new, or of too limited interest to be published." *Daubert*, 509 U.S. at 593-94. Therefore, the

Supreme Court instructs that the “lack” of peer-reviewed literature is “not dispositive” in the “consideration” of the reliability of medical or scientific opinion. *Id.* Rather, this special master follows consistently long-standing, “well-established” Federal Circuit “precedent.” *Althen*, 418 F.3d at 1281; *see e.g.*, *Gall v. Secretary of HHS*, No. 91-1642V, 1999 WL 1179611 (Fed. Cl. Spec. Mstr. Oct. 31, 1999); *Malloy v. Secretary of HHS*, No. 99-0193V, 2003 WL 22424968 (Fed. Cl. Spec. Mstr. May 1, 2003).

Ms. Moberly must agree surely that Molly’s medical records alone do not establish more likely than not that Molly’s September 17, 1996 DPT vaccination caused actually Molly’s intractable seizure disorder accompanied by developmental delay. While several of Molly’s treating physicians noted the temporal relationship between Molly’s September 17, 1996 DPT vaccination and Molly’s initial brief seizures, none offered ever a solid statement that Molly’s September 17, 1996 DPT vaccination caused probably Molly’s condition. *See, e.g.*, Pet. ex. 5 at 1-4; Pet. ex. 9 at 3-4; Pet. ex. 11 at 4-5; Pet. ex. 12 at 7. Indeed, Molly’s first treating neurologist commented specifically that Molly’s “presentation would not fall within any of the recognized syndromes that ‘may’ be related to pertussis.” Pet. ex. 5 at 4. Thus, in accordance with § 300aa-13(a)(1) and with “well-established” Federal Circuit “precedent,” Ms. Moberly depends upon medical opinion to establish her claim. *Althen*, 418 F.3d at 1279-81.

The special master did not require Ms. Moberly to proffer “objective, supportive medical literature recognizing a potential causative role of” Molly’s September 17, 1996 DPT vaccination in Molly’s condition. *Althen v. Secretary of HHS*, No. 00-0170V, 2003 WL 21439669, at \*12, n. 29. *Rather, as a tactical matter, Ms. Moberly, through Dr. Kinsbourne, advanced a theory based upon an epidemiological study—the NCES—and an exception contained in the NCES. See, e.g., Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994)(explaining that “causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms”). At hearing, Dr. Kinsbourne said that other, unidentified literature supports his opinion that Molly’s September 17, 1996 DPT vaccination caused Molly’s condition. *See, e.g.*, Tr. at 10-11. In addition, although not necessary under *Knudsen*, Dr. Kinsbourne discussed a potential biological mechanism for Molly’s condition. *See, e.g.*, Tr. at 18-20.

According to the Federal Circuit, “Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases, and based upon their accumulated expertise in the field, judging the merits of the individual claims.” *Hodges v. Secretary of HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993). Dr. Kinsbourne has appeared before the special master on several occasions. Indeed, in his original decision, the special master acknowledged that “Dr. Kinsbourne possesses a solid reputation.” *Moberly v. Secretary of HHS*, No. 98-0910V, 2005 WL 1793416, at \*28. But, Ms. Moberly (essentially, Ms. Moberly’s attorneys) should make no mistake: The special master was not in the least impressed by Dr. Kinsbourne’s testimony regarding the NCES in this case.

The special master appreciates fully that a frankly harsh evaluation of Dr. Kinsbourne's testimony may dissuade Dr. Kinsbourne from appearing in future Program cases, to the detriment of other petitioners who draw from a very limited corps of medical experts. Thus, in his original decision, the special master attempted scrupulously to temper his remarks about Dr. Kinsbourne's testimony. Yet, based upon Dr. Kinsbourne's shockingly poor testimony about the NCES in this case, the special master harbors serious concerns about Dr. Kinsbourne as an "expert" witness regarding the NCES.<sup>8</sup> The special master cites a particularly "disquieting aspect of Dr. Kinsbourne's testimony." *Moberly v. Secretary of HHS*, No. 98-0910V, 2005 WL 1793416, at \*27. At hearing, the special master—a lay person—identified "a dichotomy between Dr. Kinsbourne's opinion and NCES protocol, affecting potentially NCES statistical conclusions." *Id.* Declaring that the special master was "not in the least wrong," Dr. Kinsbourne proclaimed that the special master's observation about the dichotomy between Dr. Kinsbourne's opinion and NCES protocol "opened up a legitimate, 'horrifying panorama' about NCES protocol." *Id.*, citing Tr. at 44.

In his original decision, the special master rejected entirely Dr. Kinsbourne's testimony about the NCES—the major portion of Ms. Moberly's case. See *Moberly v. Secretary of HHS*, No. 98-0910V, 2005 WL 1793416, at \*26. At the same time, the special master decided that Dr. Kinsbourne's "contradictory and confusing" testimony about the NCES infected all other parts of Dr. Kinsbourne's testimony. *Moberly v. Secretary of HHS*, No. 98-0910V, 2005 WL 1793416, at \*26. Therefore, the special master determined that Dr. Kinsbourne failed to express "credibly and rationally an opinion using" other "disparate elements of the evidence in the case." *Id.*, at \*28 (emphasis added).<sup>9</sup> Thus, Ms. Moberly has not substantiated her claim with "medical opinion," as required by § 300aa-13(a)(1) and by "well-established" Federal Circuit "precedent." *Althen*, 418 F.3d at 1281.

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<sup>8</sup> The special master is not alone. At least one of the special master's colleagues has questioned Dr. Kinsbourne's facility with the NCES. See, e.g., *Borin v. Secretary of HHS*, No. 99-0491V, 2003 WL 21439673, at \*3, n. 1; \*10 (describing in part Dr. Kinsbourne's application of the NCES as unsubstantiated); *Valois v. Secretary of HHS*, No. 97-0433V, 1998 WL 774342, at \* 5 (describing in part Dr. Kinsbourne's application of the NCES as "cavalier").

<sup>9</sup> The special master grants readily that in September 2005, he awarded Program compensation in a case in which Dr. Kinsbourne appeared for petitioner. See *Cusati v. Secretary of HHS*, No. 99-0492V, Decision of the Special Master (Fed. Cl. Spec. Mstr. Sept. 22, 2005). The special master can distinguish easily *Cusati* from the instant case. First, in *Cusati*, Dr. Kinsbourne did not testify about the NCES. Second, the special master's decision in *Cusati* did not turn on important issues regarding medical expert witness credibility. Instead, the special master's decision in *Cusati* turned on the assessment of the totality of the evidence under the appropriate legal cause analysis rather than the inappropriate medical cause analysis.

The clerk of court shall send Ms. Moberly's copy of this decision on remand to Ms. Moberly by overnight express delivery.

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John F. Edwards  
Special Master