In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. [Redacted]V
Filed: January 30, 2009
Reissued for Publication: February 2, 2009
Reissued Redacted: March 4, 2009

TO BE PUBLISHED
PUBLIC DOCUMENT

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JANE DOE/34,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

****

REDACTED DECISION

Petitioner filed a Motion Not to Publish on February 18, 2009. In addition to requesting the decision not be published, petitioner also requested redaction of the docket number, any reference to petitioner's name, the name of her parents, family members and other witness. Respondent contacted the undersigned's office on February 3, 2009 stating respondent objected to petitioner's Motion Not to Publish and petitioner's request to redact the names of other witnesses. Respondent does not object to petitioner's request to redact the docket number, petitioner's name and the names of her family members. Petitioner's Motion is **granted** to the extent of redacting the docket number, petitioner's name and the names of her family members. There is no basis for petitioner's other requests included in the Motion, and they are denied. **The attached decision is ordered reissued in redacted form**. The Clerk of Court is instructed to withdraw the original version from publicly accessible records.

IT IS SO ORDERED

Gary J. Golkiewicz
Chief Special Master

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JANE DOE/34,	*	
Petitioner,	*	Neurological Sequelae of Reye's Syndrome; Expert Credibility.
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Paul S. Dannenberg, Paul Dannenberg, Esq., Huntington, VT, for petitioner

Glenn Alexander MacLeod, U.S. Department of Justice, Washington D.C., for respondent

DECISION ON REMAND[1]

GOLKIEWICZ, Chief Special Master.

On July 13, 2007, Judge Nancy B. Firestone granted-in-part petitioner's Motion for Review of the undersigned's Decision on Remand awarding $5,841.50 for petitioner's damages

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id.

related to suffering Reye's Syndrome for approximately 30 days. Order on Petitioner's Motion for Review, filed July 13, 2007. Judge Firestone remanded the case to the undersigned for the "limited purpose of establishing the appropriate damages period and making a damages determination." Id. at 5.

To address this issue, petitioner filed on December 11, 2007, as petitioner's Exhibit F (hereinafter "P Ex _") the expert report and CV of Dr. Ronald Jacobson. Respondent filed on March 11, 2008, the expert report and CV of Dr. John T. MacDonald. Respondent's Exhibits K and L (hereinafter "R Ex _"). In addition, at the undersigned's request, and over the stated objection of petitioner, Dr. James Heubi would be contacted to testify at the evidentiary Hearing. Dr. Heubi was petitioner's expert during the causation portion of this case and had filed previously on March 27, 2006, an affidavit addressing the issue of how long JANE DOE/34's illness lasted. P Ex B, filed March 27, 2006; see also P Memorandum Regarding Petitioners Claim for Compensation, Exhibit A, filed Dec. 14, 2005.[2] Unfortunately, due to conflicts in the doctors' schedules, the Hearing on this matter could not be scheduled until August 7, 2008. Following the Hearing, the parties filed post-Hearing briefs on November 7, 2008.[3] The case is now ripe for decision. After considering the entire record, the undersigned affirms the prior finding of an "approximate period of damages of 30 days." Hocraffer v. Sec'y of HHS, No. 99-533V, 2007 WL 914914 * 2 (Fed. Cl. Spec. Mstr. Feb. 28, 2007) (relying on both the testimony of Dr. Heubi and Dr. MacDonald).

The essential facts pertaining to the determination of the appropriate damages period are

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[2]The undersigned notes that the haphazard filing of petitioner's Exhibits was unprofessional, failed to conform with the Guidelines for Practitioners, and made location of and citation to documents extremely difficult. See Guidelines for Practice under the National Vaccine Injury Compensation Program, § II (B)(6) ("**B. Documents that Must Accompany the Petition** .. . 6. Organization of Documents The documents submitted with each petition must be organized into **separately numbered** exhibits (e.g., Ex. 1 might be the birth certificate ...) Exhibits should be numbered in logical order (preferable chronologically).") (emphasis added) (available at www.uscfc.uscourts.gov). Contrary to the Guidelines, petitioner utilized letters as opposed to numbers in identifying her exhibits. Other than duplicating respondent's lettered exhibits, this was a relatively minor issue. The major issue was petitioner's use of the same letter to identify different exhibits. For example, petitioner filed petitioner's Memorandum Regarding Petitioners Claim for Compensation on December 15, 2005, which contained Exhibits A-D. Specifically, this filing contained a copy of a document titled "The BlueCard Program, Definition of Terms" and labeled as Exhibit B. Shortly thereafter, petitioner filed another Exhibit B, Affidavit of James E. Heubi, M.D., on March 27, 2006. In other instances, petitioner used the same letter, but denoted the second usage as "2d series." Compare P Exs M, N, & O, filed on August 12, 2002 with Exs M, N, & O attached to petitioner's post-Hearing Brief. There simply is no excuse for petitioner's disorderly filing in this case.

[3] Thereafter, respondent requested informally a two-week period to decide whether to respond to petitioner's medical literature filed, inappropriately so, with petitioner's post-Hearing brief. Respondent did not file a response.

not in dispute. It is the interpretation of these medical facts that are at issue. The undersigned will only discuss the relevant facts. JANE DOE/34 was born on February 10, 1981. JANE DOE/34 received her first HepB vaccine on November 7, 1996. See P Ex A at 3. After several medical complaints and interventions not relevant to the issue at hand, JANE DOE/34 received her second dose of HepB vaccine on December 11, 1996. Id. at 4. JANE DOE/34 presented to the emergency room at Community Memorial Hospital on December 17 with complaints of vomiting since the prior day. P Ex C at 90. She was admitted with the assessment of "probable Reye's syndrome." Id. at 91. Of note, the neurological assessment performed on the 17th noted that JANE DOE/34 was "[a]lert, oriented x3. Cranial nerves 2-12 intact. No rigidity noted. Answers questions appropriately despite not feeling well." Id. at 91. JANE DOE/34 was hospitalized until December 22, 1996. Id. at 101. During her hospitalization, laboratory tests were performed and among other findings her tests results showed an increase in her liver enzymes and ammonia levels. Id. at 91, 94; see also P Ex B (Dr. Heubi's supplemental report). A lumbar puncture was performed to rule out infection. The test was normal. Id. at 92, 101. Based upon these test results, JANE DOE/34 was given the presumptive diagnosis of Reye's syndrome. Id. at 101. JANE DOE/34's liver enzymes were retested on December 31, 1996, and had yet to return to normal. P Ex B at 2; P Ex C at 116. An exact date by which JANE DOE/34's liver enzymes normalized is not available, but Dr. Heubi and Dr. MacDonald opined that by mid-January, 1997, they returned to normal. P Ex B at 2; R Ex K at 2.

JANE DOE/34 next saw Dr. Crozier on February 18, 1997. P Ex A at 15. Under the subjective[4] portion of the note (which is the information provided to the doctor by the patient or her mother), Dr. Crozier records the history of the hospitalization for Reye's syndrome and that "Pt says she's been well since then." Id. It is also noted that JANE DOE/34 has been attending school and not taking any routine medications. Id. After recording the objective findings, Dr. Crozier's assessment is "**Malaise and tiredness, probably incubating new illness, e.g. URI which is not fully apparent. Hx Reye's syndrome.**" Id. (bold in original). JANE DOE/34 returned on February 20 with the development of a sore throat. Of significance to the issues presented here, which will become apparent later in this decision, the subjective notes states "Does have some nasal congestion and sinus headache." Id. Dr. Crozier's assessment was "**Pharyngitis. URI w/possible sinusitis. Tiredness. Hx of Reye's syndrome.**" Id. (bold in original). JANE DOE/34's next visit was on March 4, 1997. It is noted in the subjective section that JANE DOE/34 felt "SOB" (shortness of breath)[5] last night. Id. Continuing under the subjective section, it is noted that the issue cleared. It is also noted that JANE DOE/34 recovered from the "recent pharyngitis & URI in Feb w/no residual symptoms." Id. Under assessment it

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[4] The acronym SOAP commonly used in medical records stands for "subjective, objective, assessment, and plans." Neil M. Davis, Medical Abbreviations, 334 (Neil M. Davis Associates 12th ed., 2005) (1983).

[5] The acronym SOB can stand for several phrases, but in the context of this visit clearly connotes "shortness of breath." Neil M. Davis, Medical Abbreviations, 334 (Neil M. Davis Associates 12th ed., 2005) (1983).

states "**Episode of SOB of uncertain etiology. URI.**" Id. (bold in original).

Dr. Crozier saw JANE DOE/34 on March 21, 1997 for "tiredness w/nausea for about 5 days." Id. at 20. Dr. Crozier's assessment was "**Nausea and tiredness**" and his plan was for a laboratory work-up due to the recent Reye's syndrome and to rule out a possible immune deficiency. Id. (bold in original). In a March 24 note of a telephone call with JANE DOE/34's mother, it is reported that the lab report was "totally normal." Id. In addition, it is noted that the mother reported that JANE DOE/34 "is feeling much better" and had gone back to school. Id. JANE DOE/34 was seen next on April 1, 1997 for a sore throat and stuffy nose. Id. She was assessed with a "**Probable viral URI.**" Id. (bold in original). The records report a series of telephone calls with JANE DOE/34's mother. Thus, on April 2, Dr. Crozier recommended that JANE DOE/34 get a strep test. Id. On April 5, JANE DOE/34's mother was informed that the strep test was negative. Id. On April 7, JANE DOE/34's mother reported that JANE DOE/34 stayed home from school with a runny nose and slight cough. Id. Dr. Crozier noted that he would see her tomorrow if there was no improvement. Id.

In fact, JANE DOE/34 was seen on April 8. Id. at 21. The notes under subjective recount the history of the recent illness. Id. In addition, it is noted that JANE DOE/34 "[s]ince her Reye's syndrome . . . has had normal LFTs on 2/20 & 3/21. . . . Went over pt's hx, no other obvious associated factors. Doing well at school. Is happy, not depressed." Id. Dr. Crozier's assessment was "**Sinusitis - right maxillary sinus. Recurrent ? URI w/significant malaise. Hx of Reye's syndrome.**" Id. (bold in original). Dr. Crozier's plan suggested seeing Dr. Ratnasamy, an infectious disease expert, for a possible immune-deficiency. Id. JANE DOE/34 did see Dr. Ratnasamy on April 14. Id. at 17.

Dr. Ratnasamy's record contains a detailed history of JANE DOE/34's medical issues. See id. at 17. She was referred for recurrent URIs. Id. His history begins with the events associated with the hepatitis B immunizations, including being hospitalized "with mental status changes, elevation of ammonia and LFT abnormalities felt to be consistent with Reye's syndrome." Id. Dr. Ratnasamy continues by noting that since the time of her Reye's syndrome, JANE DOE/34 "has had other upper respiratory illnesses with congestion, slight sore throat and cough. However, these illnesses leave her completely wiped out; and she has missed many days of school. . . . She also gets significant headaches; . . . with photophobia." Id. Under "REVIEW OF SYSTEMS" it is noted that JANE DOE/34's symptoms are "significant for the headaches, sore throats, nausea, vomiting and the upper respiratory symptoms." Id. Under "PLAN", Dr. Ratnasamy writes:

> The hepatitis B shot and the onset of illness are temporally associated; however, whether they are causally associated is not certain. Her illness in December seems most consistent with Reye's syndrome which can occur after any viral illness. Her persistent headaches are somewhat concerning. If, after an adequate course for sinusitis, she continues to have headaches, I would consider stopping birth control pills to see if the birth control pills may be playing any role in the etiology

of the headaches.

Id. at 18. Subsequently, JANE DOE/34 continued to exhibit multiple complaints of headaches and other medical issues. For purposes of this decision, it is unnecessary to catalogue those medical issues.

As stated above, the issue before the undersigned is narrow - what is the appropriate period of time for calculating the damages in this case? The determination of this period of time necessarily implicates what sequelae JANE DOE/34 suffered from her vaccine-related Reye's syndrome. Earlier decisions have found a very brief period of time for any sequelae. See Hocraffer v Sec'y of HHS, 63 Fed. Cl. 765, 779 (2005) ("Based on Dr. Heubi's testimony, the court finds that petitioner did not prove by a preponderance of the evidence that she had any sequelae from Reye's syndrome after it resolved itself shortly after she was released from the hospital in late 1996."); see also Decision on Remand, Hocraffer v. Sec'y of HHS, No. 99-533V, 2007 WL 914914 * 2 (Fed. Cl. Spec. Mstr. Feb. 28, 2007) (finding an approximate 30 day period of damages relying on Dr. Heubi's averments in his supplemental affidavit, P Ex B). Petitioner does not contest Dr. Heubi's prior statements, but now argues that while JANE DOE/34 recovered from the physical effects of her Reye's syndrome, she thereafter developed neurological sequelae. Transcript of August 7, 2008 Hearing (Tr. at _) at 4, 15. Petitioner presented the testimony of Dr. Ronald Jacobson in support of her case.[6] Dr. Jacobson stated in his report that "JANE DOE/34 has a chronic post illness encephalopathy marked by recurrent migraine headaches, hand numbness, and diminished academic performance and diminished motor skills" which resulted from her Reye's syndrome. P Ex F at 2-3. Respondent's expert, Dr. MacDonald,[7] stated in his report that he agreed with Dr. Heubi's opinion that "JANE DOE/34's neurological symptoms from the Reye's Syndrome in 1996 resolved in early 1997, and that her later multiple complaints are not directly related to the [Reye's syndrome] in December 1996." R Ex K at 3. Dr. Heubi, who testified at the Hearing at the undersigned's request, affirmed his earlier opinions given in this case, which supported an abbreviated time period for damages of about 30 days. See Tr. at 79.

After reviewing the entire record, the undersigned finds that the original finding of approximately 30 days is the appropriate period for calculating damages. This finding is based upon a determination that the testimony of Dr. MacDonald and Dr. Heubi was highly credible, while in contrast the testimony of Dr. Jacobson was highly speculative and thus not credible.

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[6] Dr. Jacobson is a well-credentialed Pediatric Neurologist. See P Ex F; Tr. at 6-7. Unfortunately, the undersigned was not impressed with Dr. Jacobson's testimony, finding it to be highly speculative and thus not credible.

[7] Dr. MacDonald is a Pediatric Neurologist who testifies with some regularity in Program cases. See R Ex L; Tr. at 91-92. The undersigned has always found Dr. MacDonald to very credible, whether ruling for or against respondent in cases in which Dr. MacDonald has offered opinions. The undersigned found Dr. MacDonald's testimony in this case to be very credible.

Dr. Jacobson's opinion was succinctly stated by respondent's counsel as JANE DOE/34 "suffered an acute encephalopathy that insulted her brain that resulted in permanent and significant neurologic sequela." Tr. at 56. Dr. Jacobson agreed. Id. However, understanding the bases for this opinion was a difficult task. While Dr. Jacobson stated in his report that JANE DOE/34's encephalopathy was "marked" by migraine headaches, hand numbness, and diminished academic and motor skills, his testimony focused solely on the migraine headaches as an indicator of the encephalopathy. Thus, he stated that the hand numbness was not part of the encephalopathy, but was a neurologic complaint. Tr. at 60 ("All I can say is that she had it afterwards. . . ."). The same was true with the diminished academic and motor skills, they occurred post Reye's syndrome but were not caused directly by the Reye's syndrome. Id. at 61-62. As Dr. Jacobson stated, they are all part of an "unfolding story of her complaints" which you have to "look at it in its entirety, this is somebody who's different before than after." Id. Dr. Jacobson explained further that:

> the best way I can work through this question as a clinician is to say these are the ways she's different before than - after than before, and in that sense saying, therefore, these are impacts upon her. Some may be impacts indirectly. Some may be precise. For example, if she's having lots of headaches, that may lead her to have trouble studying. To separate all the linkages between all the pieces would be virtually impossible.

Id. at 62. Confusingly, however, despite having said, for example, the hand numbness is not part of the encephalopathy, tr. at 60, when pressed further, Dr. Jacobson goes on to opine that more likely than not the hand numbness is related to the encephalopathy. Id. at 63. This lack of clarity and precision in Dr. Jacobson's testimony was a serious and continual problem.

Fairly read, Dr. Jacobson's opinion of a post-illness encephalopathy relied upon the evidence of JANE DOE/34's migraine headaches and their relationship to Reye's syndrome. The migraine headaches were the focus of the experts' testimony. Dr. Jacobson's reasoning is summarized from his report as follows:

> Reye syndrome is know to result in neurologic sequelae including cognitive impairments, motor impairment, and sensory dysfunction. Although migraine headaches have not been specifically linked with Reye syndrome, migraine triggers or exacerbations are known to occur because of a variety of specific insults to the central nervous system. For example, head trauma is a well-known cause of migraine headaches leading to the diagnostic term "traumatic migraines.". . . Recurrent migraine headaches cause recurrent pain and further impairments in functioning including decreased attendance at school or work and greater difficulty with the extra demands leading to increased need for sleep. Finally, the most appropriate neurologic conclusion is that JANE DOE/34 suffers from post-Reye Syndrome encephalopathy, for which there are many similar examples after other insults to the central nervous system (post-head trauma, post-

concussive syndrome, post-infectious encephalopathy are the best recognized entities.)

P Ex F at 3; see also Tr. at 25. The fundamental problem with Dr. Jacobson's position is that there is a complete absence of support for it, in the relevant medical literature, in the clinical findings in this case and from JANE DOE/34 herself. On several occasions, Dr. Jacobson stated that he "humbly struggled" trying to sort out contrary evidence apparent in this case, see Tr. at 45, but in the end he used the "rather coarse tool" of clinical thinking to conclude that "there are problems she had afterwards and there are problems that she did not have before, and that's an element in my thinking in this case." Id. at 46. The undersigned finds that not only was it an element, but in fact it was the sole basis for Dr. Jacobson's opinion in this case. And such testimony fails from lacking any indicia of reliability.[8] In fact, one is hard pressed to find any support whatsoever for Dr. Jacobson's opinion.

First, and very importantly, there is no recognized connection between Reye's syndrome and migraine headaches. Dr. Jacobson acknowledged the lack of any connection. P Ex F; Tr. at 25. Dr. MacDonald concurred. Tr. at 101. Dr. Heubi testified the same. Id. at 82.[9] In fact, Dr.

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[8] In weighing evidence, it is incumbent upon the special master to test its trustworthiness. Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that Supreme Court's decision in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, (1993) "is useful in providing a framework for evaluating the reliability of scientific evidence." Terran v. Sec'y of Dept. of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). Thus, when considering the evidence in a case, the special master is to "consider all relevant and reliable evidence, governed by the principles of fundamental fairness to both parties." Vaccine Rule 8(c); see also Campbell v. Sec'y of Dept. of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006) (Althen's requirement of a 'reputable medical or scientific explanation' "[l]ogically [ ] requires a special master to rely on reliable medical or scientific evidence . . . ." (citing Althen v. Sec'y of Dept. of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005))); Manville v. Sec'y of Dept. of Health & Human Servs., 63 Fed. Cl. 482, 491 (Fed. Cl. 2004) ("Daubert adequately serves the gatekeeping function for analysis of the admissibility of evidence; once evidence has passed that test, the trier of fact's process, simply, is to determine the probativeness of that evidence."); DeBazan v. Sec'y of Dept. of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2006) *rev'd* 539 F.3d 1347 (2008) (reversed on other grounds).

[9] Petitioner objected to Dr. Heubi testifying at this Hearing. See Tr. at 78. However, the undersigned explained to petitioner on several occasions that Judge Firestone relied upon Dr. Heubi's expertise in finding that JANE DOE/34 did not suffer "any sequelae from Reye's Syndrome after it resolved itself shortly after she was released from the hospital in late 1996." Hocraffer, 63 Fed. Cl. at 779. Thus, the undersigned found it necessary to understand if and how Dr. Heubi's opinion differed from petitioner's expert, Dr. Jacobson. In addition, the distinction must be drawn between Dr. Heubi testifying to neurological issues, which he said he was unqualified to do, see Tr. at 76, 84, and Dr. Heubi's testimony based upon his vast experience with Reye's regarding all aspects of the syndrome, including diagnosis, treatment and long-term outcomes. Petitioner utilized Dr. Heubi successfully in this capacity during the causation phase of this case as a Reye's syndrome expert, relying upon his vast

Heubi stated that "migraine headaches is not just something that's ever been brought to my attention . . . as a relationship to Reye's." Id. This is a very meaningful statement regarding this issue because of Dr. Heubi's experience with Reye's syndrome. Dr. Heubi stated at the prior Hearing on causation in this case in responding to a question regarding his credentials that "I consider myself to be pretty unimpeachable, to be honest with you, about the topic of Reye's Syndrome." Transcript of June 17, 2003 Hearing at 51; see also Hocraffer, 63 Fed. Cl 765, 777 (Judge Firestone noted that Dr. Heubi is "one of the nation's experts on Reye's Syndrome.").[10] And currently, in his position as director for the National Reye's Syndrome Foundation, he is contacted by individuals regarding the late problems of Reye's syndrome. Id. at 83. While anecdotal, migraines "has not been one of the things that I've heard about." Id.

Second, cases of mild Reye's syndrome recover uneventfully. The experts agreed that Reye's syndrome has a range of presentations, which are usually measured on a scale of 1 to 5 or 0 to 6 with the low number being the mildest. Tr. at 10, 112; see also P Exs P and R. The experts also agreed that JANE DOE/34's Reye's syndrome was mild. Tr. at 38 (Dr. Jacobson described JANE DOE/34's Reye's syndrome as mild); Id. at 80 (Dr. Heubi graded JANE DOE/34's as 1); Id. at 94 (Dr. MacDonald graded JANE DOE/34's as 1). While Dr. Jacobson stated that you can have adverse sequelae from mild Reye's syndrome, tr. at 24, Dr. Heubi, based upon his vast and far superior experience with Reye's syndrome, maintained the opinion that he expressed at the causation Hearing that the level of JANE DOE/34's encephalopathy, grade 1, did not result in any significant neurologic damage. Tr. at 79 (referencing his testimony at the June 17, 2003 Hearing at page 79 of the Transcript). While Dr. Heubi left the door open for some possibility of mild Reye's syndrome resulting in long-term damage, he said it would be unusual and rare. Id. at 81, 86. An article authored by Dr. Heubi and filed by petitioner supports Dr. Heubi's testimony as it states for grades 1 and 2 "with no progression to unconsciousness . . . [t]hese patients appear destined to recover uneventfully." P Ex P at unnumbered 2. None of the literature submitted by petitioner supports the notion that a mild Reye's syndrome results in long-term sequelae, and Dr. Jacobson provided no reliable support for his testimony on this point.

Third, and very importantly, the medical records documenting JANE DOE/34's clinical course do not support Dr. Jacobson.[11] Dr. MacDonald discussed what clinical symptoms you

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experience with the syndrome. In fact, petitioner submitted and relied upon several articles published by Dr. Heubi on the subject of Reye's syndrome. See P Ex P. The undersigned relied upon Dr. Heubi in the same manner. In fact, petitioner's counsel did the same. Tr. at 86 ("when you see it just from your experience").

[10] The contrast with Dr. Jacobson is striking. Dr. Jacobson's experience with Reye's syndrome is limited to his time as a pediatric resident in the late 1970s. Tr. at 10, 34-36. Dr. Jacobson has published no articles on Reye's, nor conducted any follow-up studies on the syndrome. Tr. at 38.

[11] Capizzano v. Sec'y of Dept. of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006) ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s]

should see in making a diagnosis of encephalopathy. He testified that:

> the mental changes should involve some degree of alteration of her level of consciousness, her ability to communicate and her level of awakeness. So typically you're looking for fairly significant lethargy, confusional state, loss of speech, and then a gradation from stupor to ultimate coma.

Tr. at 95. Regarding JANE DOE/34, in contrast to what one would expect to see with an encephalopathy, Dr. MacDonald interpreted JANE DOE/34's medical records as follows:

> [JANE DOE/34's] described as irritable. She had some initial vomiting. But I don't get a picture here of a child that's had a significant and obvious alteration of her mental status beyond the grade 1 encephalopathy scales that were used at the time. She never had any of the physical signs that we would associate with severe encephalopathy such as focal neurological damage. She didn't have any seizures. She didn't have any other hard physical signs, and they her studies were all normal except for the liver function studies.

Tr. at 95; see also Tr. at 122-23. Dr. Jacobson actually agreed with this assessment of the clinical picture. Dr. Jacobson agreed that JANE DOE/34 presented with no evidence of increased intercranial pressure, seizures, somnolence, coma, decreased motor skills, or decreased responsiveness to environmental stimuli. Tr. at 43-44. Dr. Jacobson agreed that the treating doctor's physical examination of JANE DOE/34 disclosed no focal neurologic abnormalities. Id. at 43. He agreed that no neurologic tests were performed on JANE DOE/34 during her hospitalization that would lead him to believe that JANE DOE/34 suffered a brain insult from her Reye's syndrome. Id. Dr. Jacobson could not recall any MRI scans performed on JANE DOE/34. Id. However, Dr. MacDonald pointed out that two MRIs and a CT scan were performed and they were all normal. Tr. at 102-103. Dr. MacDonald also stated that a brain injury severe enough to cause permanent brain injury would evidence on an MRI. Id. In addition, JANE DOE/34's treating doctor, Dr. Ratnasamy, who saw JANE DOE/34 at the critical April visit, testified at the June 17, 2003, causation Hearing that "[i]n my personal evaluation of her, there was no encephalopathic symptoms at the times I saw her in April and June." Tr. at 36.

The undersigned questioned Dr. Jacobson regarding JANE DOE/34's medical visits following the December hospitalization. Dr. Jacobson agreed the February 18 and 20 visits were for respiratory issues. Tr. at 64-65. He recognized that the records note that JANE DOE/34 has been doing well since her Reye's syndrome and that she is not taking medications. Id. at 65. The March 4 visit was because JANE DOE/34 "[c]omplained of shortness of breath." Id. at 65. Again, Dr. Jacobson recognized that the record of that visit indicates that JANE DOE/34

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that the vaccination was the reason for the injury.'" (citing Althen v. Sec'y of Dept. of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005))).

recovered from her recent URI in February, and was exhibiting no symptoms of encephalopathy. Id. at 66. The referral to Dr. Ratnasamy on April 14 was for "recurrrent illnesses". Id. The recurrent illnesses were URIs. Id. With regard to the headaches noted by Dr. Ratnasamy, Dr. Jacobson agreed that Dr. Ratnasamy thought that they were related to JANE DOE/34's sinusitis. Id. at 67. Dr. Jacobson again agreed that Dr. Ratnasamy indicated no concern with any encephalopathic symptoms. Id. The undersigned also questioned Dr. MacDonald about these same medical visits, inquiring essentially whether the complaints and findings at these visits are consistent with someone exhibiting an encephalopathy. Dr. MacDonald responded, with explication, that the visits and findings are inconsistent with an encephalopathy. Tr. at 121-24.

In the face of this seemingly overwhelming evidence, Dr. Jacobson maintained that JANE DOE/34 suffered a brain insult that "is not observable by any objective means other than the migraine headaches." Tr. at 44; see also Tr. at 56.

What then is the proof concerning the migraine headaches? The experts agree that the documentary evidence of migraines is in the notes from the April 14, 1997 visit with Dr. Ratnasamy. P Ex A at 17; see Tr. at 19, 124.[12] There are no references before April 14 to migraine headaches. In fact, as recognized by Dr. Jacobson, petitioner's own affidavit does not contain any references to migraines. Tr. at 31. Despite Dr. Jacobson's recognition that there is no known connection between migraines and Reye's syndrome, tr. at 25, and the lack of documentary support in JANE DOE/34's record of migraines prior to April 14, when asked whether JANE DOE/34's migraines could have been caused by her Reye's syndrome, Dr. Jacobson replied "[t]his is an interesting question in this case." Tr. at 24. Dr. Jacobson's reasoning was as follows:

> In thinking through this, though, I came to the conclusion, based on experience with taking care of large number of patients, that I see no reason to think that even though it's not actually reported as such, that given that Reye's Syndrome is an injury to the nervous system akin to trauma, that if someone did not have headaches and then shortly after having Reye's Syndrome began having recurring headaches and migraines, that migraine headaches could be a sequelae of the Reye's Syndrome.
>
> That's how I've worked through the question, and I'm admitting with humility and very humble features that this is a very difficult question to assess.

Tr. at 25.

In analyzing the reliability and thus the persuasiveness of Dr. Jacobson's testimony regarding the relationship of the migraines to Reye's syndrome, two issues jump out: 1) whether

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[12] Dr. Jacobson recognized that an earlier reference to a headache at the February 20 visit to Dr. Crozier was related to a complaint for sinus problems. Tr. at 21.

the analogy to head trauma is appropriate, and 2) what is the time frame Dr. Jacobson is referencing when he says "shortly after having Reye's"? Unfortunately for petitioner, Dr. Jacobson fell woefully short in credibly answering these two questions.

Regarding the analogy to head trauma, Dr. Jacobson never provided any meaningful support for this analogy, he simply stated it and then carried the assumed analogy through his testimony. He first discusses head trauma in relation to the "myriad" causes of migraines. Tr. at 22. Then, in response to counsel's question about whether Reye's syndrome could be a brain trauma similar to post-concussion, Dr. Jacobson makes the jump that is the foundation to his analogy. Tr. at 24. Dr. Jacobson responded by "broaden[ing]" the term, presumably the term post-concussion, to "insult to the nervous system" as a means of understanding how the brain reacts to different events. Id. This type of insult, although caused by different traumas, strokes or viruses for example, will look the same as an end product because the brain cells will react to the causative event in the same manner. Id. Thus, while Dr. Jacobson readily concedes that there are "unique differences between mechanical injuries and toxic injuries," "a broad way to hold it together would be thinking about insults to the nervous system." Id. Utilizing this line of reasoning, Dr. Jacobson is able to abandon his search for a link between Reye's syndrome and migraines and move to an "analogous" brain insult - trauma - for a supportive link. Id. at 25. This analogy to head traumas also provides Dr. Jacobson the basis for an appropriate timing for when the migraine pattern would be expected to occur - one to three months. Id. at 26.

Like virtually all of Dr. Jacobson's testimony, the only support are his words. Petitioner provided no objective confirmation for Dr. Jacobson's treatment of all insults to the nervous system in the same manner, no matter the cause. Thus, the body's reaction to being hit over the head with a baseball bat will be the same as reacting to an attack by meningitis. The undersigned is not trained in medicine and thus cannot say outright that such a proposition is nonsensical. However, that is why the Supreme Court in Daubert required judges to require some indicia of reliability to prevent glib experts from ruling courtrooms. Dr. Jacobson provided no reliable support for his analogy. And given the highly questionable and speculative testimony that marked his appearance, the undersigned has very good reason to pause on such a critical point that was supported solely by words. Of note, Dr. MacDonald, a highly respected pediatric neurologist who has testified credibly before the undersigned in this case and in others questioned the appropriateness of the analogy. See n.7, p. 5, supra. Dr. MacDonald stated that:

> [Dr. Jacobson] made an analogy between traumatic headache and migraine, but ... traumatic headaches or post traumatic headaches are a different mechanism of injury versus what would occur in a patient with Reye's Syndrome, so I can't merge the two and use it as an analogy.

Tr. at 101-02; see also Tr. at 118. And it bears noting, once again, that no treating doctor records in the contemporaneous medical records any relationship between JANE DOE/34's migraines and her Reye's syndrome. Thus, what we have is Dr. Jacobson's unsupported analogy weighed against the conceded lack of any published relationship between Reye's syndrome and migraines,

against Dr. Heubi's testimony as an established expert on the long-term impact of Reye's syndrome that he is not aware of migraines as sequela of Reye's syndrome, against no contemporaneous consideration by JANE DOE/34's treating doctors of any relationship and, finally, against Dr. MacDonald's credible testimony that the analogy is not "close". Tr. at 118. In the final analysis, the undersigned did not find Dr. Jacobson to be a credible witness. His opinions were void of any indicia of reliability and ran counter to the clinical findings of the treating doctors. On the other hand, the testimony and opinions of Dr. Heubi and Dr. MacDonald were credible and convincing and fully supported by the medical literature and the records in this case. Accordingly, petitioner failed to show by a preponderance of the evidence that her Reye's syndrome caused her migraines and other maladies.

Petitioner raises a number of issues in her post-Hearing submission that bear some mentioning. See Petitioner Post-Hearing Brief and Notice of Filing (hereinafter P PH at _) filed November 7, 2008. First, a substantial portion of petitioner's questioning at the Hearing focused on JANE DOE/34's increased ammonia levels. Dr. Jacobson testified that ammonia is a neurotoxin that can impair brain function. Tr. at 13. Dr. Heubi agreed. Id. at 88. Relying on petitioner's Exhibit E, Dr. Jacobson stated that the risk of fatalities is greater in cases of Reye's syndrome with ammonia levels greater than 45 micrograms per deciliter. P Ex E at 14. JANE DOE/34's level was significantly greater. Id. However, as the literature indicates, and the experts agreed, ammonia levels identify risk factors; they are not diagnostic in individual cases. See P Ex P at 1; Tr. at 68-9 (Dr. Jacobson stated that ammonia levels are "not diagnostic of [Reye's] after effects." They are part of the risk factors); Tr. at 72 (Dr. Heubi stated that the higher ammonia levels put JANE DOE/34 at a "higher risk". . . . It's a statistical risk factor of sequela. It doesn't prove it in and of itself."); Tr. at 104 (Dr. MacDonald agreed that higher ammonia levels equate to higher risk, but "in the individual case, it's not helpful in predicting sequela."). In addition, Dr. Jacobson testified that while you would expect to see high ammonia levels with severe cases of Reye's syndrome, you can also have high ammonia levels with moderate and mild cases of Reye's syndrome as well. Tr. at 40. As Dr. MacDonald testified, the ammonia levels confirm the diagnosis of Reye's syndrome, but once you have established the diagnosis "it's the mental status encephalopathy that's critical." Tr. at 104-07. As has been stated, JANE DOE/34 - by all records and testimony - had the mildest form of Reye's syndrome - level 1. See P Ex N at 11. The literature and testimony indicate that patients with level 1 Reye's syndrome recover uneventfully. See P Ex P at 1. Dr. MacDonald testified that JANE DOE/34's acute encephalopathy ended in four to five days. Tr. at 107; see also P Ex N at 11 (JANE DOE/34's mental status was "normal" on December 18, 1996.). Dr. Jacobson agreed that JANE DOE/34 was not clinically encephalopathic when she left the hospital. Tr. at 59. Accordingly, despite counsel's efforts to equate the high ammonia levels with a smoking gun evidence of long-term harm, there simply is no basis for such an argument.

Counsel introduces through his brief purported evidence of increased intracranial[13]

[13]During the Hearing it was referenced as "intercranial". For purposes of this decision it is unnecessary to resolve the difference.

pressure in an effort to impeach Dr. MacDonald's testimony. See P PH Brief at 7, 14. Dr. MacDonald testified that brain pressure is the number one concern because if the brain swells too much all function stops. Tr. at 96. Dr. MacDonald could find no indication in the medical records of increased intercranial pressure, and stated that JANE DOE/34's treatment indicates that the treating doctors were not concerned with elevated pressure. Id. at 96-8. Petitioner attempts to rebut Dr. MacDonald's testimony, and thus question his credibility by referencing the opening pressure measurement for JANE DOE/34's spinal tap and arguing that this is evidence of increased intracranial pressure. P PH Brief at 7, citing P Ex N at 11. The short answer to petitioner's argument is that the introduction of impeaching evidence at this stage of the proceedings is totally inappropriate.[14] See P Exs M, N, and O attached to P PH Brief. Petitioner did not question Dr. MacDonald on this issue, nor did petitioner recall Dr. Jacobson for rebuttal testimony, and probably for good reason - **Dr. Jacobson agreed that there was not evidence of any increased intercranial pressure.** Tr. at 43. Petitioner's statements, arguments and medical research cannot be used to impeach Dr. MacDonald. The undersigned is not able to say that the opening pressure for a spinal tap is the measurement for intracranial pressure; nor is petitioner's counsel qualified to make that determination. The undersigned notes that Dr. MacDonald testified to the lumbar puncture as an indicator that the brain pressure was not elevated - he stated that "if you're suspicious of elevated pressure, we frequently will defer to spinal tap." Tr. at 97-8. This makes the undersigned believe that the measurement of the spinal tap pressure is separate and distinct from the intracranial pressure. More importantly, Dr. MacDonald's fundamental point remains intact, that is the treating doctors were concerned with JANE DOE/34's persistent vomiting and upon later examination found her mental status to be normal. Tr. at 97-99; see also P Ex N at 11. Thus, Dr. MacDonald stated that JANE DOE/34 had a very mild case of Reye's syndrome and the doctors "never had to intervene to aggressively treat any signs of brain pressure problems." Tr. at 97. Petitioner's new information, appropriately presented or not, does not dictate a contrary finding.

Petitioner attempts to buttress her case by again using her counsel's "testimony" to address both the issues of whether Reye's syndrome can cause migraines and if so what would be the medically appropriate time frame for such an occurrence. See P PH Brief at 18-19. As discussed above, there is no reliable support for Reye's syndrome causing migraines. Dr. Jacobson relied on an unsupported analogy to head trauma to both establish a possible connection and for an appropriate time frame for occurrence. See Tr. at 25. "Speaking merely by analogy," Dr. Jacobson posited a one to three month period as the appropriate time frame. Id. Dr. Jacobson relied on Dr. Ratnasamy's April 14, 1997 visit, P Ex A at 17, for his highly dubious conclusion that an "established pattern" of migraine headaches had developed, having developing "four to six weeks prior, something in that range." Tr. at 27. This testimony was based upon Dr. Jacobson's interpretation of Dr. Ratnasamy's use of the word "gets," as used in the sentence "She

[14]The undersigned notes that it was equally inappropriate for petitioner to have faxed to my office on January 27, 2009 a Notice of Filing Petitioner's Exhibit P and Q (second series), which consisted of an article about idiopathic intracranial pressure and a conversion calculation for units of pressure and stress. These documents were not considered for purposes of the instant decision.

also gets significant headaches with photophobia." P Ex A at 17. The undersigned found this testimony to be the height of speculation, especially considering petitioner's own affidavits did not mention migraine headaches during that period. In this instance, Dr. Jacobson dismissed petitioner's affidavit, tr. at 31, and chose to rely upon the medical records and his "humble" interpretation. Now petitioner, in her post-Hearing brief, attempts to buttress the notion of earlier migraines by arguing that the Dr. Crozier's description of a sinus headache on February 20, 1997, P Ex A at 15, was "most probably a migraine headache." P PH Brief at 18.

Once again, counsel is testifying through his post-Hearing brief and that is patently inappropriate. In this instance, petitioner is impeaching her own witness who declined to say that the February 20 headache was anything but a sinus headache as described in the medical records. Tr. at 21. There simply is no basis for petitioner's late presented contention to the contrary. Next counsel weaves together, completely out of context, snippets of Dr. Heubi's testimony to construct the syllogism that high ammonia levels can cause neurologic injury; neurologic injury can result in long-term neurologic sequella; and thus, the manifestation of injury can take a "month, but not years" to develop. P PH Brief at 19. The primary difficulty with petitioner's argument is that it miscasts Dr. Heubi's testimony. Dr. Heubi was testifying to the delay in symptoms in patients who exhibited some degree of coma. Tr. at 87. Thus, the undersigned clarified his testimony as follows:

THE COURT: But lets be clear, Doctor. When you say coma, you're talking somewhere in the grade 3 to 5?

THE WITNESS: Yes.

THE COURT: And again, JANE DOE/34 is a 1.

THE WITNESS: That's correct.

Id.; see also Tr. at 111. Petitioner's use of Dr. Heubi's testimony is simply wrong, and borders on misrepresention. Lastly, petitioner states that the medical records establish that JANE DOE/34 had increased intracranial pressure. As discussed above, both experts, including petitioner's, disagreed.

Petitioner has attempted to build a case on the fact that JANE DOE/34 has developed issues, including the migraine headaches, academic issues, and decreased interest in sports, following her Reye's syndrome. As Dr. Jacobson stated, "there are problems she had afterwards and there are problems that she did not have before." Tr. at 46.[15] However, the linchpin for petitioner linking these various issues is the contention that the Reye's syndrome is responsible

[15] While not a component of the undersigned's decision, it is noted that both Dr. Jacobson and Dr. MacDonald recognized reasonable alternative explanations for the issues JANE DOE/34 has experienced. See Tr. at 44-45, 99-100; see also R Ex M at 4-5.

for JANE DOE/34's migraines. As Dr. Jacobson stated, her complaints are all part of the "unfolding story" with some parts being indirectly related, for example "if she's having lots of headaches, that may lead her to have trouble studying." Tr. at 62. Petitioner never made her case. There is no persuasive evidence that Reye's syndrome causes migraines. The contemporaneous medical records indicate that JANE DOE/34 suffered URIs and sinusitis. P Ex A at 15. Dr. Jacobson stated that the URIs are unrelated to the Reye's syndrome. Tr. at 63. The undersigned walked Dr. Jacobson through the medical records and he agreed that there were no indications of an encephalopathy. Id. at 66. Dr. Jacobson agreed that on April 14 Dr. Ratnasamy believed JANE DOE/34's persistent headaches were due to sinusitis. Id. at 67. He also agreed that there was no indication of an encephalopathy at that visit. Id. No test, no treating doctor, no medical literature supports Dr. Jacobson. Yet, while he "humbly struggled with trying to sort out this case," tr. at 45, Dr. Jacobson concluded based upon an unsupported analogy to head trauma that the Reye's syndrome caused JANE DOE/34's migraines and other indirectly related maladies. Dr. Jacobson's testimony amounted to no more than "post hoc ergo propter hoc" reasoning, which has been soundly rejected by the Federal Circuit. U.S. Steel Group v. U.S., 96 F.3d 1352, 1358 (Fed. Cir. 1996) ("But to claim that the temporal link between these events *proves* that they are causally related is simply to repeat the ancient fallacy: *post hoc ergo propter hoc.*"); see also Grant v. Secretary of Dept. of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("[T]he inoculation is not the cause of every event that occurs within the ten day period.... Without more, this proximate temporal relationship will not support a finding of causation." (citing Hasler v. United States, 718 F.2d 202, 205 (6th Cir.1983), *cert. denied,* 469 U.S. 817, 105 S.Ct. 84, 83 L.Ed.2d 31 (1984))). Accordingly, Dr. Jacobson's testimony is rejected, as is petitioner's allegation that she suffered continuing harm past the approximate 30 day period testified to by Dr. Heubi and agreed to by Dr. MacDonald, see Tr. at 108, and previously found by the undersigned. Decision on Remand, Hocraffer v. Sec'y of HHS, No. 99-533V, 2007 WL 914914 at *3 (Fed. Cl. Spec. Mstr. Feb. 28, 2007).

Judge Firestone remanded this case to determine "the appropriate damages period and making a damages determination." Order on Petitioner's Motion for Review at 3. The undersigned determined that the appropriate damages period is approximately 30 days. Since the undersigned previously heard evidence and made findings on the damages for that 30 day period, the undersigned awards compensation for the previously determined amount of **$5,841.50** for JANE DOE/34's vaccine-related injuries. Decision on Remand, Hocraffer, 2007 WL 914914 at *9. The Clerk shall enter judgment accordingly, unless a new Motion for Review is filed. The parties shall consult Vaccine Rule 28A for procedural guidance.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master