In the United States Court of Federal Claims

No. 98-910
(Filed under seal January 15, 2009)
(Reissued January 30, 2009)[1]

TERESA MOBERLY, as mother and next friend of her daughter, MOLLY MOBERLY, Petitioner, v. **SECRETARY OF HEALTH AND HUMAN SERVICES,** Respondent.	*	Vaccine Act; causation-in-fact; DPT vaccination; seizure disorder; deferential arbitrary and capricious review; scientific certainty; interpretation of epidemiological studies; logical sequence of cause and effect; expert witness credibility; *Daubert* factors; Vaccine Rule 8(f) waiver.

Ronald C. Homer, Conway, Homer & Chin-Caplan, Boston, MA, for petitioner.

Mark C. Raby, Senior Trial Counsel, Torts Branch, Civil Division, Department of Justice, with whom were *Peter D. Keisler*, Assistant Attorney General, *Timothy P. Garren*, Director, *Mark W. Rogers*, Deputy Director, and *Vincent J. Matanoski*, Assistant Director, all of Washington, D.C., for respondent.

OPINION AND ORDER

WOLSKI, Judge.

Petitioner Teresa Moberly has moved for review of Special Master John F. Edwards's decision which denied her compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 - 300aa-34 ("Vaccine Act" or "Act"), and which directed that judgment be entered for respondent, the Secretary of the Department of Health and Human

[1] Pursuant to Vaccine Rule 18(b) of the Rules of the United States Court of Federal Claims, the parties were given fourteen calendar days in which to object to the public disclosure of information contained in this opinion prior to its public release. No objection has been filed. Accordingly, the opinion is reissued for publication with some minor, non-substantive corrections.

Services. The petition was filed by Mrs. Moberly on behalf of her daughter, Molly Moberly, and contended that a diphtheria-pertussis-tetanus ("DPT" or "DTP") vaccination is the cause of Molly's intractable seizure disorder. Petitioner raises two objections to the Special Master's decision.

First, she argues that the Special Master committed a legal error in not finding that the DPT vaccination caused Molly's injury -- alleging that the Special Master required scientifically certain proof of causation, rather than following the preponderance standard contained in the Vaccine Act. Second, she argues the Special Master acted arbitrarily and capriciously, in finding that the conclusions of two epidemiological studies -- the National Childhood Encephalopathy Study ("NCES")[2] and its follow-up study ten years later[3] -- would not apply to Molly's factual circumstances.

Because the second objection concerned the meaning of an ambiguous phrase in the NCES, the Court remanded the case to the Special Master pursuant to 42 U.S.C. § 300aa-12(e)(2)(C), to allow the parties "to supplement the record with evidence demonstrating how the NCES authors determined that a series of convulsions [was] 'part of a single pathological process.'"[4] The parties did not submit any additional evidence on this issue, and the Special Master did not change his decision to deny petitioner compensation.[5] Petitioner's Motion for Review thus came before the Court once again. After carefully and throughly reviewing the two decisions below, the record of proceedings before the Special Master, and the briefing submitted by the parties, for the reasons stated below, the Court sustains the Special Master's decision denying compensation.

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[2] The NCES was published in Great Britain in 1981. *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 IMMUNISATION 79-184 (1981).

[3] The follow-up study to the NCES was published in 1993. 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* 35 DEV'L MED. & CHILD NEUROLOGY (Supp. 68, No. 7) 1-117 (July 1993).

[4] Order (Dec. 27, 2005) at 2.

[5] *See Moberly v. Sec'y of HHS*, No. 98-0910V, 2006 WL 659522, at *3 (Fed. Cl. Spec. Mstr. Feb. 28, 2006) (*Moberly II*).

I. BACKGROUND

A. The Vaccination and Subsequent Seizures

Molly Moberly was born in Lincoln, Nebraska on May 17, 1996. Pet.'s Ex. 7 at 31. She appeared healthy, and despite frequent spitting up and some typical childhood illnesses, her first four months were uneventful. *See* Pet.'s Ex. 12 at 4-6 (describing Molly's health before her first seizure); *see also* Pet.'s Ex. 16 at 1 (noting date of first seizure). At age two months, she received her first of two DPT vaccinations. Pet.'s Ex. 9 at 8. She received her second DPT vaccination two months later, on September 17, 1996. *Id.* Early on the morning of September 19, 1996, Molly experienced a 101-degree fever and later had two seizures of brief duration. Pet.'s Ex. 16 at 1. She was examined the following day by doctors at the Auburn Family Health Center in Auburn, Nebraska, who prescribed antibiotics for an upper respiratory illness. Pet.'s Ex. 12 at 6.

Following two additional brief seizures and a visit to the hospital on October 6, a physician determined Molly's neurological examination was normal but ordered an elective computed tomography (CT) scan, which Molly underwent on October 7. Pet.'s Ex. 2 at 9. Because the CT scan was normal, the doctor referred Molly for an electro encephalogram (EEG). Pet.'s Ex. 12 at 6. On October 10, Molly was examined by Dr. Richard Torkelson, Director of University Epilepsy Services at the University of Nebraska Medical Center. *See* Pet.'s Ex. 5 at 1-3 (detailing Dr. Torkelson's findings). Doctor Torkelson believed Molly "looked 'so healthy' that he was 'inclined to' consider her seizures 'a transient disturbance.'" *Id.* at 3. He noted that her EEG was "totally normal" and contained "nothing suspicious." *Id.*

Further seizures, consisting of "twisting of the arm and a blank stare," followed in October. Pet.'s Ex. 5 at 7. On October 24, Mrs. Moberly spoke with personnel at the State Health Department who, according to petitioner, "felt that [Molly's] seizures could possibly be a reaction to a DPT" vaccination and recommended "in the future" that she only receive a diphtheria-tetanus (DT) vaccine. Pet.'s Ex. 12 at 8. Several more seizures followed between October 24 and November 4, including one lasting at least twelve minutes, which Mrs. Moberly videotaped. Pet.'s Ex. 5 at 4; Pet.'s Ex. 12 at 7-8. Molly underwent a magnetic resonance imaging scan on November 4, which yielded a normal result. Pet.'s Ex. 5 at 4. According to Dr. Torkelson, at that time Molly's clinical condition "would not fall within any of the recognized syndromes that 'may' be related to pertussis." *Id.* Doctor Torkelson prescribed Tegretol, an anticonvulsant, which he believed would "not really help at all" if Molly's seizures were fever-driven (as Mrs. Moberly believed). *Id.* at 4-5. At this point, Dr. Torkelson believed that Molly had "very good odds of outgrowing" her seizures. *Id.* at 5. Although Molly had remained seizure-free for over a week by November 7, Mrs. Moberly elected to delay starting Molly on the Tegretol, a decision with which Molly's physician at the Auburn center concurred as long as Molly did not experience further recurrent or prolonged seizures. Pet.'s Ex. 12 at 8. Although Molly suffered several other illnesses, she remained seizure-free for twelve weeks. Pet.'s Ex. 5 at 7.

Molly's next seizure occurred on January 22, 1997. Pet.'s Ex. 17 at 18. It lasted between seven and ten minutes, and involved a fever. Pet.'s Ex. 5 at 7. Doctor Torkelson examined Molly on January 27, and prescribed Valium for Molly's intermittent seizures. *Id.* He noted that if another seizure quickly followed he would reconsider chronic treatments, and would prefer Depakote if the seizures appeared "again precipitated by a fever." *Id.* Soon thereafter, he started Molly on Tegretol, but by February 19, he had decided to "taper off" the Tegretol and begin Molly on Depakote. Pet.'s Ex. 12 at 10. Molly went for her nine-month well-child examination on February 19, when she received a DT vaccination and her third hepatitis B vaccination. *Id.* The afternoon following the vaccinations, Molly had another seizure.[6] Pet.'s Ex. 9 at 3-4. The seizures continued into March, along with respiratory illnesses that were accompanied by fever and congestion. Pet.'s Ex. 12 at 11-12.

On April 1, 1997, Molly was examined by Dr. Christopher Harrison and Dr. Alice Pong, two physicians at Children's Hospital of Creighton University. Pet.'s Ex. 9 at 3-4. These doctors noted that her initial seizure was "temporally related to" a DPT vaccination, and that a later seizure followed on the heels of a DT vaccination, but they nonetheless considered her condition's etiology "unclear." Pet.'s Ex. 9 at 4. These doctors drew no conclusions on the cause or causes of her underlying seizure condition, but they did note the possibility of DPT causation. *Id.* Their neurological examination found her to be normal, and they believed she was "doing well from a development standpoint" at that time. *Id.* at 3-4. In early May, Molly missed several doses of the Depakote and had been experiencing congestion and fever when, on May 13, she had a "breakthrough seizure secondary to fever and decreased intake of" her Depakote. Pet.'s Ex. 12 at 13. On May 26, Molly arrived at the Skaggs Community Health Center Emergency Department in Branson, Missouri, after suffering what was reportedly a "prolonged seizure" lasting about an hour. Pet.'s Ex. 15 at 2-3; Pet.'s Ex. 21 at 4 (noting hour-long seizure on Memorial Day 1997). Prior to that date, Molly's seizures were of a relatively brief duration, with none reported to be longer than twelve minutes.

Prior to her May 26 seizure, on May 13, 1997, a doctor at the Auburn Family Health Center diagnosed Molly with otitis media and an upper respiratory infection.[7] Pet.'s Ex. 12 at 13.

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[6] Two physicians who examined Molly in April 1997 noted that the apparent relation between the DT vaccination and the subsequent seizure was rendered inconclusive by the fact that Molly "may have had a concomitant febrile illness at the time and was in transition with her anticonvulsive medication." Pet.'s Ex. 9 at 4.

[7] Otitis media "is an infection or inflammation of the middle ear. This inflammation often begins when infections that cause sore throats, colds, or other respiratory or breathing problems spread to the middle ear. These can be viral or bacterial infections." Nat'l Inst. on Deafness & Other Commc'n Disorders, http://www.nidcd.nih.gov/health/hearing/otitism.asp (last visited Dec. 29, 2008). Onset of otitis media is fairly common, with "[s]eventy-five percent of children experienc[ing] at least one episode . . . by their third birthday." *Id.*

The middle-ear inflammation, accompanied by fevers, continued into late June 1997. Pet.'s Ex. 12 at 15. Her physician at the Auburn facility reported she suffered a "mild exacerbation" of her seizure disorder, "secondary to her fevers." *Id.* On June 22, Mrs. Moberly brought Molly to the Nemaha County Hospital Emergency Room, and reported that Molly had experienced fevers up to 105 degrees Fahrenheit and four seizures over the course of several days. Pet.'s Ex. 3 at 3. The doctor treating Molly again observed otitis media, and Dr. Torkelson "felt that [Molly's] seizures were probably aggravated by [Molly's] fevers," so further evaluation of her seizures was unnecessary. *Id.*

On June 26, 1997, Molly returned to the Auburn Family Health Center for a follow-up appointment regarding her ear and upper respiratory infections. Pet.'s Ex. 12 at 15. During the visit, her mother expressed concern about "some developmental delays" and Molly "not walking," but the doctor examining Molly found her to be "very social and interactive" and found her "ambulation" skills were within the normal limits. *Id*. at 15-16. The doctor did note that Molly had no "appreciable speech" and determined Molly should be monitored "for evidence of developmental delays." *Id*.

Molly did not exhibit any further seizures until August 11, 1997, when Molly suffered six seizures and ran a fever of up to 104 degrees Fahrenheit. *Id*. at 17; Pet.'s Ex. 21 at 9. According to petitioner, one of these seizures lasted 45 minutes to one hour. Pet.'s Ex. 12 at 45. After Molly's prolonged seizure, her mother called an ambulance. *See* Pet.'s Ex. 21 at 2, 7, 9; Pet.'s Ex. 12 at 17. An emergency room doctor examined Molly and found her to be "alert" and to have "good tone of all four extremities." Pet.'s Ex. 21 at 7. The doctor did find, however, that Molly's ear drums were "red" and administered medicine to treat Molly's ear infection. *Id*. at 2, 7. While still at the Medical Center, Molly suffered another seizure. *Id*. at 8. She then underwent an MRI of her brain, which was "[n]ormal." *Id*. at 28. After the MRI, she suffered yet another seizure and was admitted to the hospital. *Id*. at 8. Once admitted, Molly did not suffer from any more seizures, but appeared "slightly more irritable than usual." *Id*. at 2. She was discharged from the hospital on August 12, 1997. Pet.'s Ex. 21 at 2.

Throughout September and October 1997, Molly suffered from recurrent fevers, persistent upper respiratory illnesses, and frequent seizures. Pet.'s Ex. 12 at 18-20; Pet.'s Ex. 3 at 4. In early October, she received a DT booster vaccination and by late October, Molly's pediatricians planned an "indepth seizure eval[uation]." Pet.'s Ex. 12 at 20-21. On November 10, 1997, Molly was admitted to the Epilepsy Unit at Children's Health Care-St. Paul, Minnesota for her seizure evaluation. Pet.'s Ex. 11 at 3. Doctor Frank Ritter, M.D., oversaw her care. *See id*. at 7. During her stay, Molly suffered three seizures, which were recorded by an EEG monitor. *Id*. at 3. Dr. Ritter evaluated these seizures and conducted an occupational therapy evaluation. *Id*. at 3-4. The evaluations revealed deficits in Molly's motor and cognitive skills, but also showed "many strong skills," including the desire "to move and explore objects." *Id*. Doctor Ritter did not identify a cause for Molly's seizures, but did discuss "[t]he issue of immunization" with Molly's parents. *Id*. at 4-5. Though Dr. Ritter could not predict Molly's future development and found that she "did not have symptoms for any progressive disease," he did not believe that

Molly would outgrow her seizures. Pet.'s Ex. 11 at 4-5. He discharged Molly from the Epilepsy Unit after recommending a trial of different medications. *See id*. at 6.

Molly suffered her next seizure episode on December 31, 1997, with six seizures that day associated with a slight fever. *See* Pet.'s Ex. 12 at 23. In early 1998, Molly exhibited "break-through seizures about every two to three weeks" as Dr. Ritter attempted to adjust her anticonvulsant medicine. Pet.'s Ex. 22 at 1. Doctor Torkelson then evaluated Molly on March 6, 1998 and found that Molly's "growth parameters" were "looking excellent" and that a "review of systems" revealed "nothing" of significance with the exception of "developmental delays." *Id*. He then diagnosed her with "alternating hemiconvulsions" and characterized the seizures as "largely generalized" and "medically intractable." *Id*. at 2. He was uncertain as to the etiology of Molly's condition. *Id*.

On May 23, 1998, Molly arrived at the Nemaha County Hospital Emergency Room with a seizure that lasted "approximately" one and one-quarter hours, during which she stopped breathing. Pet.'s Ex. 3 at 16-18. Her next reported seizure, lasting five to seven minutes, occurred seven weeks later, on July 1, 1998. Pet.'s Ex. 10 at 22. Her seizures continued to recur, well beyond the initiation of this case. *See*, *e.g*., Pet.'s Ex. 29 at 13 (seizure reported June 17, 1999); Pet.'s Ex. 30 at 3 (grand mal seizure on October 22, 1999); Pet.'s Ex. 37 at 8 (seizures reported in January and February 2000); *id.* at 6 (seizures reported for August and September 2000); *id.* at 5 (seizures reported in December 2000); *id.* at 4 (brief seizure reported February 7, 2001); *id.* at 2 (four seizures reported in July 2001); Pet.'s Ex. 50 at 14 (three seizures reported August 24, 2001); Pet.'s Ex. 47 at 1 ("recent increase in seizure activity" noted on October 26, 2001); Pet.'s Ex. 46 at 2-3 (30 minute long seizure on January 17, 2002); Pet.'s Ex. 48 at 1-2, 4 (seizure on July 28, 2002); Pet.'s Ex. 46 at 5 ("increasing seizure activity" noted on November 26, 2002); Pet.'s Ex. 53 at 2 (noting that, as of May 26, 2005, Molly "continue[d] to experience seizures every few days"); *see also* Pet.'s Ex. 31 (seizure report for December 31, 1997 through April 4, 2000); Pet.'s Ex. 51 (seizure journal for April 2000 to February 2003). As a result of her seizures, Molly's treating physicians changed her medication and instituted a special diet hoping to control her condition. Pet.'s Ex. 47 at 3-6. Her seizures, however, remained "medically refractory" and her developmental skills appeared to regress as her seizures increased. Pet.'s Ex. 50 at 16-17.

B. The Petition and Hearing Before the Special Master

Petitioner filed a petition for compensation under the Vaccine Act on December 4, 1998, claiming that the DPT vaccine Molly received on September 17, 1996 caused her illness. Pet. at 1. The parties did not dispute the facts "as reflected" in Molly's medical records, Joint Status Rep. (Jan. 10, 2003) at 1, and the Special Master heard oral testimony from each party's expert concerning the medical issues in the case. *See Moberly v. Sec'y of HHS*, No. 98-0910V, 2005 WL 1793416, at *1 (Fed. Cl. Spec. Mstr. June 30, 2005) (*Moberly I*). These experts were Dr. Marcel Kinsbourne for petitioner, and Dr. Robert J. Baumann for respondent. *Id.* Both medical doctors are neurologists. *See* Pet.'s Ex. 33(A) at 1-2 (listing Dr. Kinsbourne's experience as a

professor of neurology at several universities); Resp.'s Ex. A at 1, 3 (identifying Dr. Baumann as a professor of neurology and pediatrics at the University of Kentucky); Resp.'s Ex. C at 2 (same). Each witness gave his general opinion, based on Molly's medical records, as to whether the DPT vaccination was the cause of her seizure disorder, and specifically focused on two issues: whether the conclusions of the NCES apply to Molly's circumstances, and the theory that the whole-cell pertussis vaccine can cause medical conditions similar to those suffered by Molly. *See*, *e.g.*, Tr. (Mar. 7, 2003) ("Tr.") at 11-17, 21, 25-26, 33-39, 41-44 (Dr. Kinsbourne on applicability of NCES); *id.* at 18-20, 26-30, 32 (Dr. Kinsbourne on medical theory of causation); *id.* at 53-59, 69-75, 97-101 (Dr. Baumann on applicability of NCES); *id.* at 93-95 (Dr. Baumann's criticism of causation theory); *see also Moberly I*, 2005 WL 1793416, at *17-22.

1. The Applicability of the Conclusions of the NCES

a. The NCES.

The NCES was a British study developed in 1976 in response to concerns about the safety of pertussis immunization, and was designed "to assess the risks of certain serious neurological disorders associated with immunization in early childhood and to identify factors that might cause or predispose to such disorders." NCES at 80; *see* Pet.'s Ex. 33(B) at 4.[8] The authors of the study were primarily concerned with acute neurological illnesses that could result in death or permanent brain damage. *Id.* at 101. The study considered whether these illnesses could be associated with "recent immunization," which the authors of the study defined as "within 28 days." *Id.* at 141. The authors used a "case-control" method, which involved collecting "a series of individuals with a particular disease and comparing their history of exposure to the suspected agent with that of an appropriately selected group of individuals who do not have the disease." *Id.* at 97. To this end, the authors established criteria or qualifying conditions for "case" children, which included convulsions lasting "more than about" half an hour. *Id.* at 157.[9] The authors also excluded certain conditions, including "[u]ncomplicated fits or a series of fits lasting less than about" half an hour. *Id.*

To identify potential cases, the authors enlisted doctors to report to the study those children that were between the ages of two months and thirty-six months, and who were admitted to a hospital with one of the qualifying conditions. NCES at 101. If the authors determined that the case appeared to satisfy the study's criteria, they asked the identifying physician to complete a

[8] Tab B to Petitioner's Exhibit 33 contains a reproduction of the NCES. For the sake of convenience, the Court will henceforth follow the convention of citing just the page number of the report itself, instead of numbering the pages as they appear behind Tab B.

[9] Other criteria which qualified a child for the case study included suffering convulsions followed by a coma lasting at least two hours, or "followed by paralysis or other neurological signs not previously present, lasting 24 hours or more"; unexplained loss of consciousness; infantile spasms; and Reye's syndrome. NCES at 157.

questionnaire regarding the child's history, condition on admission, and condition on the sooner of the fifteenth day after admission or the day of discharge. *Id*. at 102. If the study's authors confirmed with the questionnaire that the case satisfied the NCES criteria, the child was admitted to the study as a case child. *Id*. The authors matched each case child with two non-case children from the same community according to gender and age. *Id*. at 105. These were the "control" children. *Id*. The authors obtained medical histories, including immunization records, for all case and control children. *Id*.

To enable the authors to assess any possible relationship between a vaccination and a case child's illness, they also assigned a date of onset of the qualifying condition to each case child. NCES at 102. While the authors initially assumed that the interval would generally be short between the onset of symptoms of a qualifying neurological disorder and the child's admission to a hospital, this assumption was not always borne out by circumstances. *Id*. As a result, the authors decided that the date of onset was "*the date on which acute neurological symptoms or signs related to the current illness first developed*." *Id.* To make the determination of the date of onset more uniform, an epidemiologist and a pediatrician member of the study team were assigned to each case to review the records and determine this date. *Id.* When a case child who was reported to the study "after severe convulsions" had "had any earlier convulsion," the NCES authors used a particular standard to determine the date of onset of the illness:

> When a series of fits appeared to be part of a single pathological process, as in cases with progressive mental deterioration, for the purpose of the Study the *date of onset of illness* was taken to be the *date of the first convulsion*. However, where a child had a series of convulsions *without* any obvious and continuing underlying clinical or pathological explanation, the date of onset of that child's illness was regarded as the date of the major convulsion for which the child was admitted to hospital and notified to the Study.

Id. at 147. Both experts have referred to this language as describing an "exception" to the rule dating the onset of the qualifying illness. Tr. at 12, 57.

The NCES found "a statistically significant increased risk of having received DTP vaccine within 7 days before the onset" of the qualifying illness for a case child, and this "risk was greatest within 72 hours and in those with convulsions or encephalopathy." NCES at 148. Thus, the acute neurological illnesses studied were found to "occur more frequently . . . than would be expected by chance" in those circumstances. *Id.* at 149. The study concluded "that on the balance of the available evidence, DTP vaccine probably can cause acute neurological reactions." *Id*. at 141. The NCES cautioned, however, that because "of possible alternative explanations of the clinical findings in cases associated with DTP . . . attribution of a cause in individual cases is precarious." *Id.* at 149.[10]

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[10] Of the 35 cases of children whose onsets of illness were within 7 days of receiving a DPT vaccine, an "alternative explanation for their condition was found" for all but nine. NCES

Ten years after the NCES was published, a follow-up study was released. 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* 35 DEV'L MED. & CHILD NEUROLOGY (Supp. 68, No. 7) at 1-117 (July 1993) ("Follow-up Study"); *see also* Pet.'s Ex. 33(C) (containing a reproduction of the Follow-up Study). This study examined the children included in the NCES, to assess the permanence of any neurological damage suffered by the case children who participated in the initial study. *See* Follow-up Study at 1-2 (describing the nature of the study). The Follow-up Study found that NCES case children showed signs of neurological dysfunction, or died since the NCES, at a much higher rate than the control children. Follow-up Study at 100.

On the specific question of whether "pertussis vaccine might sometimes lead to permanent brain damage," which was initially believed to be "a very rare event" if it "occurred at all," the authors of the Follow-up Study merely stated that they "have re-examined the evidence in the light of the present follow-up study, and the findings and conclusions will be reported elsewhere." Follow-up Study at 2. The report containing these other findings is not a part of the record of this case. It is, however, discussed in an Institute of Medicine report submitted as an attachment to Dr. Kinsbourne's expert medical report. *See* Pet.'s Ex. 33(D) (containing a reproduction of KATHLEEN R. STRATTON, *et al.*, INSTITUTE OF MEDICINE, DPT VACCINE AND CHRONIC NERVOUS SYSTEM DYSFUNCTION: A NEW ANALYSIS (1994)) ("1994 IOM").[11] Apparently, "the balance of evidence was consistent with a causal relation between DPT and the forms or chronic system dysfunction described in the NCES in those children who experience a serious acute neurologic illness within 7 days after receiving DPT vaccine," but not for other children receiving a DPT vaccine. 1994 IOM at 2.[12]

b. The Expert Testimony Interpreting the NCES.

The NCES was designed to determine whether certain serious neurological illnesses, requiring admission to a hospital, are more likely to befall children within 28 days of immunization. NCES at 141. The study found a statistically-significant increase in the occurrence of these illnesses within 7 days of receipt of a DPT vaccination, and particularly within 72 hours. *Id.* at 148. Both parties' experts agree that the first seizure that would have qualified Molly for inclusion as a case child in the NCES occurred much more than 7 days after her receipt of a DPT vaccination. Petitioner's expert, Dr. Kinsbourne, was of the opinion that the qualifying illness was the hour-long seizure of May 26, 1997, which necessitated a hospital

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at 149.

[11] Citing David Miller, *et al.*, *Pertussis Immunisation and Serious Acute Neurological Illnesses in Children*, 307 BRIT. MED. J. 1171-76 (1993).

[12] Citations to pages from this exhibit will also follow the convention of using the page number of the report itself, rather than numbering the pages as they appear behind Tab D.

emergency room visit. *See* Tr. at 12; *see also* Pet.'s Ex. 15 at 2-3. Doctor Baumann, respondent's expert, believed that the August 11, 1997 seizures (which included one of forty-five minute duration), resulting in Molly's hospital admission, constituted the qualifying event. Tr. at 90; *see also* Pet.'s Ex. 21 at 2. As acute illnesses, each of these events resulted in a trip to the hospital many months after the September 17, 1996 vaccination, and thus the NCES results would not support the theory that these seizures were caused by DPT -- unless the date of onset could be fixed much earlier than the date of the visit or admission to the hospital.

Thus, critical to the question of whether the NCES results support DPT causation in Molly's case is the exception to the rule for dating the onset of illnesses. As the NCES explained, this exception was adopted in response to circumstances in which "a particular dose of vaccine might be followed by one or more short convulsions and then, some months later, a prolonged or complicated convulsion might lead to admission to hospital (which should have prompted notification to the Study)." NCES at 146. The study's authors posited two opposing but "equally well" made arguments concerning such occurrences -- either "the immunization 'triggered' a series of events leading much later to a serious convulsion," or the "immunization might be considered to be 'responsible' for the first short convulsion" but not the subsequent ones, which instead resulted from the child's "lower than usual threshold for convulsions in response to a variety of stimuli." *Id.* at 146-47. The NCES team "attempted" to "determin[e]" which cases fit the former argument better than the latter argument, and thus "could have been regarded as 'vaccine-associated'" due to an earlier date of onset. *Id.* at 147.

Key to this determination was the identification of a "pathological process" connecting the series of seizures. *Id*. As was noted above, the NCES distinguished between two categories of cases: those in which "a series of fits appeared to be part of a single pathological process, as in cases with progressive mental deterioration," which were assigned a date of onset based on the initial, though short, convulsion; and those involving "a series of convulsions *without* any obvious and continuing underlying clinical or pathological explanation," which measured the date of onset "as the date of the major convulsion for which the child was admitted to hospital." *Id.* The study did not elaborate further on this classification scheme. Petitioner's expert, Dr. Kinsbourne, conceded that the "wording" of the exception was "not clear" and "a matter of debate," and he "believe[d] more than one interpretation is legitimate." Tr. at 13. He testified that "it is a matter of interpretation as to how one construes what the authors might have meant." *Id.*

In interpreting this language, Dr. Kinsbourne initially testified that "progressive mental deterioration" referred to diseases that could not be caused by DPT. He took this reference to mean the effects of illnesses such as Tay-Sachs disease, *id.* at 17, 44, conditions caused by "various well-known syndromes which one would not mistake for DPT injury." *Id.* at 15; *see also id*. at 41 (interpreting the phrase to mean "diseases which have nothing to do with DPT"). Doctor Kinsbourne emphasized that "DPT injuries are not of a kind that lead to progressive

mental deterioration," and that "[n]o one thinks" otherwise. *Id.* at 15.[13] Petitioner's expert explained that progressive mental deterioration and "seizures triggered by a variety of different stimuli" constituted "two extremes of a spectrum of what in fact can happen after [a vaccination of] DPT," and that neither is caused by DPT. Tr. at 14-16. In his view, "cases in between those two limits" are those presenting examples of DPT causation. *Id*. at 16. That is where he placed Molly's case, which he believed "certainly isn't just convulsions happening to be triggered by various random events," and "certainly isn't a tangible progressive process leading across [her] history." *Id.*

Doctor Kinsbourne testified that a single pathological process linked Molly's initial convulsions -- suffered within two days of receiving a DPT vaccination -- with the subsequent convulsions, culminating in the severe seizure of May 26, 1997. *See id*. at 12-13. He based this on her "particular seizure pattern of . . . focal seizures implying focal lesions or focal dysfunctions," as "multiple areas of the brain [were] firing pathologically." *Id*. at 16. Because this "pattern repeated and repeated and repeated," her problem "[wa]sn't changing in its nature," but was "the same kind of problem happening over a period of time." *Id.* at 17. Petitioner's expert stated that he "wonder[ed] if that doesn't meet the criterion, what could," *id.*, and later emphasized that he "really couldn't think of a type of clinical picture much different from the one we have here as qualifying for inclusion." Tr. at 37. To Dr. Kinsbourne, if Molly's seizures were not the result of a single pathological process, "nothing would be, which would leave it a vacant category." *Id.*

The Special Master asked Dr. Kinsbourne if he disagreed with the way the NCES authors treated cases exhibiting progressive mental deterioration. Tr. at 33. Doctor Kinsbourne explained that he interpreted the pertinent language in the study to merely be "for illustrative purposes," reflecting presumably one example of something which can result from a single pathological process. *Id.* at 34. He found this illustration to not be "helpful," because "[i]f there were a history of progressive loss of mental skills or motor skills or both, then there are other disorders that cause that, and DPT would not be on one's radar screen." *Id.* But Dr. Kinsbourne seemed to contend that this "illustrative criterion of what might be included" in the study had no impact on the study's results, as "it's not among the range of events that in fact you're going to come across." *Id.* Thus, in his opinion the study's authors used this phrase only as an illustration and did not, in fact, pre-date the onset of such illnesses, because "the question of DPT causation would not even be raised legitimately if there were a history of progressive loss of mental skills." *Id.*

But this passage from the NCES seems to describe what the authors had actually done when determining the date of onset of illnesses, identifying "cases with progressive mental deterioration" as an example of those for which, "for the purpose of the Study the date of onset of

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[13] Doctor Kinsbourne further explained: "I think a DPT injury is more like a head injury. It's a sudden injurious event, in itself, self-limited. Of course, it then sets up a pathology of the brain which then unloads in its own fashion." Tr. at 15.

illness *was taken to be* the date of the first convulsion." NCES at 147 (emphasis added; emphasis in original omitted). After the Special Master pointed this out to Dr. Kinsbourne, the latter recognized the "need to say something more in response." Tr. at 35. He then gave the opinion that Molly "did progressively lose mental skills," and believed it occurred "because of the severity of her seizures." *Id.* When asked if the medical records suggested that mental deterioration did not occur until after the more prolonged seizures, perhaps supporting the alternative argument that her convulsions were the response to various stimuli and not to the DPT vaccination, petitioner's expert explained that such deterioration is not usually constant and gradual, but "in most such cases, the deterioration gathers momentum as the seizures get worse because epilepsy tends to be a self-enhancing process." *Id.* at 36-37. He stressed that the NCES authors "don't say when this progressive mental deterioration is supposed to occur," and added the caveat: "But I wasn't in my initial statement actually relying on meeting this provision." *Id.*

Doctor Kinsbourne went on to explain that Molly's case history illustrated a "clinical picture [which] would reasonably approximate the appearance of a common cause" that could relate to a DPT vaccination. Tr. at 39. During re-cross examination, he articulated further his understanding of the exception to the rule for dating the onset of illnesses, contending that the NCES authors would look to see "if the initial event and the criteria event are linked by a common process such as a progressive change from Point A to Point B, such as a mental deterioration." *Id*. at 42. Petitioner's expert conceded that this exception was not limited to pathological processes that could be caused by DPT, but was instead used to date the onset of an illness and thus determine the illness's temporal relationship to a DPT vaccination. *See* Tr. at 42-44. He acknowledged that his interpretation of "progressive mental deterioration" allowed for the possibility of "a horrifying panorama," were the NCES authors "to include in their causative sample a case of Tay-Sachs disease that happens to begin with a seizure, which happens right after a DPT [vaccination]." *Id.* at 44. If that had happened, then some individual cases figuring in the total demonstrating a correlation with DPT vaccination would be ones which "clearly ha[d] nothing to do with DPT." *Id.* Doctor Kinsbourne stated, somewhat equivocally, "as far as I know, because they do tell us the cases they included, more or less, they didn't do that." *Id.* But he acknowledged that he "can't disagree with" the "argument that that might have happened, given these criteria." *Id.*

Respondent's expert, Dr. Baumann, disagreed with Dr. Kinsbourne's interpretation of the NCES and did not believe that the DPT vaccination caused Molly's seizure disorder. *See* Tr. at 47-50, 55-58, 73-74, 101-04. He explained that the NCES authors "were looking at acute neurological injury that shortly followed immunization." *Id.* at 54. Doctor Baumann testified that Molly "didn't have any of the evidence of an acute severe neurologic injury in the time after" the seizures which closely followed the DPT vaccination. *Id.* at 47. He referred to Dr. Torkelson's notes, which he termed "excellent medical records" that contained "great detail." *Id*. In the notes following the October 10, 1996 examination of Molly, Dr. Torkelson wrote that "[o]n neurologic examination" Molly was "very interactive" and "would socially smile quite quickly," and that "[h]er social interaction is age-appropriate." Pet.'s Ex. 5 at 2; Tr. at 48. After her November 4, 1996 visit, Dr. Torkelson wrote of Molly that "at present, her presentation

would not fall within any of the recognized syndromes that 'may' be related to pertusssis." Pet.'s Ex. 5 at 4; Tr. at 49. Doctor Baumann thus concluded that Dr. Torkelson "carefully looked at these issues at the time it was all occurring, and found no evidence to support that she had a serious acute neurologic injury." He added that Dr. Torkelson had "a reputation of being careful and diligent." Tr. at 49.

Interpreting the NCES language concerning the date of onset of illness, Dr. Baumann stressed that "'obvious and continuing' is an important ingredient of that definition." *Id*. at 56. He gave as examples of cases that would qualify for the pre-dating of the onset "a child who has a cluster of seizures, perhaps lasting three minutes; the next day, perhaps has some additional seizures; over the next week or two weeks, has some more seizures, and is not attentive, interactive, the way the child was, or within the ensuing five or six weeks has additional seizures, gets progressively worse." *Id.* Doctor Baumann testified that the dating rule "exception" would apply when, after initial convulsions in proximity to a vaccination, "within a reasonable time period, you had this obvious and continuing underlying clinical disorder." *Id.* at 57.

Respondent's expert believed that all of Molly's seizures were related, as "whatever is wrong with Molly's brain that caused the seizures was present when they started," but he did not consider hers "a case . . . of a single pathologic process with an obvious and continuing underlying clinical pattern." *Id.* He thought it was "quite clear from Dr. Torkelson's note that Dr. Torkelson did not see this as an obvious and continuing underlying clinical progress." *Id.* Doctor Baumann testified he "assumes that" there is one cause for Molly's seizures, as he was of the opinion she had "idiopathic epilepsy" and "the current belief in the field" was that this results from the way such children "are made [--] i.e., that somehow in the way their brains were put together and wired, this was not done correctly, and it leads them to have seizures." Tr. at 75-76. Doctor Baumann testified that it would not be consistent with the NCES to apply the dating exception to all children whose seizures were related, as this would then apply to all children with epilepsy. *Id.* at 58; *see also id*. at 99.

On cross-examination, Dr. Baumann was pressed to explain his interpretation of the NCES language concerning a series of seizures that is "part of a single pathological process," which would qualify a child for the dating exception; and of the language referencing the absence of "any obvious and underlying clinical or pathological explanation," which would disqualify a child from the exception. *See id.* at 70-75. He testified that both the modifiers "obvious and continuing" and the "example" of "progressive mental deterioration" were used by the NCES authors "purposefully." *Id.* at 74. Respondent's expert explained that he believed "obvious and continuing underlying clinical or pathological explanation" meant "an obvious neurologic disease that has been continuing through [the] whole time, from the first seizure to the seizure or whatever event caused notification." *Id*. at 71. The requisite pathological process, in his opinion, was an "overt neurological disease" which an "experienced physician" would recognize. *Id.* at 74. On the other hand, in the absence of such a process, a physician would find "a child who looks otherwise well, except for these seizures." *Id*. at 73. Doctor Baumann believed that seizure disorder was not an overt neurological disease meeting the pathological process

definition, as "children who are in the middle of a seizure disorder [can,] between seizures, seem okay." Tr. at 74. He explained that "if you have a child who has a single pathologic process that's obvious and continuing, you can usually then make some reasonably confident prediction of what's going to happen," but testified that this is not the case for children with idiopathic epilepsy, such as (in his opinion) Molly. *Id*. at 75.

The Special Master questioned whether it was realistic to have expected Dr. Torkelson, in November 1996 -- several months *before* the occurrence of any of Molly's seizures that were long enough to have potentially qualified as reportable events -- to be considering whether a single pathological process meeting the NCES definition was observable. *See id.* at 96-99. Doctor Baumann insisted that if Molly "had an ongoing[,] obvious [and] continuous neurologic illness," this "would have been evident" in October and November 1996, and Dr. Torkelson would have noted it. *Id*. at 98. He reiterated his view that Molly suffered from a "static abnormality" that has resulted in epilepsy, which is not "an ongoing[,] continuing pathologic process in the terms that a child neurologist would think of it." *Id.* at 99. Doctor Baumann identified the "common pattern" of "children who at irregular intervals have seizures" as an example of children whose first seizure's proximity to a DPT vaccination would be "happenstance," and would not qualify for the dating exception. Tr. at 100-01. After testifying that Molly has idiopathic epilepsy, Doctor Baumann was asked by the Special Master if Molly's medical records support the conclusion that a variety of stimuli caused her seizures. *Id*. at 101. Doctor Baumann could not cite any such supporting records, responding: "I guess I never looked at the records with that question in mind." *Id.* at 102.

Respondent's expert concluded his testimony concerning the NCES by explaining that even if the May 1997 seizure cited by Dr. Kinsbourne would have resulted in a notification to the NCES were it to have occurred in Great Britain during the time of the study, he would still not find DPT to be the cause of Molly's seizure disorder. Tr. at 104. He explained that Molly "didn't have an acute encephalopathy in association with her DPT [vaccination]," and stated that he saw "no evidence that she was part of this exception of a single obvious and continuing pathological process." *Id*. Doctor Baumann testified that signs and symptoms of such a pathological process would have been apparent when Dr. Torkelson examined Molly in 1996, had they been present. *Id*. at 105. He pointed out that even after Molly's March 6, 1998 visit, Dr. Torkelson still explicitly noted that Molly's etiology was uncertain. Tr. at 107 (citing Pet.'s Ex. 22 at 2).

c. The Special Master Finds that the NCES Does Not Support Petitioner's Claim.

In determining whether or not the statistical conclusions of the NCES can prove that Molly's second DPT vaccination caused her seizure disorder, the Special Master began by noting that the parties agreed that based on her age and her hospitalization for a prolonged seizure, Molly met the NCES protocol for inclusion in the study. *Moberly I*, 2005 WL 1793416, at *24. He then noted that petitioner's expert, Dr. Kinsbourne, conceded that Molly's two brief seizures

which occurred within 48 hours of the DPT vaccination did not themselves satisfy the NCES reporting criteria, and that her seizures which did satisfy these criteria were suffered many months later. *Id.* Thus, the statistical conclusions of the NCES -- showing an association with DPT vaccinations received within 7 days, and particularly with those received within 72 hours, of reportable illnesses -- would not apply to Molly's case, unless the "exception" to the rule for dating the onset of her illness applied. *Id*.

The Special Master then considered Dr. Kinsbourne's testimony concerning this exception. *Id.* Petitioner's expert believed that "'a particular' repetitive 'seizure pattern'" exhibited by Molly demonstrated "that 'a common pathological process unites' Molly's initial, brief seizures in September 1996 and Molly's later presentation that would have prompted notification to the NCES." *Id.* (quoting Tr. at 13, 16-17). The Special Master next looked at the language from the study which explained the exception to the rule for dating the onset of illness, noting that it appeared "in a section of the NCES that NCES authors titled 'Possible Defects in the Study.'" *Moberly I*, 2005 WL 1793416, at *25 (citing NCES at 144-47). He pointed out that the NCES authors in this section stated it was "difficult to answer with confidence" the question whether their method of analysis appropriately identified "'vaccine-associated' cases." *Id.* (quoting NCES at 146). The Special Master "[f]rom his lay perspective" stressed that the "NCES authors vacillated apparently about the propriety of aspects of NCES protocol," and described concerns about under- and over-inclusion of cases used to derive the statistical results. *Id*. (citing NCES at 141, 143-44, 146-47). He then lamented that "neither Dr. Kinsbourne nor Dr. Baumann addressed directly the validity of the hypothesis underlying the exception that Dr. Kinsbourne cites." *Id*.

As was discussed above, the exception dated the onset of an illness using the date of an earlier convulsion, rather than the date of the major convulsion which required hospitalization, "[w]hen a series of fits appeared to be part of a single pathological process, as in cases with progressive mental deterioration." NCES at 147. The Special Master commented that the "NCES authors provided little, if any, objective information about the process they used to assess cases" under this exception. *Moberly I*, 2005 WL 1793416, at *26. He found that they "did not define explicitly their use of the term 'single pathological process.'" *Id*. (citing NCES at 147). The Special Master felt that the language used in the NCES "implies that NCES authors deemed other cases to reflect 'a single pathological process,'" in addition to the "one descriptive example of . . . cases involving 'progressive mental deterioration.'" *Id*. (citing NCES at 147). But he noted that the study's "authors were wholly silent on the types of other cases that may have comported with their concept of a 'single pathological process.'" *Id*. (citing NCES at 147). As a result, as even petitioner's expert acknowledged, this exception took on a "'subjective' character." *Id*. (citing Tr. at 17).

After discussing portions of Dr. Kinsbourne's testimony -- in which the expert admitted the meaning of the exception "is not clear" and variously testified that "progressive deterioration" was either not associated with DPT, was not a helpful example, or meant a loss of mental skills which was not tied to a particular time in the course of seizure disorder, *see id*.

(citing Tr. at 13, 15, 34-38, 41-42) -- the Special Master concluded that the former's "testimony about the exception in the NCES was contradictory and confusing." *Moberly I*, 2005 WL 1793416, at *26.[14] As a consequence of this evaluation, the Special Master "decide[d] that in the absence of objective information regarding the process NCES authors used to assess cases involving 'any earlier convulsion,' attempts to interpret NCES authors' use of the phrase 'single pathological process' constitute simply speculation." *Id*. Not knowing the meaning of the exception, the Special Master concluded it was "not a suitable basis on which to ground an actual causation claim," and accordingly held "that statistical conclusions of NCES data do not apply to Molly." *Id.*

In what amounted to a long afterword, the Special Master then discussed another topic that was prompted by a "serious, disquieting aspect of Dr. Kinsbourne's testimony." *Moberly I*, 2005 WL 1793416, at *27. He cited "Dr. Kinsbourne's premise that progressive mental deterioration is not characteristic of DPT injury." *Id.* If Dr. Kinsbourne were correct in his interpretation of the term "progressive mental deterioration," then this meant that "the NCES authors counted cases, and based statistical conclusions on cases, that could be in no way related to DPT." *Id.* To interpret medical literature, "a lay reader must approach medical studies and medical texts through the prism of medical knowledge," and thus special masters are guided by experts such as Dr. Kinsbourne, who "possesse[d] a solid reputation." *Id*. at *27-28. The Special Master found that Doctor Kinsbourne's testimony regarding the NCES "revive[d] . . . substantive concerns about the viability of the NCES as an element of proof of causation-in-fact." *Id.* at *28. Because of these concerns, he announced that in future cases invoking the NCES he anticipated requiring "a comprehensive presentation from a medical expert regarding NCES design; NCES method; NCES conclusions and [Institute of Medicine] reviews of the NCES." *Id.* at *28.

2. The Special Master Rejects Dr. Kinsbourne's Causation Theory

During the hearing, petitioner's expert advanced what he termed a "biologically plausible" mechanism purporting to explain how a DPT vaccination can cause neurological damage such as that suffered by Molly. *See* Tr. at 18-20, 27. Doctor Kinsbourne apparently stated this "position" in an article that he co-authored for publication in 1990. *Id.* at 18.[15] As he

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[14] The Special Master also found that respondent's expert's "interpretation of NCES protocol" concerning the requirement of hospital admission "appear[ed] more correct" than Dr. Kinsbourne's interpretation of the same, and reflected greater "facility with the NCES." *See Moberly I*, 2005 WL 1793416, at *24 n.16.

[15] The article is not part of the record in this case, but was listed in the bibliography contained in Dr. Kinsbourne's curriculum vitae. *See* Pet.'s Ex. 33(A) at 27 (item number 311, described as "Menkes, J.H. & Kinsbourne, M. (1990). Workshop on neurological complications of pertussis and pertussis vaccination. Neuropediatrics, 21, 171-176."). The article was apparently an abstract of a workshop discussion, and was "clearly not a peer-reviewed article."

explained, the pertussis toxin contained in DPT is known to be neurotoxic, and can bind to the G proteins on the surface of neurons. *Id.* These "G proteins are instrumental in facilitating what is called intercellular signaling," and their inactivation by the pertussis toxin would cause "a deficiency of inhibition, leading to a net surplus of excitation which is capable of damaging the cell by having it fire too much or die." *Id.* at 18-19. The pertussis toxin, traveling in the blood stream, normally cannot reach the brain cells. But Dr. Kinsbourne testified that another component of the whole-cell pertussis vaccine, endotoxin, "is known to be capable of increasing the permeability of the walls of blood vessels." *Id.* at 19. He "suggested" that the endotoxin thus "permits pertussis toxin to gain access to the brain itself." Tr. at 19.

On cross-examination, Dr. Kinsbourne conceded that he knew of no study in any peer-reviewed publication that "critiqued" or even "addressed" his proposed mechanism, and that he knew of no "formal tests of an empirical nature of the mechanism." *Id*. at 27. He admitted, "[n]ot only has there been no testing, but it would be hard to imagine how one would" test it. *Id.* Petitioner's expert explained that of the "multiple steps in the mechanism" he proposes as biologically plausible, "some of them are untested, and maybe some of them will never be tested." *Id*. at 28-29. The critical step in the proposed mechanism is the hypothesis that endotoxin can permit the pertussis toxin to breach the blood-brain barrier, but the acellular version of the pertussis vaccine now in use has very little endotoxin. *Id*. at 19-20. According to Dr. Kinsbourne, because of the advent of the acellular vaccine, "there is no longer any motivation for studying [his proposed mechanism] at all." Tr. at 27. But he testified that "serious neurological events such as encephalopathies and serious seizures, had greatly decreased in incidence since [the acellular] vaccine has been introduced," which he felt was "some validation of" or "consistent with" his claim, although "not a direct demonstration." *Id.* at 20, 30. In response to a question from the Special Master, Dr. Kinsbourne conceded that among Molly's medical records there were no "particular oratory findings or physiological findings which further support" his theory. *Id.* at 32.

Doctor Baumann agreed that the parts of Dr. Kinsbourne's theory concerning the neurotoxicity of pertussis toxin, the toxin's ability to injure the brain, and the role of G proteins were accepted. *Id.* at 93-94. But he was of the opinion that the reason "no study has really addressed" Dr. Kinsbourne's theory "is that people in the field don't think it's biologically plausible and do not wish to spend their time and effort investigating." *Id*. at 94. Respondent's expert conceded that the acellular vaccine "has a significantly lower seizure rate than the whole cell" version. *Id*. at 95. But he pointed out that Dr. Kinsbourne's theory was not studied even though it was raised before the introduction of the acellular vaccine; that scientists would still have academic reasons for studying it; and that potential terrorist use of biological agents would maintain interest in such mechanisms of injury. Tr. at 95. He opined that "to have a theory and not have it critiqued in the literature . . . is a very strong indication that people don't find it biologically plausible." *Id*.

Borin v. Sec'y of HHS, 2003 WL 21439673, at *11 (Fed. Cl. Spec. Mstr. May 29, 2003).

After reviewing the testimony, the Special Master stressed Dr. Kinsbourne's concession that his theory had not been tested, and the expert's acknowledgment "that Molly's medical records do not contain any evidence supporting the application of his blood brain barrier theory in Molly's case." *Moberly I*, 2005 WL 1793416, at *28. On this basis, the Special Master concluded that the theory was of "dubious" utility "as an element of proof of causation-in-fact in this case." *Id*.

3. The Special Master Determined Molly's Medical Records Do Not Prove Causation

Petitioner's expert also testified that he had a "clinical" basis for believing that the DPT vaccination caused Molly's seizure disorder. Tr. at 10. He explained that she had "no evidence of any prior brain [insult] or seizure tendency" before her second DPT vaccination, but shortly after the vaccination suffered "not just generalized convulsions, not just febrile, benign febrile seizures, but a seizure type which clearly is based on abnormality of the cerebrum of the brain." *Id.* at 10-11. He described the resulting seizures as focal, affecting separately her left and right sides, and "quite relentless." *Id*. at 11. Doctor Kinsbourne testified that the seizure activity "indicates a child with damaged brain," and he saw "evidence for no other causation for that damage than the DPT vaccination." *Id.* Petitioner's expert added that he was "aware of sufficient literature to indicate that DPT is capable of causing, on rare occasion, damage such as Molly has." *Id.*[16] He concluded that based on his review of Molly's medical records, the medical literature of which he was aware, and his proposed biological mechanism, that the DPT vaccination was the cause of Molly's seizure disorder. Tr. at 21.

As was discussed above, Dr. Baumann was of the opinion that Molly "didn't have any of the evidence of an acute severe neurologic injury" following the initial seizures. *Id*. at 47. Rather, he believed that she had idiopathic epilepsy. *Id*. at 50. Respondent's expert attributed her seizures to a brain abnormality that was already present, that reflected "the way" her brain was "put together and wired." *Id.* at 57, 75-76, 102. He suggested that Molly's lack of seizures in her first four months after birth, until the second DPT vaccination, did not undercut the conclusion that she suffered from idiopathic epilepsy based on a brain abnormality, as human beings "don't have seizures in utero," and most epileptics do not have seizures neonatally or shortly thereafter. *Id*. at 103.

The Special Master was "not persuaded by Dr. Kinsbourne's testimony regarding 'literature' and Molly's clinical condition." *Moberly I*, 2005 WL 1793416, at *23. He found "an important aspect of Dr. Kinsbourne's opinion to be largely undeveloped," as -- besides the NCES -- petitioner's expert "did not discuss other literature that buttresses possibly his opinion." *Id*. The Special Master also was "not satisfied completely by Dr. Kinsbourne's description of Molly's clinical condition," as the expert failed to specify whether one of Molly's initial seizures

[16] The only literature that was submitted or mentioned by Dr. Kinsbourne was the NCES, the Follow-up Study, and the two Institute of Medicine reports which discussed the NCES. *See* Pet.'s Ex. 33(B)-(D); Tr. at 11-17, 20-21, 25-26, 33-39, 41-44.

was febrile, and "many special masters have ruled that medical evidence establishes that DPT does not cause 'afebrile' seizures." *Id*. (citations omitted). The Special Master also considered whether "some combination of the evidence that [petitioner] has submitted establishes more likely than not that Molly's September 17, 1996 DPT vaccination caused actually Molly's intractable seizure disorder." *Id*. at *28. He concluded that "the evidence as a whole does not demonstrate affirmatively a logical sequence of cause and effect," as he "deem[ed] much of Ms. Moberly's evidence to be infirm," and "was not impressed that Dr. Kinsbourne has expressed credibly and rationally an opinion using the disparate elements of the evidence." *Id.*

C. Petitioner's Motion for Review

After the Special Master decided that she was not entitled to compensation, petitioner moved for review in this Court pursuant to 42 U.S.C. § 300aa-12(e). Petitioner organized her argument on review into two objections to the Special Master's decision. First, she argues that the Special Master erred as a matter of law, alleging that he imposed upon her a higher standard than the preponderance of the evidence specified in 42 U.S.C. § 300aa-13(a)(1). *See* Pet.'s Mem. in Supp. of Mot. for Rev. ("Pet.'s Mem.") at 2-3, 19-29. To petitioner, the Special Master's determinations that the NCES does not support her claim and that Dr. Kinsbourne's proposed mechanism of injury was "dubious" and "not tested" are the equivalent of "requir[ing] scientific certainty." *Id*. at 20. Petitioner argues that certain facts that "are not in dispute" add up to a demonstration by a preponderance of the evidence that Molly's injury was likely caused by the DPT vaccine, and thus "statistically significant epidemiology" or "a generally accepted, 'tested,' mechanism of injury" is unnecessary. *Id*. at 19-20. She contends that the purpose of the Vaccine Act was contravened by the Special Master's requirement that she prove that the DPT vaccination was the "cause-in-fact" of, or caused "actually," Molly's injury. *See id.* at 22-23. Petitioner argues that she met her burden of proving causation, as Molly's first seizures occurred within 72 hours of a DPT vaccination, which is the "scientifically appropriate time for a neurological event following a pertussis vaccine" per the Vaccine Injury Table. *Id*. at 28 (citing 42 U.S.C. § 300aa-14). Since "no alternate cause of [Molly's] illness has been identified," petitioner concludes that causation has been demonstrated by a preponderance of the evidence. *Id.* at 29.

Petitioner's second objection is that the Special Master abused his discretion by not properly evaluating the scientific evidence presented. Pet.'s Mem. at 3. She contends that her expert testified that "Molly's seizures are clearly part of a common 'pathological process,'" and thus the statistical conclusions of the NCES should apply. *Id*. at 30 (citing Tr. 15-16). Petitioner states that this pathological process "is both obvious and continuing," and then provides a time-line summarizing Molly's seizure disorder. Pet.'s Mem. at 31-33. Without any record citation in support, petitioner alleges that "[e]ach expert . . . and each treating physician viewed Molly's seizure disorder as a single pathological process." *Id.* at 33.[17] She later states that she has

[17] She includes among these experts Dr. Ronald S. Gabriel, who did not testify at the hearing and whose report was found "worthless" by the Special Master due, in part, to the

demonstrated that the "single pathological process" exception to the rule for dating the onset of illness applies in Molly's case, based on unspecified "medical records, affidavits, expert reports, expert testimony, a plausible mechanism of injury, scientific literature, and an epidemiological study." *Id*. at 35. Petitioner contends the Special Master acted arbitrarily in not finding that the conclusions of the NCES applied to Molly's circumstances. *Id*. She further argues that the Special Master acted arbitrarily, abused his discretion, and legally erred because he "completely ignored the findings" of the Follow-up Study. *Id*. According to petitioner, the Follow-up Study shows, among other things, that: (1) Molly was at higher risk for permanent neurological damage because she experienced seizures within thirty-six hours after her DPT vaccination, Pet.'s Mem. at 36-37; (2) Molly's appearance as neurologically intact during an initial follow-up after hospitalization meant little, as neurological damage appeared later than the NCES authors originally postulated, *id.* at 38-39; and (3) "children with an initial seizure after the pertussis vaccine were **8.6** times more likely to have chronic seizures than even those children who had seizures before the pertussis!" *Id.* at 41 (citing Follow-up Study at 116).

Respondent disagrees with petitioner's characterization of the standard of proof applied by the Special Master. While conceding that the Federal Circuit "properly rejected the proposition that a petitioner may never prevail . . . without medical literature support" in a case where petitioner must prove causation, respondent observes that this "does not mean that a medical witness's theory must be accepted without any consideration of whether that theory is reliable." Resp.'s Resp. to Pet.'s Mot. for Rev. ("Resp.'s Br.") at 7 (citing *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005)). Respondent notes that any causation theory "must be supported by a 'sound and reliable medical or scientific explanation.'" *Id.* (citing *Knudsen v. Sec'y of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994)). In respondent's view, the Special Master did not require scientific certainty, but was seeking to fulfill his duties under the Act. *See id.* at 9 (citing 42 U.S.C. § 300aa-13(b)(1)). Petitioner failed to prove her case, according to respondent, not "because the [S]pecial [M]aster imposed an impermissible evidentiary burden, but because the evidence she submitted was considered and found infirm." *Id.* at 9-10.

Respondent also objects to petitioner's characterization of the facts. *See id.* at 2-3, 10-15. Respondent disputes that there was any agreement "that the temporal relationship between Molly's vaccination and her symptoms was 'scientifically and medically appropriate.'" *Id*. at 2; *see also id.* at 11-12. The Secretary argues that the NCES was the only evidence offered by petitioner to attempt to establish an appropriate temporal relationship, and that the time frame employed in the Vaccine Injury Table -- pertaining to a different injury than is alleged in this case -- is irrelevant. Resp.'s Br. at 12 & n.8. Respondent contends that the Special Master's evaluation of the credibility of Dr. Kinsbourne's testimony concerning the NCES is a finding of fact entitled to a high amount of deference. *Id.* at 10-11 (citing *Munn v. Sec'y of HHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992); *Lampe v. Sec'y of HHS*, 219 F.3d 1357, 1360 (Fed. Cir. 2000); *Hambsch v. Dept. of Treasury*, 796 F.2d 430, 436 (Fed. Cir. 1986)). Respondent argues that

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proposed witness's failure to explain how Molly's condition could meet the definition of encephalopathy adopted for purposes of the Vaccine Act. *See* Order (Sept. 3, 1999).

regardless of the significance of the temporal association, petitioner failed to establish "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury," *id.* at 13 (quoting *Grant v. Sec'y of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)), as the Special Master found Dr. Kinsbourne's causation theory to be dubious. *Id.* at 14. Respondent also disputes petitioner's assertion that the parties agreed that a "single pathological process" is responsible for Molly's seizures. *Id.* at 16 n.9 (citing Tr. at 57).

Finally, respondent contests petitioner's claim that the Special Master arbitrarily ignored the Follow-up Study. *Id*. at 16-17. The Secretary points out that the only testimony concerning the Follow-up Study was contained in a brief exchange between petitioner's counsel and Dr. Kinsbourne. *See* Resp.'s Br. at 16-17 (citing Tr. at 20-21). Petitioner's expert merely stated that "the follow-up did demonstrate that a proportion of cases" in which the onset of a "seizural encephalopathy" occurred within one week of vaccination "did indeed result in permanent brain damage," and that the Institute of Medicine "accepted those conclusions." Tr. at 21. Respondent contends that the Special Master "considered the study and afforded it the same significance as did petitioner's medical witness," Resp.'s Br. at 17, as the Special Master noted that the "Follow-up Study revealed that NCES 'case children' exhibited 'chronic neurologic dysfunction' at a remarkably higher rate than 'non-case children.'" *Id*. (quoting *Moberly I*, 2005 WL 1793416, at *2). Respondent asserts that petitioner's discussion of the Follow-up Study is merely an "attempt to expand upon [Dr. Kinsbourne's] testimony regarding the study" and "constitutes nothing more than unsupported argument, made for the first time on review." *Id.*

D. Remand from this Court and the Special Master's Decision on Remand

After reviewing petitioner's memorandum, the Secretary's response, the Special Master's decision, and the record, it was apparent to the Court that the critical issue on review concerned the manner in which the NCES authors determined the date of onset of illnesses -- in particular, what the authors meant by the words "a single pathological process." Order (Dec. 27, 2005) at 1. This did not present a legal question, as would the interpretation of a contract or statute, and did not call for the usual role of an expert to interpret data and determine how closely a child's case fits with a particular study. *Id*. Instead, the interpretation of the phrase in question required knowledge of exactly what the NCES authors did. *Id*. at 1-2. Recognizing this, and mindful of the important role that epidemiological studies can play in establishing causation under the Vaccine Act, *id*. at 1 (citing *Knudsen v. Sec'y of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994)), the Court remanded the case to the Special Master to allow the parties -- through oral or written testimony of NCES authors, records reflecting the medical history of relevant NCES case children, or whatever else the parties could produce -- "to supplement the record with evidence demonstrating how the NCES authors determined that a series of convulsions were 'part of a single pathological process.'" *Id.* at 2.

The Special Master convened three status conferences to discuss proceedings on remand. *See Moberly II*, 2006 WL 659522, at *2-3. At the third of these "[t]he parties represented that they had not discovered any evidence that may satisfy the intent of the Court's remand order" and

"stated that they would not be supplementing the record." *Id*. at *3. The Special Master noted that petitioner argued that the Follow-up Study supported Dr. Kinsbourne's interpretation of the onset dating exception. *Id*. at *3 n.7. But "Dr. Kinsbourne did not assert in any way that the [Follow-up Study] had any bearing on his interpretation of the NCES exception," and petitioner did not file a supplemental opinion from her expert covering this point. *Id*. With no additional evidence to review, and after he "studied carefully his original decision," the Special Master decided on remand not to revise his original decision. *Id*. at *3.

The Special Master did, however, address petitioner's argument raised during proceedings on remand that the Federal Circuit's decision in *Althen v. Secretary of HHS*, 418 F.3d 1274 (Fed. Cir. 2005) "alters somehow the legal analysis of actual causation claims in the [Vaccine] Program." *Moberly II*, 2006 WL 659522, at *3. In *Althen* the Federal Circuit rejected the approach followed by the Chief Special Master -- first enunciated in *Stevens v. Secretary of Department of Health and Human Services*, No. 99-0594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001) -- which required "objective confirmation" of medical theories by peer-reviewed literature. *See Althen*, 418 F.3d at 1279-81. The Special Master explained that he had never followed, but instead explicitly rejected the *Stevens* approach, as it "offends" the instruction of the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-94 (1993). *Moberly II*, 2006 WL 659522, at *4 (citing *Daubert*, 509 U.S. at 593-94).

He then reiterated his determination 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." *Id*. The Special Master noted that none of Molly's treating physicians "offered ever a solid statement that" this vaccination "caused probably Molly's condition." *Id.* (citing Pet.'s Ex. 5 at 1-4; Pet.'s Ex. 9 at 3-4; Pet.'s Ex. 11 at 4-5; Pet.'s Ex. 12 at 7). He quoted the comment of her "first treating neurologist" that her "'presentation would not fall within any of the recognized syndromes that 'may' be related to pertussis.'" *Id.* (quoting Pet.'s Ex. 5 at 4). Since the medical records alone did not suffice to prove causation, petitioner "depend[ed] upon medical opinion to establish her claim." *Id*. (citing *Althen*, 418 F.3d at 1279-81).

The Special Master then elaborated upon his assessment of petitioner's expert's testimony. He stated he was "not in the least impressed by" this testimony. *Moberly II*, 2006 WL 659522, at *5. He found the testimony regarding the NCES "shockingly poor," creating "serious concerns" about the witness's credibility as an expert on the NCES. *Id*. Not only had the Special Master "rejected entirely Dr. Kinsbourne's testimony about the NCES," but he decided that the witness's "'contradictory and confusing' testimony about the NCES infected all other parts of [his] testimony." *Id*. at *6 (quoting *Moberly I*, 2005 WL 1793416, at *26). Thus, in the Special Master's judgment, petitioner's expert witness did not provide a credible and rational medical opinion. *Id.*

E. The Supplemental Briefing

After the remand decision was entered, the Court permitted the filing of supplemental briefs by the parties. Petitioner used the opportunity for two primary purposes. First, petitioner recapitulated and refined arguments made in her initial memorandum. *See* Pet.'s Supp. Mem. in Support of Mot. for Rev. ("Pet.'s Supp. Mem.") at 3-6. She argues that in focusing upon the NCES and Dr. Kinsbourne, the Special Master failed to consider "the record as a whole." *Id.* at 4 (quoting 42 U.S.C. § 300aa-13(a)(1)). She contends that, even without Dr. Kinsbourne's testimony and the NCES, the record contains "preponderant evidence in support of her claim." *Id.* at 4-5. She argues that this evidence, "albeit circumstantial," is found among "the filed affidavits, Molly's medical records, the statements of her treating physicians contained in her records, the expert opinion of Dr. Gabriel, and in the concessions of respondent's expert Dr. Baumann." *Id*. at 5. In this regard, petitioner highlights the temporal relationship between Molly's first seizures and her second DPT vaccination, noted by some of her doctors, and the fact that her physician ordered that Molly receive no more pertussis vaccinations. *Id*. at 7 (citing, *inter alia*, Pet.'s Ex. 5 at 2; Pet.'s Ex. 9 at 3; Pet.'s Ex. 12 at 7, 9). Petitioner also cites the testimony of respondent's expert as showing that he "agreed that all of Molly's seizures are 'related' . . . and due to 'one' particular cause." *Id*. at 10 (quoting Tr. at 64, 84). She argues that the case was "doomed from the outset" because the Special Master framed the critical issues around the NCES and, in her view, "required [her] to show conclusive scientific literature to qualify for compensation." Pet.'s Supp. Mem. at 8 & n.7. And she contends that, although the NCES and the Follow-up Study were "unnecessary" due to the other proof in the record, "these studies provide substantial circumstantial evidence" and contain conclusions which "need no 'expert' explanations." *Id*. at 6.

Second, petitioner stressed the applicability of post-*Moberly I* case law, especially *Althen*. *See* Pet.'s Supp. Mem. at 2 & n.2, 13-18. Relying on *Althen*'s approval of circumstantial evidence, acknowledgment of the limited nature of scientific literature on causation, and admonition that "'close calls regarding causation'" should favor claimants, *id.* at 13 (quoting *Althen*, 418 F.3d at 1280), petitioner contends that the Special Master "*required* her to prove [Molly] would have been an NCES case child," and thus erred. *Id.* at 13-14 (emphasis in original). Petitioner argues that Molly's medical records show that the seizures occurred "well within a scientifically appropriate time." *See id.* at 15 (citing *Pafford v. Sec'y of HHS*, 64 Fed. Cl. 19, 31(2005);[18] *Hocraffer v. Sec'y of HHS*, 63 Fed. Cl. 765, 775 (2005)). And petitioner contends that Molly's "treating physicians associated her injury with her vaccine," *id*. at 16, citing the Federal Circuit opinion in *Capizzano v. Secretary of Health and Human Services*, 440 F.3d 1317 (Fed. Cir. 2006) -- which stated such medical opinions are "quite probative" as "treating physicians are likely to be in the best position to determine whether 'a logical sequence

[18] After the petitioner submitted her supplemental memorandum, the Federal Circuit affirmed the decision announced in *Pafford*. *See Pafford v. Sec'y of HHS*, 451 F.3d 1352, 1360 (Fed. Cir. 2006).

of cause and effect shows that the vaccination was the reason for the injury.'" *Id*. at 1326 (quoting *Althen*, 418 F.3d at 1280).

Respondent's response to petitioner's supplemental memorandum contained four central arguments. First, regarding petitioner's criticism of the Special Master's framing of the critical issues around the NCES, respondent points out that petitioner's counsel agreed with this statement of the issues at the hearing, Resp.'s Resp. to Pet.'s Supp. Mem. ("Resp.'s Supp.") at 5 (citing Tr. at 3-4); that petitioner stated in her written closing argument that the issue to be decided was whether Molly's seizures were "part of a single, pathologic process, such that for purposes of the NCES study the date of onset of her illness would have been deemed to be the date of the first seizure," Resp.'s Supp. at 5-6 (quoting Pet.'s Closing Arg. at 8-9); and that petitioner "noted no disagreement" with these issues in her initial memorandum supporting her motion for review. *Id.* at 6 (citing Pet.'s Mem. at 10). Respondent thus concludes that this argument was waived by petitioner. *Id*. at 6 n.3 (citing Vaccine Rule ("VR") 8(f), App. B to the Rules of the United States Court of Federal Claims ("RCFC")).

Second, the Secretary argues that it was petitioner who raised the issue of the applicability of the NCES as "the l[i]nchpin" of her case, to attempt to establish that "Molly's series of seizures occurred within a 'scientifically significant' time." Resp.'s Supp. at 8. While *Althen* rejected any requirement of "objective confirmation" via medical literature, *id*. at 6-7 (citing *Althen*, 418 F.3d at 1279-80), respondent argues that this does not mean that the Special Master must find reliable any theory upon which petitioner chooses to proceed. *See id.* at 6-10 (citing, *inter alia*, VR 8(c) (noting a special master may only consider relevant and reliable evidence); *Knudsen*, 35 F.3d at 548 (holding that a "sound and reliable medical or scientific explanation" must support a theory of causation); *Grant v. Sec'y of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("A reputable medical or scientific explanation must support this logical sequence of cause and effect.")). Third, respondent disputes petitioner's assertion that the physicians who treated Molly believed that the vaccine caused her condition. Resp.'s Supp. at 11-13. The Secretary notes to the contrary that Dr. Torkelson, after acknowledging that Molly's parents were concerned that her seizures were related to the vaccine, wrote, "at present, her presentation would not fall within any of the recognized syndromes that 'may' be related to pertussis." Resp.'s Supp. at 12 (quoting Pet.'s Ex. 5 at 4). Respondent argues that, in any event, treating physicians' statements must themselves satisfy the tests propounded in *Grant* and *Althen* to be proof of actual causation. *Id*. at 13.

Finally, respondent reiterates the argument that petitioner's claims concerning the Follow-up Study are merely arguments raised for the first time on review, and now contends that under Vaccine Rule 8(f) "they cannot form a basis for disturbing the [S]pecial [M]aster's decision." *Id*. at 11. Respondent repeats the contention that the Special Master "afforded [the Follow-up Study] no less significance than did petitioner's medical witness," and argues that this study's conclusions would, in any event, not apply to Molly unless her case fell under the exception for dating the onset illnesses. *Id*.

In her reply, petitioner denies that she waived any facts or arguments, and contends that the argument that "the record as a whole" establishes causation cannot be waived, as it is part of the Vaccine Act. *See* Pet.'s Reply at 5-6 (quoting 42 U.S.C. § 300aa-13(a)(1)). In addition, petitioner claims that the Special Master "flatly ignored" rules that required him to "'afford[] each party a full and fair opportunity to present its case and creat[e] a record sufficient to allow review'" and to "'consider all relevant and reliable evidence, governed by principles of fundamental fairness to both parties.'" *Id.* at 6 n.11 (quoting VR 3(b), 8(c)).

II. DISCUSSION

Prior to the hearing before the Special Master, the parties "agreed that the underlying facts of this case, as reflected in [Molly's] medical records, and upon which the parties' medical witnesses will base their opinions, are not in dispute." Joint Status Report (Jan. 10, 2003) at 1. These records show that Molly Moberly had no reported seizures her first four months after birth. *See* Pet.'s Ex. 12 at 4-6. On September 19, 1996, within 36 hours of receiving her second DPT vaccination, she had two brief seizures of a very short duration, accompanied by a low fever. Pet.'s Ex. 16 at 1. Seventeen days later, she experienced two more convulsions, first shaking on one side of the body, then the other, each lasting a couple of minutes. Pet.'s Ex. 2 at 5. Over the next seven and one-half months, Molly suffered seizures of varying lengths and varying frequencies, going at times as long as eleven weeks without seizures but then having several in the same day. *See Moberly I*, 2005 WL 1793416, at *7-12. Her first prolonged seizure, lasting about an hour, occurred on May 26, 1997, necessitating a hospital emergency room visit. Pet.'s Ex. 15 at 2-3. Within the next month, she had several seizures accompanied by a high fever, *see* Pet.'s Ex. 3 at 3, but then appeared to be seizure free for seven weeks. But then on August 11, 1997 she suffered six seizures, including a prolonged one lasting between 45 minutes and one hour, and was admitted to the hospital. Pet.'s Ex. 21 at 2, 4. Her seizures continue to persist, resulting in severe developmental delays. *See Moberly I*, 2005 WL 1793416, at *14-17; Pet.'s Ex. 50 at 16-17.

With this factual backdrop, petitioner's expert witness testified that it was his clinical opinion that the second DPT vaccination injured Molly's brain, causing her seizure disorder. Tr. at 10-11, 21. He also testified as to what he terms is a "biologically plausible" mechanism explaining how a DPT vaccination can cause this type of neurological damage. *Id*. at 18-20, 27. But the bulk of his testimony concerned whether the statistical conclusions of the NCES support Molly's petition. *See id*. at 11-17, 21, 25-26, 33-39, 41-44. After the parties filed written closing arguments, the Special Master determined that petitioner was not entitled to compensation, rejecting petitioner's expert witness's opinions concerning Molly's clinical condition, the NCES, and the proposed mechanism of injury, and finding that the evidence in the record does not establish that the DPT vaccination caused Molly's injuries. *Moberly I*, 2005 WL 1793416, at *23-26, 28.

Petitioner raises two objections to the Special Master's decision. Her first is that allegedly undisputed facts in the record establish causation by a preponderance of the evidence,

and that the Special Master committed a legal error by imposing a burden of proof which she characterizes as "scientific certainty." *See* Pet.'s Mem. at 2-3, 19-29; Pet.'s Supp. Mem. at 4-7. Her second is that the Special Master's evaluation of the NCES was arbitrary, and his treatment of the Follow-up Study was arbitrary, an abuse of discretion, and an error of law. *See* Pet.'s Mem. at 3, 29-43. Before considering the merits of these objections, the Court must first address the threshold issue of whether any of these arguments or facts were waived by petitioner.

Vaccine Rule 8(f) provides: "Any 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." Respondent argues that petitioner had acquiesced in the Special Master's statements that the hearing was held for the purpose of addressing two issues: the applicability of the NCES to petitioner's case, and whether that was sufficient to prove causation. Resp.'s Supp. at 5-6. Thus, the Secretary seems to contend that petitioner cannot now argue that the "record as a whole" establishes that the DPT vaccination caused Molly's condition. *See id*. at 6 n.3. But, as was discussed above, petitioner's medical expert was allowed to testify as to matters other than the NCES. *See* Tr. at 10-11, 18-20, 26-30, 32. While Petitioner's Prehearing Memorandum stated that the Special Master "must decide whether the NCES applies in Molly's case," it identified two broader issues for resolution: "Can DPT cause seizures and encephalopathy? [¶] Did the DPT cause seizures and encephalopathy in Molly's case?" Pet.'s Prehrg. Mem. at 1. Although petitioner's written closing argument stated "[t]he issue" was whether Molly's seizures were "part of a single, pathologic process" for purposes of the exception to the rule for dating the onset of illnesses under the NCES, Pet.'s Closing Arg. at 8-9, petitioner also discussed Dr. Kinsbourne's clinical opinion, *see id*. at 11, and provided two detailed recitations of facts based on Molly's medical records. *See id*. at 1-8, 19-21. And, of course, the Special Master himself addressed both Dr. Kinsbourne's opinion as to Molly's clinical condition, as well as whether any combination of record evidence establishes that the DPT vaccination caused Molly's illness. *Moberly I*, 2005 WL 1793416, at *23, 28.

Under these circumstances, the Court cannot conclude that petitioner has waived the argument that facts in the record establish that DPT was the cause of Molly's injury. Those facts, however, are limited to those which the parties agreed were the underlying facts of this case -- namely, those reflected in Molly's medical records. *See* Joint Status Report (Jan. 10, 2003) at 1. Other materials, such as petitioner's affidavits or the opinion of Dr. Gabriel, cannot be relied upon to establish causation. This brings us to the second waiver argument of respondent, which concerns one of these other materials -- the Follow-up Study. Respondent argues that the Follow-up Study can have no greater significance than it was given in Dr. Kinsbourne's testimony. Resp.'s Supp. at 11; Resp.'s Br. at 16-17 (citing Tr. at 20-21). The Follow-up Study does not appear to have even been mentioned in petitioner's written closing argument. *See* Pet.'s Closing Arg. at 1-23. Respondent is correct that any argument concerning this study, other than that which can be implied from the testimony of Dr. Kinsbourne, has been waived by petitioner's failure to raise it in the record before the Special Master. *See* VR 8(f). The Court now turns to petitioner's objections.

A. Legal Standards

1. Court's Standard of Review of a Special Master's Decision

Under the Vaccine Act, the special master must award compensation if, "on the record as a whole," he finds "that the petitioner has demonstrated by a preponderance of the evidence" the claims of the petition. 42 U.S.C. § 300aa-13(a)(1)(A). By this same standard, the special master must find that nothing else is responsible for causing the injury. *Id*. § 300aa-13(a)(1)(B). "The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." *Id*. § 300aa-13(a)(1). The special master must consider all the "relevant medical and scientific evidence contained in the record," including any "diagnosis, conclusion, medical judgment, or autopsy . . . regarding the nature, causation, and aggravation of petitioner's illness, disability, injury, condition, or death" and "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." *Id*. § 300aa-13(b)(1). The Act further specifies that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court." *Id*. The special master is entrusted with evaluating the "weight to be afforded to any" of these sources of information. *Id*. A special master's "assessments of the credibility of the witnesses" are "virtually unchallengeable on appeal." *Lampe v. Sec'y of HHS*, 219 F.3d 1357, 1362 (Fed. Cir. 2000). This deference rests on the special master's "broad discretion in determining credibility because he saw the witnesses and heard the testimony." *Bradley v. Sec'y of Dep't of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Dep't of HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). These records are "generally contemporaneous to the medical events," and "accuracy has an extra premium" because a patient's proper treatment is "hanging in the balance." *Id*. Moreover, because medical records are contemporaneous documentary evidence, conflicting oral testimony "deserves little weight." *Id*. (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947)).

In reviewing a special master's decision, the Court may "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. § 300aa-12(e)(2)(B). Findings of fact are to be reviewed under the "arbitrary and capricious" standard; legal questions are to be reviewed under the "not in accordance with law" standard; and an abuse of discretion standard is used for discretionary rulings. *See Munn v. Sec'y of Dep't of HHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). With respect to the arbitrary and capricious review, "no uniform definition of this standard has emerged," but it is "a highly deferential standard of review" such that "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Sec'y of Dep't of HHS*, 940 F.2d 1518, 1527-28 (1991).

2. Standard of Causation in Vaccine Cases

A special master may award compensation through an "off-table" or "causation-in-fact" case. *Pafford v. Sec'y of Dep't of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). Causation-in-fact -- the basis for the legal entitlement to compensation when a petitioner's injury is either not listed in the Vaccine Injury Table or did not occur within the time period set forth in the Table -- must be proven under two formulations adopted by the Federal Circuit. *See Pafford*, 451 F.3d at 1355. The petitioner must establish that the vaccine was both a "but-for" cause of the injury and a substantial factor in causing the injury. *See Shyface v. Sec'y of Dep't of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Under a three-part test more recently articulated by the Circuit, the petitioner must prove "(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." *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).[19] The petitioner bears the burden of proving causation by preponderant evidence. *See* 42 U.S.C. § 300aa-13(a)(1)(A).

A petitioner must show more than a proximate temporal relationship between the vaccination and the injury to meet her burden of showing actual causation. *Althen*, 418 F.3d at 1278; *see also Grant v. Sec'y of Dep't of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Furthermore, "[t]here may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine." *Capizzano v. Sec'y of Dep't of HHS*, 440 F.3d 1317, 1327 (Fed. Cir. 2006). A petitioner could meet the first and third prongs of the *Althen* test without "satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence." *Id*. The sequence only has to be "'logical' and legally probable, not medically or scientifically certain," and thus can be established by "epidemiological evidence and [a] clinical picture," even "without detailed medical and scientific exposition on the biological mechanisms." *Knudsen*, 35 F.3d at 548-49. Nonetheless, the Federal Circuit has stated that while "epidemiological studies are probative medical evidence relevant to causation," *Grant*, 956 F.2d at 1149, they are not always dispositive. *See id.*

If a petitioner satisfies her burden, she is entitled to compensation "unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Althen*, 418 F.3d at 1278 (quoting *Knudsen*, 35 F.3d at 547) (alteration in original).

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[19] Although the Federal Circuit has described the *Althen* test as an "alternative," the very same opinion makes plain that the *Althen* "prongs must cumulatively show" that the *Shyface* standard is met. *See Pafford*, 451 F.3d at 1355.

3. Standard for Evaluating Expert Testimony

In determining the reliability or sufficiency of scientific evidence of causation in a case, the special masters are guided by the factors identified by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals*, *Inc*., 509 U.S. 579 (1993). *See Terran v. Sec'y of HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999); *Manville v. Sec'y of HHS*, 63 Fed. Cl. 482, 489-91 (2004). These non-exclusive factors relate to an "assessment of whether the reasoning or methodology underlying [expert scientific] testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592-93. According to the Supreme Court, "a key question" to be asked of a proposed theory is "whether it can be (and has been) tested," as the scientific method entails "generating hypotheses and testing them to see if they can be falsified." *Daubert*, 509 U.S. at 593 (citations omitted). "Another pertinent consideration is whether the theory . . . has been subjected to peer review and publication." *Id.* And "[w]idespread acceptance can be an important factor" in determining the reliability of a theory, although it is not necessary. *Id.* at 594, 597. Concerning the applicability of epidemiological studies, the Supreme Court has explained: "[N]othing in . . . *Daubert* . . . requires a [trial] court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and opinion proffered." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

B. The Special Master's Evaluation of the Epidemiological Studies was Not Improper

Taking petitioner's second objection first, she contends that the Special Master did not properly evaluate and apply the statistical conclusions of the NCES, and improperly ignored the Follow-up Study. *See* Pet.'s Mem. at 3, 29-43; Pet.'s Supp. Mem. at 2. As a preliminary matter, the Court notes that petitioner appears, under this objection, to invoke all three grounds for setting aside the findings or conclusions of a special master -- if by the terms "error of law," *see* Pet.'s Mem. at 3, 35, 37; Pet.'s Supp. Mem. at 2, or "legal error," *see* Pet.'s Mem. at 43, she means "not in accordance with law" as per 42 U.S.C. § 300aa-12(e)(2)(B). But this objection concerns the interpretation of language contained in epidemiological studies, not statutory construction or any other legal issue (such as contract interpretation), and thus the "not in accordance with law" standard does not apply. *See Hines*, 940 F.2d at 1527. Petitioner neither cites any authority supporting the use of this standard in the circumstances presented, nor explains why or how this standard would apply.[20]

[20] In a few places, petitioner asserts in passing that the conclusions of the NCES are "legally binding," Pet.'s Mem. at 17; Pet.'s Supp. Mem. at 11, or are "legally conclusive." Pet.'s Mem. at 3. Perhaps petitioner is suggesting that since some special masters have found causation to be established on the basis of the NCES and the timely onset of a neurological injury that would have been reportable under the NCES -- as the Special Master explained in detail, *see Moberly I*, 2005 WL 1793416, at *2 -- this somehow makes the question of the applicability of the NCES to Molly's case one of law. The Federal Circuit, however, in discussing the NCES has noted, "[a] study of many individual cases may be useful evidence as to causation, but it does not

Nor does the second standard, "abuse of discretion," apply to this objection. The Federal Circuit has explained that this standard is "ordinarily used where the tribunal under review had a finite range of discretion (e.g. to select a penalty, or to award a specific sum as damages, from within a range of permissible alternatives)," *Hines*, 940 F.2d at 1527, but no such limits are involved here. And while the Federal Circuit has recognized that the abuse of discretion standard applies "where the special master excludes evidence," *Munn*, 970 F.2d at 870 n.10, the Special Master did not in this case exclude the NCES, or even the Follow-up Study, from the record. Rather, he considered the NCES, and the testimony of the expert witnesses concerning the "exception" to the rule for dating the onset of illnesses contained in the NCES, *see Moberly I*, 2005 WL 1793416, at *3-6, 18-19, 21-26, and concluded that "the exception . . . is not a suitable basis on which to ground an actual causation claim." *Id*. at *26. This is a "factual determination," *see Lampe*, 219 F.3d at 1366, involving the weight and probative value assigned evidence, and the credibility of an expert witness. As such, the objection is properly considered under the "arbitrary and capricious" standard. *See id.* at 1360; *Munn*, 970 F.2d at 871. Under this "uniquely deferential" standard, our court "is not to second guess the Special Master[s'] fact-intensive conclusions," "especially" when "medical evidence of causation is in dispute." *Hodges v. Sec'y of Dept. of HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993). And to the extent an expert witness's credibility is at issue, a special master's determination is "virtually unchallengeable," *Lampe*, 219 F.3d at 1362, under the "broad discretion" given the special master due to his having seen and heard the testimony. *Bradley*, 991 F.2d at 1575; *see also Doe v. Sec'y of HHS*, 76 Fed. Cl. 328, 335 (2007).

The Court notes that petitioner attempts to insulate this objection from the last point, by arguing that "the conclusions of" the NCES and the Follow-up Study "need no 'expert' explanations," and as record evidence "should have been weighed independently of any testimony by" her expert witness. Pet.'s Supp. Mem. at 6; Pet.'s Reply at 4. Petitioner provides no citation to any authority for this proposition, and the Court is not aware of any Federal Circuit precedents that are directly on point. The proposition is consistent, however, with the Federal Circuit's recognition of the special masters as a "group of specialists" who employ "accumulated expertise in the field" when deciding the merits of cases, *Hodges*, 9 F.3d at 961, and as having been "accorded the status of expert" by Congress. *Munn*, 970 F.2d at 871; *see also Lampe*, 219 F.3d at 1362 (quoting *Hodges*, 9 F.3d at 961). Indirect support for the proposition can be found in the Federal Circuit's opinion in *Grant*, where the court considered whether epidemiological studies cited by the Secretary outweighed the evidence supplied by the petitioner, and found that they did not (without mentioning any need for expert testimony interpreting the former). *See*

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compel the finder of fact to find causation in a particular case." *Lampe*, 219 F.3d at 1366 (citing *Hodges v. Sec'y of Dep't of HHS*, 9 F.3d 958, 961 n.4 (Fed. Cir. 1993)). In any event, the real question is still one of fact -- did Molly's history "fit the NCES paradigm closely enough for that study to shed light on the issue of causation in her case"? *Id*.

Grant, 956 F.2d at 1148-49.[21] And there are opinions from our court which (uncritically) seem to indicate that a special master had evaluated medical studies firsthand, without reference to the opinions of expert witnesses. *See*, *e.g.*, *Estep v. Sec'y of Dep't of HHS*, 28 Fed. Cl. 664, 668-69 (1993). Perhaps, given the role of special masters under the Vaccine Act, the proposition is so obvious and uncontroversial that it never needed to be stated in an opinion. In any event, the Court has no trouble concluding that a special master may interpret and apply the conclusions of a medical study introduced into the record by a party, without the guidance of expert witnesses.

But merely because a special master, as a medical expert himself, *may* interpret a medical study without assistance does not mean that he *must* conclude that a particular study, or aspects of a study, can be understood absent such assistance. His conclusion to the contrary, of course, is subject to review for arbitrariness under the deferential standard which applies to the evaluation and weighing of evidence. *See Lampe*, 219 F.3d at 1360. But as the Federal Circuit has explained, the NCES "does not compel the finder of fact to find causation in a particular case," as "to be instructive" an epidemiological study's "conclusions must fit the facts of the case under consideration." *Id*. at 1365-66. The problem facing petitioner in this regard is that the NCES only supports the claim that a DPT vaccination caused certain serious neurological illnesses when the onset of one of those illnesses was within seven days, and in particular within 72 hours, of receipt of the vaccination. *See* NCES at 148. Only one category of these illnesses was suffered by Molly -- convulsions lasting more than a half hour. *See id*. at 157. The earliest of these occurred on May 26, 1997, *see* Tr. at 12; Pet.'s Ex. 15 at 2-3, and the first one to meet the NCES protocol of a hospital admission occurred August 11, 1997. *See* Tr. at 90; Pet.'s Ex. 21 at 2; *see also Moberly I*, 2005 WL 1793416, at *24-25 & n.16. These convulsions occurred hundreds more than seven days after Molly received the September 17, 1996 DPT vaccination, and thus the NCES would not appear to be instructive on the question of causation.

The only way to fit Molly's case under the conclusions of the NCES would be to date the onset of these later convulsions to coincide with the brief seizures Molly experienced on September 19, 1996. As was discussed above, an epidemiologist and a pediatrician from the NCES team were assigned to each child's case to determine the date of onset of the qualifying illness, which was "the date on which acute neurological symptoms or signs related to the current illness first developed." NCES at 102 (emphasis omitted). The qualifying illnesses did not include all seizures or series of seizures, but instead those of a particular severity -- namely, those lasting more than one-half hour, those followed by a coma lasting at least two hours, or those followed by paralysis or new "neurological signs" lasting at least twenty-four hours, *id*. at 157 -- and "[u]ncomplicated fits or a series of fits lasting less than about ½ hour" were specifically excluded. *Id.* Since only certain seizures were deemed severe enough to warrant inclusion of a child in the study, this would suggest that the "symptoms or signs related to" the qualifying

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[21] The Federal Circuit also quoted from Vaccine Act legislative history which disjunctively referenced "evidence in the form of scientific studies or expert medical testimony," suggesting that the former does not require the latter. *See Grant*, 956 F.2d at 1148 (quoting H.R. Rep. No. 908, pt. 1, at 15 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6356).

illness, for purposes of determining the date of onset, *see id*. at 102, would be restricted to ones relating to the severe seizures, rather than earlier, less severe ones.

But the NCES authors recognized the possibility that an immunization which is "followed by one or more short convulsions" might be said to have "'triggered' a series of events leading much later to a serious convulsion, and perhaps to brain damage." *Id.* at 146. On the other hand, they also recognized that "[i]t could equally well be argued that such children might have had a lowered threshold for convulsions in response to a variety of stimuli," so that the vaccination was only responsible for the initial short convulsions. NCES at 146-47. As a result, the NCES authors adopted an approach, called an "exception" to the date of onset rule by the parties' experts, *see* Tr. at 12, 57, by which they "attempted" to "determin[e]" when to count earlier convulsions as relating to the subsequent, qualifying illness for purposes of their analysis. NCES at 147. Not every child with a history of seizures and whose qualifying illness was a severe convulsion had the date of onset of illness traced back to the initial seizures. The Follow-up Study seems to indicate that of 334 case children identified as having had severe convulsions as the qualifying illness, 64 were known to have had convulsions prior to the onset of the qualifying illness. *See* Follow-up Study at 79 (Table 10.1). But some case children did have the date of onset of their qualifying illness traced back prior to the date of hospitalization under the "exception." A table in the NCES shows that using the date of onset rather than the date of hospital admission shifted, on net, a total of sixteen cases into different temporal relationship categories. *See* NCES at 119 (Table V.12).[22] As has been much discussed, the NCES authors explained their approach as follows:

> When a series of fits appeared to be part of a single pathological process, as in cases with progressive mental deterioration, for the purpose of the Study the *date of onset of illness* was taken to be the *date of the first convulsion*. However, where a child had a series of convulsions *without* any obvious and continuing underlying clinical or pathological explanation, the date of onset of that child's illness was regarded as the date of the major convulsion for which the child was admitted to hospital and notified to the Study. The preceding convulsions in these cases were regarded as part of the previous medical history.

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[22] The number immunized within 72 hours of illness jumped from 14 to 20; immunized more than 72 hours but within 7 days moved from 12 to 15; immunized more than 7 but within 14 days increased from 10 to 12; and immunized more than 14 but within 28 days jumped from 22 to 27. *See* NCES at 119. From this table, of course, it cannot be determined which of these were due to the operation of the regular date of onset rule and which were due to the prior convulsions exception; how many actually had different onset dates from admission dates (since these net figures obscure the amount of actual movement); and how many had dates of onset which were far removed from the date of hospital admission (including those which would as a consequence pre-date immunization or would still have occurred more than 28 days after immunization).

Id. at 147 (emphasis in original).

The Special Master carefully reviewed the relevant language from the NCES. *See Moberly I*, 2005 WL 1793416, at *4-5, 25-26. He found that the "NCES authors provided little, if any, objective information about the process they used to assess cases" under this date of onset exception. *Id.* at *26. He recognized that the "NCES authors did not define explicitly their use of the term 'single pathological process,'" and that they "offered just one descriptive example of cases comporting with their concept of" this term, that being "cases involving 'progressive mental deterioration.'" *Id*. (citing NCES at 147). And he noted that, although the study's "language implies that NCES authors deemed other cases to reflect 'a single pathological process,'" the "NCES authors were wholly silent on the types of other cases that may have comported with their concept of" this term. *Id.* (citing NCES at 147). The Court's review of the NCES shows that these judgments are correct, and confirms that it was not arbitrary for the Special Master to conclude that the NCES on its face lacked sufficient information concerning how this onset-dating exception was applied to enable one to determine whether Molly's circumstances could have invoked it.

Turning to the testimony of petitioner's expert witness for guidance, the Special Master explained in detail how this "testimony highlights particularly the difficulty with applying the NCES in this case." *Id.* He noted that petitioner's expert "expressed readily that the exception that he cites 'is not clear,'" *id.* (citing Tr. at 13), and recounted the expert's shifting views concerning the meaning and significance of the "progressive mental deterioration" example. *Moberly I*, 2005 WL 1793416, at *26 (citing Tr. at 13, 15, 34-38, 41-42). The Special Master concluded that petitioner's expert's "testimony about the exception in the NCES was contradictory and confusing," and that this attempt at interpreting the language was "simply speculation." *Id*. Not being able to understand the meaning of this exception, based on the ambiguous term "single pathological process," the Special Master decided the exception was "not a suitable basis" for placing the onset of Molly's severe and prolonged seizures within close proximity of her second DPT vaccination. *Id*. Thus, he held that the "statistical conclusions of NCES data do not apply to Molly." *Id*.

On these points, as well, the Special Master's decision was not arbitrary and capricious. He considered the language of the NCES and the testimony of petitioner's expert, and articulated a rational basis for his conclusion that the expert's testimony was not credible or persuasive. *See id*. at *24-26. A review of petitioner's expert's testimony reveals that this witness did not seem to have a firm understanding of the very exception from the NCES that he sought to invoke. The study identified "cases with progressive mental deterioration" as those in which "a series of fits appeared to be part of a single pathological process," and which were thus given an onset date based on "the date of the first convulsion." NCES at 147. But rather than recognizing these cases as examples of cases to which the dating exception was applied by the NCES authors, Dr. Kinsbourne testified that the reference to "cases with progressive mental deterioration" instead meant "diseases which have nothing to do with DPT." Tr. at 41; *see also id.* at 14-17, 44. After it was pointed out that this category of cases was used to define cases involving "a single

pathological process," he attempted to brush them off as merely a poor example given to illustrate such a process, but without consequence since "the question of DPT causation would not even be raised legitimately if there were a history of progressive loss of mental skills." *Id*. at 34. But upon realizing that this language appeared to describe what the NCES authors actually did in determining the dates of onset of illnesses, petitioner's expert provided a different interpretation of the phrase; opined that Molly "did progressively lose mental skills"; and tried to explain that this progressive loss could have occurred after the severe, qualifying seizures were suffered and still reflect a single pathological process linking the latter seizures to the earlier seizures. *See id*. at 35-37.

In light of this testimony, which the Special Master found to be "shockingly poor" and creating "serious concerns" about the witness's credibility as an expert on the NCES, *Moberly II*, 2006 WL 659522, at *5, it cannot be said that the Special Master's credibility determination was arbitrary and capricious. The Special Master further explained that petitioner's expert's testimony regarding the meaning of "progressive mental deterioration" was "particularly 'disquieting.'" *Id*. (citing *Moberly I*, 2005 WL 1793416, at *27). If Dr. Kinsbourne were correct in his interpretation of this term, this meant that the "NCES authors counted cases, and based statistical conclusions on cases, that could be in no way related to DPT." *Moberly I*, 2005 WL 1793416, at *27. Thus, either Dr. Kinsbourne was wrong, or the NCES authors were wrong, and neither alternative helps petitioner's case. Moreover, the Special Master also explained that respondent's expert's "interpretation of NCES protocol appears more correct than" petitioner's expert's interpretation, in the context of the hospital admission requirement. *Id.* at *24 n.16. Especially considering the great deference given to the credibility determinations of a special master who has seen and heard the testimony of an expert witness, *see Lampe*, 219 F.3d at 1362; *Bradley*, 991 F.2d at 1575; *Doe*, 76 Fed. Cl. at 335, the Special Master's rejection of Dr. Kinsbourne's interpretation of the NCES exception was not arbitrary and capricious.

Petitioner's assertion that respondent's expert "viewed Molly's seizure disorder as a single pathological process," Pet.'s Mem. at 33, made without a record citation, is not borne out by a review of the hearing transcript. Petitioner appears to be arguing that because Dr. Baumann focused on the phrase "obvious and continuing underlying clinical or pathological explanation" in deciphering what the NCES authors meant by "a single pathological process," and recognized that Molly's seizures were all related in that they all resulted from the same brain abnormality, he was conceding that "a single pathological process" was involved. *See id*. at 31. Thus, according to petitioner, since Molly's seizures were "obvious and continuing," the "single pathological process" must have been, as well. *Id*. But Dr. Baumann clearly testified as to his opinion that Molly's seizure disorder was *not* a single pathological process. *See* Tr. at 74-75, 99. He explained that he interpreted the NCES language to mean the presence of an "overt neurologic disease." *Id.* at 74. In respondent's expert's view, seizure disorder was not such a disease, because children can appear to be otherwise well between seizures, and physicians cannot predict their future outcomes. *See id*. at 73-75. He also explained that if a seizure disorder were considered a single pathological process for purposes of the date of onset exception, then the exception would have been applied to every child with epilepsy -- which obviously was not the

case. *See id*. at 58, 99. Thus, the record does not contain any concession on this point from the Secretary's witness.

Unless the NCES exception can be understood to apply to Molly's situation, her prolonged convulsions were not in close enough proximity to the DPT vaccination for the NCES statistical conclusions "to shed light on the issue of causation in her case." *Lampe*, 219 F.3d at 1366. The Special Master was not convinced that the exception would apply, and he "appears to have considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." *Hines*, 940 F.2d at 1527-28. The Court remanded the matter to give petitioner the opportunity to supplement the record with additional evidence shedding light on how the NCES authors used the date of onset exception, but none was apparently found. *See Moberly II*, 2006 WL 659522, at *3. The Special Master's determination that the NCES was not probative of causation in Molly's case was amply explained and supported, and accordingly will not be set aside by the Court.

The Follow-up Study warrants a briefer discussion. As petitioner acknowledges, the results of the ten-year follow-up study "were published in two separate journals." Pet.'s Mem. at 39. Only one of these two articles was submitted into the record by petitioner. That article, attached as an exhibit to the expert report of Dr. Kinsbourne, looked at the subsequent medical histories of all the case children and controls who could be located a decade after the original study. *See* Pet.'s Ex. 33(C) (a copy of the article which has been referenced throughout this opinion as the "Follow-up Study"). A close review of this article reveals that it does not address at all the issue of DPT association or causation; rather, it states that "the findings and conclusions" regarding "the possibility that pertussis vaccine might sometimes lead to permanent brain damage" were "reported elsewhere." *See id.* at 2. This other article, with the specific findings regarding DPT, is cited by petitioner in passing, *see* Pet.'s Mem. at 35 n.21, 39 n.22 (citing David Miller, *et al.*, *Pertussis Immunisation and Serious Acute Neurological Illnesses in Children*, 307 BRIT. MED. J. 1171-76 (1993)), but she inexplicably did not submit it for the record. The third piece of medical literature (other than the NCES and the Follow-up Study) submitted with Dr. Kinsbourne's initial report -- a 1994 report by the Institute of Medicine -- relates, however, that the pertussis-specific article found that case children who had received a DPT vaccination within 7 days prior to their qualifying illness were significantly more likely than control children to suffer serious dysfunction, but "no more or no less likely" than the other case children. 1994 IOM at 10. Based on this, the Institute of Medicine report concluded that "the *balance of evidence is consistent with* a causal relation between DPT and the forms of chronic nervous system dysfunction described in the NCES in those children who experience a serious acute neurologic illness within 7 days after receiving DPT vaccine," *id.* at 15, but "*remains insufficient to indicate* the presence or absence of a causal relation between DPT and chronic nervous system dysfunction under any other circumstances." *Id*. at 16.

In the initial proceedings before the Special Master, the Follow-up Study was only referenced twice. The first time was only an implicit mention, as Dr. Kinsbourne in his first report wrote: "The Institute of Medicine endorsed the conclusion of the NCES in a report dated

1994, both with respect to the acute event *and the neurological disabilities that are its aftermath*." Pet.'s Ex. 33 at 3 (emphasis added). The second was during Dr. Kinsbourne's testimony, in which he briefly explained that "the NCES had, of course, by its design, been able to document only the acute event" which qualified a child as a case child, but "the follow-up did demonstrate that a proportion of cases of that kind did indeed result in permanent brain damage." Tr. at 21. Petitioner made no mention of the Follow-up Study in her written closing statement before the Special Master. *See* Pet.'s Closing Arg. at 1-23. In his decision, the Special Master noted that some special masters "reason that the 1993 NCES Follow-up Study revealed that NCES 'case children' exhibited 'chronic neurologic dysfunction' at a remarkably higher rate than 'non-case children,'" and quoted the passage from the Institute of Medicine report concerning the relationship between DPT vaccinations received 7 days before the qualifying illness and chronic nervous system dysfunction. *Moberly I*, 2005 WL 1793416, at *2 (citations omitted).

With this backdrop, the Court considers petitioner's contention that the Special Master erred by "completely ignor[ing] the findings of the 10-Year Follow-up Study." Pet.'s Mem. at 35. This aspect of her objection is without merit. In the first place, even if one were to charitably construe Dr. Kinsbourne's two brief allusions to the results of the follow-up as being tantamount to the explicit claim that children who suffered an NCES qualifying illness within 7 days after receiving a DPT vaccination had an elevated risk of permanent brain damage, this claim still turns on the date of onset of the qualifying illness. Thus, these results have no relevance unless the date of onset exception can be shown to apply in Molly's case. As the Special Master noted, petitioner's expert did not identify anything in the Follow-up Study that sheds any light on the meaning of the exception. *Moberly II*, 2006 WL 659522, at *3 n.7. Second, petitioner attempted to raise the argument on remand that she makes here, that the Follow-up Study demonstrates that the date of onset of Molly's prolonged seizures was within 36 hours of a DPT vaccination. *Compare* Pet.'s Mem. at 37 *with* Tr. (Feb. 13, 2006) at 8. The Special Master, appropriately, determined that such argument from counsel was not additional evidence comporting with the remand order. *Moberly II*, 2006 WL 659522, at *3 n.7. The argument, moreover, is unavailing, as the Follow-up Study in the record discusses, nearly verbatim, the *general* rule used in the NCES for dating the onset of illnesses, *not* the exception for cases with prior convulsions. *See* Follow-up Study at 16-17; NCES at 102. The Follow-up Study does not appear to mention the "single pathological process" matter, and, as was discussed above, the general rule would not pre-date Molly's severe convulsions to the time of her initial, brief seizures.

Finally, even if it were the case that the Special Master erred in not giving the Follow-up Study more attention than the petitioner did, this error would be harmless. *See Johnson v. Sec'y of HHS*, 33 Fed. Cl. 712, 728-29 (1995), *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996) (table). While it would seem to be the case that the pertussis-specific report that was never submitted for the record supports the argument that a DPT vaccination can cause permanent neurological damage when a qualifying illness occurs within 7 days after the vaccination, *see* 1994 IOM at 2, 15, petitioner's arguments that the Follow-up Study in the record provides similar support are simply incorrect. The findings that petitioner cites and discusses, *see* Pet.'s Mem. at 36-43, do not

concern the relationship between long-term neurological dysfunction and DPT vaccination, but rather analyze the relationship between long-term neurological dysfunction *and the illness which qualified the case children for inclusion in the NCES*. *See* Follow-up Study at 17-18, 78-88, 92-94, 116. Thus, for example, petitioner is mistaken in construing the "[l]oglinear model"on page 116 of the Follow-up Study as comparing odds of chronic seizures based on whether or not a child had seizures before or after *receiving a pertussis vaccination* -- instead, the relevant point of departure was whether seizures were experienced *before the qualifying (or index) illness*. *Compare* Pet.'s Mem. at 41 (referencing pertussis vaccine) *with* Follow-up Study at 116 (referencing "index illness"). The Follow-up Study may support the proposition that Molly's prolonged seizures, suffered in 1997, have caused her subsequent neurological problems, but has no bearing on the question of what caused those particular seizures. The Special Master's treatment of the Follow-up Study provides no ground for setting aside his findings and conclusions in this case.

C. The Special Master Did Not Err in Finding that Petitioner Failed to Prove Causation

Petitioner's other objection is an allegation that the Special Master applied the wrong standard for proving causation. *See* Pet.'s Mem. at 2, 19-29; Pet.'s Supp. Mem. at 3-6, 13-18; Pet.'s Reply at 2, 4. According to petitioner, the Special Master in effect required "scientific certainty," *see* Pet.'s Mem. at 20, 22-23, and thus failed to consider whether a preponderance of the evidence contained in Molly's medical records demonstrated that the DPT vaccination caused her seizure disorder. *See id*. at 29; Pet.'s Supp. Mem. at 3-6. Petitioner argues that the Special Master required that she prove her case with either epidemiological evidence or a generally accepted mechanism of injury, Pet.'s Mem. at 20, 23; Pet.'s Supp. Mem. at 3-4, 13, and that the evidence when properly considered proves causation. *See* Pet.'s Mem. at 29; Pet.'s Supp. Mem. at 18.

Unlike the rulings reviewed in *Althen*, 418 F.3d at 1279-81, and *Capizzano*, 440 F.3d at 1324-27, the Special Master in this case did not impose any rigid, extra-statutory requirements for proof of causation-in-fact. He properly stated that petitioner's burden was to "demonstrate by the preponderance of the evidence that" the DPT vaccination was both a "but for" cause of Molly's injury, and a "substantial factor in bringing [it] about." *Moberly I*, 2005 WL 1793416, at *1 (citing *Shyface*, 165 F.3d at 1352). He correctly explained that petitioner needed to "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*. (quoting *Grant*, 956 F.2d at 1148). And he accurately recognized that petitioner's "medical or scientific explanation need not be 'medically or scientifically certain.'" *Id*. (quoting *Knudsen*, 35 F.3d at 549). It bears noting that the Special Master relied upon the same authorities that were used by the Federal Circuit to restate the proper test for causation-in-fact. *See Althen*, 418 F.3d at 1278-80 (citing, *inter alia*, *Shyface*, 165 F.3d at 1352-53; *Grant*, 956 F.2d at 1148-49; and *Knudsen*, 35 F.3d at 549). What petitioner really objects to is that the Special Master found that Molly's medical records "alone do not reflect an independent basis for him to conclude more likely than not that Molly's September 17, 1996 DPT vaccination caused actually Molly's

intractable seizure disorder accompanied by developmental delay," *Moberly I*, 2005 WL 1793416, at *22, and then found the epidemiological evidence and expert testimony insufficient to establish causation. *See id*. at *23-26, 28. His decision was an example of the "case-by-case" approach endorsed in *Althen*, 418 F.3d at 1281, and did not impose an erroneous legal standard. Indeed, in the decision on remand he explained that he had expressly rejected the *Stevens* formula for causation. *Moberly II*, 2006 WL 659522, at *3-4.

The Special Master "canvassed thoroughly the record," *Moberly I*, 2005 WL 1793416, at *22, and discussed the facts in great detail. *See id*. at *6-17. After a close review of the record, and a careful reading of the two decisions, the Court concludes that the Special Master was not arbitrary and capricious in deciding "that the evidence as a whole does not demonstrate affirmatively a logical sequence of cause and effect." *Id*. at *28. While Molly's medical records establish a temporal relationship between the second DPT vaccination and her first reported seizures, *see* Pet.'s Ex. 9 at 8; Pet.'s Ex. 16 at 1, this "mere showing" does not "suffice[], without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278 (citing *Grant*, 956 F.2d at 1149). Petitioner attempts to leverage the probative value of the temporal proximity by arguing that "[t]he Vaccine Table defines the scientifically appropriate time for a neurological event following a pertussis vaccine," Pet.'s Mem. at 28, but the Vaccine Table does not deal with just *any* neurological event, but only "encephalopathy" as defined for purposes of the Act. *See* 42 C.F.R. § 100.3(a), (b)(2). Whether 36 or 72 hours is the scientifically appropriate time within which a seizure disorder will be caused by a DPT vaccination -- and, if so, whether more severe seizures than those suffered at that time by Molly would be the hallmark of such an injury -- is not established by the record evidence.[23] And, as was addressed above, the NCES would not support a theory of causation, as Molly's initial seizures had not been as long as half an hour.

If it were the case that any of Molly's treating physicians had provided a diagnosis concluding that a DPT vaccination had caused her seizure disorder, such evidence *could* be sufficient proof of causation, *see Capizzano*, 440 F.3d at 1326, and would, at the least, require the Special Master to explain how other evidence outweighed these medical records. Petitioner argues that Molly's "treating physicians associated her injury with her vaccine." Pet.'s Supp. Mem. at 16. While petitioner seems to imply that this association was causal, citing the *Capizzano* discussion of "a logical sequence of cause and effect," she provides no record citations with this argument. *See id*. (citing *Capizzano*, 440 F.3d at 1326); *see also* Pet.'s Reply at 7. Presumably, she is referring to the medical records she highlighted earlier in her supplemental brief. *See* Pet.'s Supp. Mem. at 7 (citing, *inter alia*, Pet.'s Ex. 5 at 2, 4; Pet.'s Ex. 9 at 3; Pet.'s Ex. 12 at 7, 9); *see also* Pet.'s Mem. at 5-6, 9. Citing nearly all of these same records, the Special Master found that "several of Molly's treating physicians noted the *temporal* relationship between Molly's September 17, 1996 DPT vaccination and Molly's initial brief

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[23] Molly's brief medical history prior to her initial seizures does not reduce the likelihood that their temporal proximity to the DPT vaccination was coincidental. *See* Tr. at 103 (Dr. Baumann testifying that epileptics rarely would experience seizures neonatally or shortly thereafter).

seizures," but determined that "none offered ever a solid statement that . . . [the] vaccination caused probably Molly's condition." *Moberly II*, 2006 WL 659522, at *4 (citing Pet.'s Ex. 5 at 1-4; Pet.'s Ex. 9 at 3-4; Pet.'s Ex. 11 at 4-5; Pet.'s Ex. 12 at 7). The Special Master emphasized that "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.'" *Id*. (citing Pet.'s Ex. 5 at 4).

A review of the record shows that it was not arbitrary and capricious for the Special Master to have found that none of Molly's treating physicians concluded that a DPT vaccination was the cause of her seizure disorder. Looking first at the records highlighted by petitioner, Dr. Torkelson's first report to the referring physician -- dated October 10, 1996 -- merely notes that Molly "apparently did receive an immunization about two days prior to the first episode." Pet.'s Ex. 5 at 2; *see also Moberly I*, 2005 WL 1793416, at *8. At that time, he was "inclined to look at this as a transient disturbance." Pet.'s Ex. 5 at 3. The record from Molly's pediatrician, dated October 24, 1996, states: "Of note is that [the seizures] began two days after Molly[']s second set of immunizations and she will review this further with Dr. Torkelson when he calls." Pet.'s Ex. 12 at 7. Doctor Torkelson's report the following month noted the etiology of Molly's disorder was "unknown" and related that her "parents are understandably concerned that it is related to the DPT immunization." Pet.'s Ex. 5 at 4. This is the report in which the doctor disclaimed a connection with "any of the recognized syndromes that 'may' be related to pertussis," *id.*, and in it Dr. Torkelson ultimately concluded "we may never know the cause" of her seizures. *Id*. at 5. After discussing Molly's seizures, the December 17, 1996 record from her pediatrician's office reads simply, "[a]pparently we will not be able to give her the Pertussis vaccination anymore," without further explanation. *See* Pet.'s Ex. 12 at 9. And the Children's Hospital record dated April 1, 1997 noted the "question of whether [Molly's] seizures are related to her DPT vaccine," Pet.'s Ex. 9 at 3; stated her seizure disorder was of "unclear etiology," *id.* at 4; and concluded that "[c]ausality cannot be proven at this time between the seizures and the immunizations" but "the possibility that the DPT may have provoked an underlying convulsive condition cannot be ruled out." *Id.* The doctors "recommend[ed] limiting the next booster to the tetanus (T) component only," in order "to minimize the possibility of future events." *Id.*[24] In sum, the medical records cited by the petitioner note the temporal relationship of Molly's first seizures with the second DPT vaccination, acknowledge her parents' concerns, admit the *possibility* of DPT causation, and prescribe the precautionary measure of avoiding pertussis vaccinations. Each of these records falls far short of an opinion that Molly's second DPT vaccination caused her seizure disorder.

The Court cannot find any instance of a treating physician concluding that Molly's seizure disorder was caused by the DPT vaccination. An October 24, 1996 record from Molly's pediatrician's office noted that *Mrs. Moberly* had called to say that an unidentified person at the

[24] The doctors writing this record hoped that "by the time she is two years old, the nature of Molly's seizure disorder will be more clear and future immunizations with diphtheria vaccine and/or acellular pertussis vaccine can be discussed." Pet.'s Ex. 9 at 4.

"State Health Department" told her that "they felt that Molly's seizures could *possibly* be a reaction to a DPT" and recommended that Molly receive only the DT vaccination "in the future." Pet.'s Ex. 12 at 8 (emphasis added). A record from the same office two weeks later described her "seizure disorder" as "[i]diopathic." *Id.* A November 13, 1996 record from Nemaha County Hospital mentions pertussis in the notes concerning Molly's seizure disorder, but states "etiology as yet uncertain." Pet.'s Ex. 4 at 8; *see also* Pet. ¶ 12. The record from that visit also noted her "[h]istory of idiopathic seizure disorder." Pet.'s Ex. 4 at 5. The medical records relating to Molly's November 1997 seizure evaluation at Children's Health Care-St. Paul noted the "question of the underlying cause for seizure which may also be causing delays in her development." Pet.'s Ex. 11 at 4. The doctors at that facility apparently considered the link between the vaccination and her condition, but drew no conclusions on causation: "The issue of immunization was discussed as some people do appear to have immunological link to seizures. . . . At this point Molly does not have symptoms for any progressive disease, and further researching would probably not be beneficial." Pet.'s Ex. 11 at 4-5. In March 1998, Dr. Torkelson still was of the opinion that the etiology of Molly's seizures remained "uncertain." Pet.'s Ex. 22 at 2. The hospital records relating to Molly's May 23, 1998 seizures, which note her "seizure disorder that was diagnosed at four months of age after a DPT shot," Pet.'s Ex. 8 at 11; *see* Pet.'s Mem. at 9, also noted that the "[e]tiology for seizures or developmental delay is unknown." Pet.'s Ex. 8 at 9. And when Molly was three years old she was again evaluated at Nemaha County Hospital, where a doctor noted that Molly had "a long standing history of seizure disorder felt to *possibly* be due to reaction to DPT vaccination." Pet.'s Ex. 30 at 3 (emphasis added). All but the last of these records was discussed by the Special Master. *See Moberly I*, 2005 WL 1793416, at *8-12, 15-17. His finding that Molly's treating physicians failed to conclude that the DPT vaccination caused her seizure disorder is amply supported by the record, and was not arbitrary and capricious.

Finding petitioner's claim unproven by Molly's medical records or the opinions of Molly's treating physicians, the Special Master turned to petitioner's expert witness for a medical opinion that could substantiate causation, under 42 U.S.C. § 300aa-13(a)(1)(A). *See id*. at *22; *Moberly II*, 2006 WL 659522, at *6. But, as was discussed in part II.B above, the Special Master did not find petitioner's expert witness to be credible. He "decided that Dr. Kinsbourne's 'contradictory and confusing' testimony about the NCES infected all other parts of Dr. Kinsbourne's testimony." *Moberly II*, 2006 WL 659522, at *6 (quoting *Moberly I*, 2005 WL 1793416, at *26). The Special Master was "not in the least impressed by" this testimony, which he found to be "shockingly poor." *Id*. at *5. As the Court has already explained, the Special Master provided ample justification for his assessment of the credibility and reliability of this witness, and these assessments must be given great deference by reviewing courts. *See Lampe*, 219 F.3d at 1362; *Bradley*, 991 F.2d at 1575; *Doe*, 76 Fed. Cl. at 335.

The Special Master did not find Dr. Kinsbourne's cursory clinical opinion concerning causation to be persuasive. *Moberly I*, 2005 WL 1793416, at *23. Petitioner's expert testified that he was "aware of sufficient literature to indicate that the DPT vaccination is capable of causing, on rare occasion, damage such as Molly has." Tr. at 11. In this very brief discussion of

his clinical opinion, he failed to identify this literature to which he referred. *See id.* at 10-11. No medical literature was submitted or discussed by Dr. Kinsbourne in this regard other than the NCES and related reports, *see supra* note 16, which were not probative for the reasons discussed above. The Special Master thus, properly, concluded that "an important aspect of Dr. Kinsbourne's opinion [was] largely undeveloped." *Moberly I*, 2005 WL 1793416, at *23. Drawing upon his "accumulated expertise," *Hodges*, 9 F.3d at 961, the Special Master also identified as unsatisfactory petitioner's expert's failure to "distinguish *medically* Molly's seizure with fever as a 'febrile' seizure." *Moberly I*, 2005 WL 1793416, at *23 (citation omitted). These findings are adequately explained and supported, and are not arbitrary and capricious.

Finally, the Special Master did not err in finding Dr. Kinsbourne's proposed biological mechanism of causation to be "dubious." *Id*. at *28. A petitioner's "logical sequence of cause and effect" must be "supported by 'reputable medical or scientific explanation.'" *Althen*, 418 F.3d at 1278 (quoting *Grant*, 956 F.2d at 1148). But petitioner's expert's credibility was damaged by his testimony about the NCES, *see Moberly II*, 2006 WL 659522, at *5-6, which itself was enough to support a finding that his opinion was unreliable in other regards. And while *Althen* does not allow special masters to rigidly require any type of medical literature as an element of proof of a petitioner's case, *see Althen*, 418 F.3d at 1280, it also does not prevent them from considering the *Daubert* factors relating to the reliability of expert scientific testimony. *See Terran*, 195 F.3d at 1316; *Knudsen*, 35 F.3d at 548-49. Petitioner's expert testified that not only was his theory untested, but he could not imagine how it could be tested and thought that "maybe" some steps of his theory "will never be tested." *See* Tr. at 27-29. But whether a theory has been or can be tested is a "key question" in considering its reliability. *Daubert*, 509 U.S. at 593. While the Federal Circuit has clearly held that "identification and proof of specific biological mechanisms" are not required to establish causation, *see Knudsen*, 35 F.3d at 549, and that "a sequence hitherto unproven in medicine" can suffice, *see Althen*, 418 F.3d at 1280, this does not mean that a special master cannot consider the reliability and soundness of theories of biological mechanisms of causation that are proposed by parties.

The Special Master noted that petitioner's expert "conceded that his blood brain barrier theory has not been tested," *Moberly I*, 2005 WL 1793416, at *28 (citing Tr. at 27, 29), and that he "acknowledged that Molly's medical records do not contain any evidence supporting the application of his blood brain barrier theory in Molly's case." *Id*. (citing Tr. at 32). Particularly in light of the Special Master's assessment of the credibility of this witness, these findings adequately support his conclusion that the witness's theory was dubious. The Special Master did not improperly require "scientific certainty," or the general acceptance of the theory proposed -- although in these circumstances the total lack of acceptance, *see* Tr. at 27, 94-95, would have been a proper consideration. *See Daubert*, 509 U.S. at 594, 597. His conclusion that petitioner's expert had not "expressed credibly and rationally an opinion using the disparate elements of the evidence," *Moberly I*, 2005 WL 1793416, at *28, cannot be set aside, as it is not arbitrary and capricious.

III. CONCLUSION

After reviewing the submissions of the parties, the evidence in the record, the transcript of the hearing, and the decisions of the Special Master, for the foregoing reasons the Court concludes that the Special Master did not err when he denied compensation to petitioner under the Vaccine Act. The Special Master applied the correct legal standard and was not arbitrary or capricious in his decision.

Accordingly, the decision of the special master is **SUSTAINED**. The petition for review is **DISMISSED** with prejudice. The Clerk of Court is directed to enter judgment for respondent.

IT IS SO ORDERED.

s/ Victor J. Wolski
VICTOR J. WOLSKI
Judge