In the United States Court of Federal Claims

No. 05-626 V
(Filed October 26, 2012)[1]

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JESSIE CONTRERAS,	*	
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Petitioner,	*	National Childhood Vaccine
	*	Injury Act of 1986, 42 U.S.C.
v.	*	§§ 300aa-1 to -34 (2006); Proof
	*	of Causation; Petitioner's
SECRETARY OF HEALTH AND	*	Burden to Establish Prima Facie
HUMAN SERVICES,	*	Case; Remand.
	*	
Respondent.	*	
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Jeffrey S. Pop, Beverly Hills, CA, for petitioner.

Linda S. Renzi, United States Department of Justice, with whom were *Stuart F. Delery*, Acting Assistant Attorney General, *Rupa Bhattacharyya*, Director, *Mark W. Rogers*, Deputy Director, *Voris E. Johnson, Jr.*, Trial Attorney, Washington, DC, for respondent.

OPINION AND ORDER

Bush, *Judge*.

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[1]/ Pursuant to Rule 18(b) of Appendix B of the Rules of the United States Court of Federal Claims, this Opinion and Order was initially filed under seal on September 28, 2012. Pursuant to ¶ 4 of the ordering language, the parties were to propose redactions of the information contained therein on or before October 19, 2012. No proposed redactions were submitted to the court.

Now pending before the court is petitioner's motion for review of the special master's final decision, *see Contreras v. Sec'y of Health & Human Servs.*, No. 05-626V, 2012 WL 1441315 (Fed. Cl. Spec. Mstr. Apr. 5, 2012),[2] denying Jessie Contreras's petition for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2006) (the Vaccine Act).[3] The principal questions before the court are whether, under precedent binding on this court, the special master was permitted to: (1) diagnose petitioner's illness before proceeding to an analysis of causation; (2) deny the petition without making findings on all three *Althen* prongs;[4] (3) deny the petition without making a finding as to whether petitioner had ruled out alternative causes of his illness; (4) assign little weight to the opinions of treating physicians as to *Althen* prong three; and, (5) require a heightened level of proof as to a proximate temporal relationship between the vaccinations received and petitioner's illness. Because all but one of these questions must be answered in the negative, the court grants petitioner's motion for review, vacates the special master's decision denying compensation, and remands for proceedings in accordance with the principles of law and the instructions set forth in this opinion.

The court observes that this litigation is now entering its eighth year. It has often been said that one goal of the Vaccine Act is to avoid lengthy tort litigation and to provide awards, quickly and with generosity, to petitioners who have suffered vaccine injuries. *E.g.*, *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1327 n.7 (Fed. Cir. 2006) (citation omitted). The court does not fault

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[2]/ The court cites not to the Westlaw version of this opinion, but follows the practice of the parties and cites to the opinion version (Opin.) available on this court's website.

[3]/ Hereinafter the court will refer to Mr. Contreras, now age twenty-two, as "petitioner" or "Jessie," because he was thirteen years old at the time of his alleged vaccine injury.

[4]/ *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The three *Althen* prongs provide elements of proof for a prima facie case that a vaccine caused a petitioner's illness:

> (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id.

the special master currently assigned to this case, or his predecessor, or the chief special master who attempted to resolve this case through alternative dispute resolution, or the parties, or their counsel, or their experts, for the unfortunate delays that have prolonged this litigation.[5] A lot of very good work has been devoted to this case, and the court is highly impressed with the quality of the representation of both parties, with the courteous tone of the hearings, and with the excellent state of the documentary record.

It is this large evidentiary record which the court now reviews, not to re-weigh the evidence, but to determine if the precedent binding on this court has been followed by the special master. The record is heavily laden with articles discussing epidemiological studies, laboratory experiments on rodents, and reported cases of illnesses or injuries that might or might not be linked to vaccinations. The record includes Jessie's medical records. There are also affidavits from treating physicians and multiple expert reports. Another important part of the record is the transcript of two hearings, one held on April 19-20, 2010 in California, the other held by video-conference on July 28, 2011, which recorded the testimony of the fact and expert witnesses, as well as the dialogue of these witnesses with the special master. The court will restrict its discussion to the most salient aspects of that record, even though its review of the record has been painstaking and thorough.[6]

BACKGROUND[7]

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[5]/ One of petitioner's experts died in 2010. His declining health prevented him from testifying for Jessie at a hearing held earlier that year, and he was, of course, unavailable to testify at a second hearing held in 2011.

[6]/ One of the difficulties in interpreting such a record is to distinguish between relevant science and irrelevant science. The special master's unenviable task was to obtain sufficient expert testimony to interpret dense and highly-technical articles in scientific journals and to decide whether these articles supported the parties' arguments. The court finds no fault in the special master's overall approach, during his management of this case, to understanding some of the articles submitted by the parties. As petitioner suggests, however, the special master's "passion for scientific explanation" may have led him to heighten the standard of proof required to establish causation in a vaccine case. Petitioner's Reply (P's Reply) at 7.

[7]/ Petitioner's exhibits in this case are numbered (*e.g.*, Ex. 1), while respondent's exhibits are marked alphabetically (*e.g.*, Ex. A). There are some duplicate exhibits, which is not

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I. Factual History

A. Jessie, a Healthy Thirteen-Year Old

Jessie was born on May 14, 1990. Ex. 1. His birth and his health as a child were normal. Exs. 8-11; Tr. at 10-11, 45-54. He had routine childhood immunizations, including five shots of diptheria-tetanus-pertussis vaccine (DTaP) (in 1990, 1990, 1991, 1993, 1994), without adverse reaction.[8] Ex. 4 at 8, 44; Ex. 8 ¶¶ 6-10. He also had his first two inoculations with a Hepatitis B vaccine (HepB) without adverse reaction, on January 23, 2001 and on August 23, 2001. Ex. 4 at 9; Ex. 8 ¶¶ 11-12.

On June 16, 2003, to prepare for school in the fall, Jessie's mother took him to his primary care clinic to get required vaccinations. Ex. 4 at 49; Ex. 8 ¶ 15. Jessie received his third HepB shot in one arm and a tetanus-diptheria shot (Td) in the other. Ex. 4 at 44. Jessie also had a physical, which included drawing blood and having it analyzed, that same day. The results of the physical showed that Jessie was healthy on June 16, 2003, and that he was not experiencing infections or other serious health problems. Ex. 11 ¶¶ 4-5; Tr. at 49, 52-54.

Thus, until he received the vaccinations on June 16, 2003, Jessie was healthy. Testimony at the hearing indicates that in the thirty days before receiving the vaccinations, Jessie experienced no infections, and that no one in his household was ill during this time. Tr. at 12. For the rest of the day on June 16, 2003, Jessie experienced no unusual symptoms. That evening, Jessie told his father that his arms hurt where he had received the shots. Ex. 9 ¶ 10; Tr. at 31-32.

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[7]/ ...continue
surprising given the length of this litigation. The transcript (Tr.) records both hearings held by the special master: the first hearing is reported in transcript pages 1-555; the second hearing is reported in transcript pages 556-689. Obvious errors in the transcript are corrected in brackets ([ ]).

[8]/ Jessie's early medical records contain gaps and inaccuracies. Records of his birth are no longer extant. Ex. 2. His birth date is often recorded as April 14, 1990, rather than May 14, 1990, and his first DTaP vaccination is recorded, presumably incorrectly, as occurring on May 12, 1990, two days before his birth. Ex. 4 at 2-3, 5, 8-9.

B. Jessie, a Critically-Ill Thirteen-Year Old

On June 17, 2003, approximately twenty-four hours after receiving his vaccinations, Jessie complained to his mother that "his hands were numb and he had a very strong pain in his back."[9] Tr. at 15. Jessie was crying, and his mother became alarmed. First calling her husband, who returned to the house, they together called Jessie's primary care clinic and were advised to take Jessie to the emergency room. *Id.* at 16. While on the way to the emergency room, Jessie had trouble maintaining his balance in the back seat of the car, and experienced nausea. He needed assistance getting into the hospital. *Id.* at 17.

The court omits a detailed discussion of Jessie's diagnostic evaluation in the emergency room (ER), and in the hospital to which he was transferred, as unnecessary for the purposes of this opinion. Suffice it to say that Jessie was very sick, with rapidly escalating symptoms, and he was evaluated in the ER for approximately four and a half hours. Ex. 12 ¶ 3; Tr. at 74. He had weakness and paresthesia in his arms, and difficulty standing or walking, also due to weakness.[10] Tr. at 67-69. The arm weakness was described as "true paralysis." *Id*. at 75. He developed difficulties with urination, which required catheterization, as well as priapism (erection of penis). Ex. 12 ¶ 4. Jessie was transferred to a hospital with a pediatric intensive care unit (PICU), Long Beach Memorial Hospital (also known as Miller's Children's Hospital).

Upon arrival at the Miller's Children's Hospital around 6 P.M. on June 17, 2003, Jessie was described as having presented with "progressive neuromuscular deterioration and life-threatening respiratory failure." Ex. 13 ¶ 5. He was admitted to the PICU. Ex. 7 at 39. The record does not clearly show when Jessie's symptoms peaked, but he appears to have been intubated and put on a respirator on June 19, 2003. *Id*. at 2. He suffered a variety of symptoms of his illness while at Miller's Children's Hospital, including quadriplegia and neurogenic bladder. Ex. 13 ¶ 7. Apparently Jessie was "weaned" off the respirator and had a tracheotomy

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[9]/ The court adopts twenty-four hours as a shorthand reference to what the special master determined to be "approximately 25 hours," the time between the vaccinations and the onset of the symptoms of Jessie's illness. Opin. at 2 n.2.

[10]/ Paresthesia is a tingling sensation "when nerves are not properly functioning." Tr. at 68.

on July 3, 2003. Ex. 7 at 2. On July 9, 2003, Jessie had a procedure for the installation of a stomach tube. *Id.* The stomach tube and the tracheotomy tube were removed on August 27, 2003. *Id.* One of petitioner's experts estimated that Jessie's symptoms peaked approximately four or five days after June 17, 2003, and that estimate is largely unrebutted by respondent. Tr. at 523.

C. Jessie, Stabilized But No Longer in Good Health

After weeks of treatment and rehabilitation, Jessie's health stabilized. He was discharged from Miller's Children's Hospital on September 11, 2003. Ex. 13 ¶ 5. His subsequent school career required accommodations due to his ongoing symptoms, which included mobility impairments ("incomplete quadriplegia") and incontinence ("neurogenic bowel and bladder"). Ex. 80 at 2, 4; Ex. 84. There appear to be emotional sequelae to his illness, as well. Ex. 83 at 7; Tr. at 19. Sadly, even today he continues to suffer from neuromuscular problems and is somewhat dependent on his family due to his deficits. Tr. at 19, 39.

II. Procedural History

While Jessie was at Miller's Children's Hospital, Jessie's parents expressed a concern that the June 16, 2003 vaccinations had caused Jessie's illness. Ex. 7 at 147. One of the treating physicians at the hospital scheduled an appointment with Jessie's parents to discuss with them, through an interpreter, the lack of evidence of a causal link between Jessie's illness and the HepB vaccine. *Id.* On June 15, 2005, approximately two years later, Jessie's father, acting for Jessie, filed a petition under the Vaccine Act, alleging that the HepB vaccine and the Td vaccine that Jessie received on June 16, 2003 had caused the onset of transverse myelitis (TM) and Guillain-Barré Syndrome (GBS). Pet. ¶ 35.

Respondent (hereinafter respondent or Secretary) opposed the petition, arguing that neither Td nor HepB had been shown to cause TM or GBS, both of which are "demyelinating neurological disorders." R's Rule 4(b) Report at 8-9.[11] Respondent also argued that the temporal relationship between the vaccinations and the injury was too short, *i.e.*, that neither TM nor GBS could plausibly occur

[11]/ Due to the large number of briefs filed in this case, and their lengthy titles, the court adopts these abbreviations for petitioner and respondent in citations to these briefs: "P's" and "R's."

within 24 hours of a triggering event. *Id.* at 9. The government argued that a plausible interval, if the biological mechanisms contemplated by certain scientists were assumed to have occurred, would be "5-45 days." *Id.*

At this early point in the litigation, the special master then assigned to the case recognized that the appropriate time-frame for the onset of symptoms of TM and GBS would be a hotly contested issue. *See* Order of Nov. 18, 2005. That special master suggested that the parties obtain the expert opinions of immunologists or neuroimmulogists. *Id.* at 2. Petitioner's expert report from Dr. Lawrence Steinman, M.D., filed on March 9, 2006, was founded on his experience as a neurologist, an immunologist, and as a researcher. Ex. 55 at 5. That special master noted that Dr. Steinman has "impressive professional credentials." Order of Apr. 21, 2006. Respondent, rather than immediately countering Dr. Steinman's expert report with its own supplemental expert report, suggested that the parties be given sixty days for a "litigation risk settlement." Status Report (SR) of May 12, 2006.

For approximately a year and a half, as documented in about a dozen status reports, the parties engaged in settlement discussions. On September 21, 2007, the parties reported that respondent had "submitted a detailed litigative risk settlement offer which includes life-long medical care, lost wages and pain and suffering." SR of Sept. 21, 2007 at 1. On November 8, 2007, the special master granted the parties' request for a referral to alternative dispute resolution (ADR); an ADR proceeding was scheduled with the chief special master, to be held on December 20, 2007 in California. Orders of Nov. 8, 2007 and Dec. 11, 2007. On February 27, 2008, the special master, requesting a report on the progress toward settlement of this case, noted that respondent, in the absence of a tentative settlement, must submit an expert report addressing the opinion of Dr. Steinman, and that "[t]he special master anticipates that respondent's medical expert will possess credentials that are commensurate with Dr. Steinman's credentials." Order of Feb. 27, 2008.

On April 2, 2008, the parties reported that "[d]espite intensive efforts, the parties have not been able to reach a tentative settlement in this case" and agreed that further negotiations would not be productive at that time. SR of Apr. 2, 2008 at 1. In this report, the parties noted that respondent had retained an expert to

"address[] Dr. Steinman's opinion."[12] *Id.* Before any expert report was filed by respondent, however, the chief special master contacted the parties and suggested that another attempt at ADR might resolve this litigation. SR of June 3, 2008. That summer, the chief special master re-assigned this case to a new special master, the special master who continues to preside over this case.[13] Order of July 23, 2008. The parties engaged in ADR proceedings with the chief special master, again in California, on September 3, 2008.

At a status conference held in December 2008, the parties appear to have abandoned settlement negotiations, returning instead to the task of proving or disproving Jessie's entitlement to compensation. Order of Jan. 21, 2009. Respondent retained Dr. J. Lindsay Whitton, M.D., Ph.D., to address Dr. Steinman's opinion. Exs. L, M. Dr. Whitton is a research scientist with extensive experience relevant to the biological mechanisms disputed here.[14] Tr. at 406-09. The court sees no need for a detailed discussion in this opinion of the content of the expert reports and of the exhibits relied upon by the parties.[15]

A. The 2010 Hearing, and the Diagnosis Issue

The special master scheduled a hearing in California for April 19-20, 2010. In two pre-hearing orders, the special master expressed an interest in the diagnosis

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[12]/ The expert named in this report is not the expert that respondent eventually engaged to address Dr. Steinman's opinion.

[13]/ The special master originally assigned to this case was no longer available to decide cases.

[14]/ Dr. Whitton earned an M.B. and Ch.B. from the University of Glasgow, which are the "U.K. equivalent to MD." Ex. M at 1. He is not, however, a practicing physician nor is he licensed to practice medicine in the United States. Tr. at 452-53. His testimony does not indicate that he does research involving human subjects or human cells. *Id.* at 453-54.

[15]/ The expert reports (submitted by non-treating doctors) filed before the hearing held in 2010 include two by Dr. Charles M. Poser, M.D., a neurologist for petitioner (Ex. 22, filed June 15, 2005; Ex. 23, filed Nov. 14, 2005); two by Dr. John T. Sladky, M.D., a neurologist for respondent (Ex. I, filed first on Oct. 27, 2005 and re-filed on Dec. 2, 2005; Ex. P, filed Mar. 22, 2010 and designated at that time as Exhibit O); three by Dr. Steinman (Ex. 55, filed March 9, 2006; Ex. 105, filed June 29, 2009; Ex. 124, filed Feb. 17, 2010); and two by Dr. Whitton (Ex. L, filed Feb. 19, 2009; Ex. N, filed Sept. 8, 2009).

of Jessie's illness, *i.e.*, whether Jessie's illness was TM, or GBS, or both. First, the special master stated that "[i]t is the undersigned's understanding that respondent does not challenge the accuracy of these [TM and GBS] diagnoses." *See* Order of Jan. 8, 2012 at 3. In support of his understanding of the record, the special master cited Dr. Whitton's expert report which states that he agreed that Jessie suffered from both TM and GBS. *Id.* (citing Ex. L at 2-3). Next, the special master encouraged the parties "to discuss any information by Jessie's treating doctors (citing to exhibit and page number) regarding a diagnosis of Jessie's condition." Order of Apr. 1, 2010 at 2.

Both parties submitted pre-hearing briefs. Petitioner's brief (P's Pre-Trial Br.) was filed on March 8, 2010. The government's brief (R's Pre-Trial Br.) was filed on March 22, 2010. The government's brief does not clearly answer the special master's question as to whether respondent was or was not challenging petitioner's contention that Jessie experienced both TM and GBS after his vaccinations on June 16, 2003.

The onset of Jessie's illness and the opinions of the experts and treating physicians as to causation were discussed in live testimony at the 2010 hearing.[16] The special master noted that respondent had not offered a factor unrelated to the vaccines as the cause of Jessie's illness. Order of Apr. 22, 2010 at 5. The special master ordered post-hearing briefs, noting particular topics to be addressed. Order of Apr. 22, 2010 at 2. The special master listed "Diagnosis of Mr. Contreras" as the first topic under "Elements of Petitioner's Case."[17] *Id.* The special master stated that "[r]espondent maintained that [Jessie] suffered from transverse myelitis only."[18]

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[16]/ Dr. Poser, as previously noted, was unavailable to testify at the hearing due to his health. *See supra* note 5. Dr. Jeremy S. Garrett, M.D., a treating physician at Miller's Children's Hospital who submitted an affidavit in support of Jessie's petition, was unable to testify because he had relocated to Missouri and his responsibilities at a hospital there did not permit his attendance. Ex. 147 at 2.

[17]/ Petitioner's case (*i.e.*, burden to prove causation) was described in the order as containing four elements, in the following sequence: diagnosis, *Althen* prong one, *Althen* prong two, and *Althen* prong three. Order of Apr. 22, 2010 at 2-5.

[18]/ In the court's view, respondent's position in its pre-hearing brief is that Jessie suffered from TM, but the government takes no clear position on the question of whether or not

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Id. In their post-hearing briefs, the parties were prompted to address whether or not Jessie had suffered from GBS, and were instructed to "explain why determining whether Mr. Contreras suffered from [GBS] affects the outcome of this case." *Id.*

Petitioner filed his post-hearing brief (P's Post-Trial Br.) on August 23, 2010. Respondent's post-hearing brief (R's Post-Trial Br.) was filed on November 24, 2010. In that brief, the government disclaimed the need, in this case, for the special master to diagnose the illness from which Jessie suffered after his vaccinations. In the section of the brief required by the special master to address Jessie's diagnosis, respondent noted:

> Dr. Sladky testified that whether Jessie suffers from TM, GBS, or an overlapping of these two conditions, does not change his opinion regarding whether Jessie's condition was caused by the Hep B vaccine.

R's Post-Trial Br. at 5. The court notes that respondent's other expert, Dr. Whitton, had opined that Jessie suffered from both TM and GBS, although he stated that he was less than certain of his diagnosis of Jessie at the hearing. *Compare* Ex. L at 2-3 *with* Tr. at 437-38. Dr. Whitton testified that for his opinion about causation in this case, it does not really matter whether Jessie had TM or GBS. Tr. at 438.

Respondent's post-hearing brief noted that "the experts do not agree on an exact diagnosis." R's Post-Trial Br. at 5. The government concluded the "diagnosis" section of its brief with these statements:

> The special master is not required to make a finding regarding Jessie's exact diagnosis as a prerequisite to determining vaccine causation. Whether Jessie's

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[18]/ ...continue
Jessie also suffered from GBS, despite the special master's invitation to do so in his January 2010 pre-hearing order. The government's pre-hearing brief mentions GBS numerous times and never states that Jessie did not have GBS. *See* R's Pre-Trial Br. at 2-3, 10 n.4, 23 (stating that "respondent recognizes that it is theoretically plausible that a vaccine might cause GBS"); 25 (stating that "several large population studies . . . have found no association between vaccinations and GBS or other neurodemyelinating diseases"), 28. Thus, the special master appears to have based his impression as to what respondent "maintains" on the tone of government counsel's questioning of witnesses during the hearing.

> neurodemyelinating condition is TM or GBS does not change the fact that petitioner has failed to present a reliable medical theory that Hep B vaccine can cause either condition within twenty-four hours of administration.

Id. In a footnote, respondent notes further that "it appears that both parties agree that the special master does not need to determine whether Jessie has TM, GBS, or an overlapping condition." *Id.* n.8.

Indeed, petitioner argued that:

> This is not a situation where the identification of one disease over another might dictate the identification of an alternative cause of injury unrelated to the vaccine. Given the similarity of the two diseases and their underlying cause, identification of one or both should not [a]ffect the outcome of this case since the testimony is that the cause of each disease was the vaccines administered.

P's Post-Trial Br. at 15 (emphasis removed). Thus, the parties were unified in their view that the analysis of causation, in this case, did not require a precise diagnosis of TM, GBS, or TM combined with GBS.

B. The Closing of the Evidentiary Record, Its Re-Opening, and the 2011 Hearing

The special master had alerted the parties that the numerous exhibits filed in this case, many of which were highly-technical articles from medical journals, might not be considered persuasive unless these articles were discussed by experts at the 2010 hearing. *See* Order of Apr. 1, 2010 at 3. Specifically, the special master stated that:

> [T]he parties are encouraged to elicit testimony from an expert about the significance of a particular article. Arguments in post-hearing briefs about the relevance of a particular article that has not been the subject of expert testimony may not be persuasive.

Id. At the opening of the 2010 hearing, the special master again warned the parties that expert testimony was very important in establishing the relevance of a particular article submitted as an exhibit during the course of this lengthy litigation:

> The general rule of thumb is that if the attorneys think the article is so important that the attorney wants to cite it in a post[-]trial brief, then we should have an expert testify about it while they're here. But what I want to avoid happening is one of the attorneys arguing the most important article is the Jones article, and then when I look at the transcript, no one has discussed the Jones article. So you want to take advantage of people[']s knowledge while they're here.

Tr. at 6-7.

Petitioner's counsel expressed some doubts that the hearing schedule permitted discussion by experts of every relevant article submitted by the parties, and noted that Dr. Garrett and Dr. Poser were unavailable to testify:

> It[']s virtually impossible to limit a time to go through all the articles and say they're important. And I know a lot of the articles that we've submitted and Dr. Garrett and Dr. Poser submitted on behalf of their affidavits that they thought were important. And I know some that you [Dr. Steinman] know obviously . . . or you believe so, too.

Tr. at 175 (near the end of counsel's direct examination of Dr. Steinman). After the hearing, the special master closed the evidentiary record, except for a few specific exhibits that the parties were ordered to file to support specific testimony that was given at the 2010 hearing. *See* Order of Apr. 22, 2010 at 1-2. Petitioner, despite instructions to the contrary, submitted two new, unsolicited articles in support of his post-hearing reply brief. *See* P's Exs. 148-49.

The special master re-opened the record and eventually decided a second hearing was appropriate to examine the new evidence received after the 2010 hearing. *See* Order of May 9, 2011 at 1. The new evidence included petitioner's exhibits 148 and 149; respondent's exhibits W, X, Y, Z, and AA; a supplemental

report by Dr. Steinman (Ex. 152); petitioner's exhibits 153-57; and, a supplemental report by Dr. Whitton (Ex. BB). The day before the second hearing was to be held, the special master also indicated that he wished to hear further expert testimony on Ex. 118, an article by F. Odoardi of the Max Planck Institute for Neurobiology (Martinsried, Germany). Order of July 27, 2011. Thus, the scope of the second hearing was limited to the new evidence supplied after the evidentiary record had been closed, and the Odoardi article.[19] *Id.*

At the hearing held by video conference on July 28, 2011, both Dr. Steinman and Dr. Whitton returned to testify for petitioner and respondent, respectively. The special master set a post-hearing brief schedule, to include a brief by petitioner (P's Post-Trial Supp. Br.), a brief by respondent (R's Post-Trial Supp. Br.), and petitioner's reply brief (P's Post-Trial Supp. Reply). The special master indicated that "[i]t would be helpful if the . . . briefs focused on whether approximately 26 hours is a medically acceptable time from which to infer causation."[20] Order of Sept. 19, 2011.

C. The Special Master's Decision, Challenged By Petitioner's Motion for Review

On April 5, 2012, the special master issued a decision denying Jessie compensation under the Vaccine Act. The special master found, first, that the sole diagnosis of Jessie's illness is transverse myelitis, by a preponderance of the evidence. Opin. at 12. The special master stated that this finding "is not particularly important to the outcome" of this case, noting the similarities between

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[19]/ The court notes that the "topic" of the second hearing was initially described as "tuberculosis in mice and men." Order of May 9, 2011. This topic is indicative of the special master's increasing focus on Dr. Steinman's and Dr. Whitton's diverging opinions as to the science relevant to determine a medically-appropriate time-frame for the onset of Jessie's illness, and decreasing focus on other evidence in the record.

[20]/ The court notes that the phrasing used by the special master to describe *Althen* prong three in this order is a subtle but significant departure from the description of *Althen* prong three in *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008), an error which is examined in the analysis section of this opinion.

TM and GBS.[21] *Id.* The special master observed, in particular, that TM and GBS are both "diseases in which portions of the nervous system are demyelinated [and that both] diseases may be caused via an autoimmune process." *Id.* After stating that the parties did not view the exact diagnosis of Jessie's illness as an important part of this case, the special master repeated his finding that Jessie only suffered from TM and opined that:

> It is important to emphasize that the same result would be reached if Mr. Contreras suffered from both transverse myelitis and Guillain-Barré syndrome. The outcome of Mr. Contreras's case depends on the interval between his vaccinations and the onset of his disease, not on the specific disease.

Id. at 13.[22]

The special master made no findings as to *Althen* prongs one and two. Opin. at 11. The special master also did not address whether petitioner had ruled out alternative causes of Jessie's illness, although petitioner had repeatedly argued that no alternative cause for Jessie's illness had been identified. *See, e.g.*, P's Pre-Trial

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[21]/ The court disagrees with the special master as to his observation that diagnosing Jessie as having TM, and not TM as well as GBS, is not important. A significant amount of Dr. Sladky's, Dr. Whitton's and Dr. Steinman's testimony regarding the blood brain barrier and the central nervous system, *see, e.g.*, Tr. at 308-09, 418, 481, 516-21, 527-29, 551, 577-78, 580, 612-13, 630-31, 633-42, 647, 650, 652, 658-62, 668, 670, 678, 680-82, gains much greater importance if the diagnosis of GBS, a disease of the *peripheral* nervous system, is not applicable to Jessie.

[22]/ The court cannot assume, as does the special master, that the outcome of this case would be the same regardless of Jessie's diagnosis. Too much reliance is placed by the special master on expert testimony that is relevant only to TM, a disease of the *central* nervous system, and not relevant to GBS, a disease of the *peripheral* nervous system, *see supra* note 21, to infer that he has conducted a thorough review of all relevant evidence regarding *Althen* prong three and an alleged vaccine injury of a combination of TM and GBS. *See, e.g.*, Opin. at 28 (finding Dr. Steinman "not persuasive" on one of his principal arguments on the timing issue, "most importantly" because of Dr. Whitton's testimony regarding the blood brain barrier). Indeed, the special master's opinion is focused, almost exclusively, on his conclusion that the *central* nervous system could not have been attacked and damaged within twenty-four hours so as to causally link Jessie's TM with his vaccinations. *See, e.g., id.* at 11 n.8, 29-30, 34.

Br. at 23; P's Post-Trial Br. at 5, 12, 55. Instead, the special master found that Jessie's illness had not occurred within a medically-appropriate time-frame, so as to satisfy *Althen* prong three, and denied petitioner compensation for this reason. Opin. at 15, 34. The special master's determinative finding included an erroneous formulation, *see supra* note 20, of petitioner's burden on *Althen* prong three:

> [W]hether the medical community would accept one day as being a basis for inferring that the hepatitis B vaccine caused the transverse myelitis.

Opin. at 34.[23]

On May 4, 2012, petitioner filed a motion for review (P's Mot.) of the special master's decision. Respondent filed a response brief (R's Resp.) on June 4, 2012. The court granted petitioner's request to file a reply brief (P's Reply), which was filed on June 25, 2012. Petitioner's motion is now ripe for decision.

DISCUSSION

I. Standard of Review

This court has jurisdiction to review the decision of a special master in a Vaccine Act case. 42 U.S.C. § 300aa-12(e)(2). "Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]'" *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1350 (Fed. Cir. 2008) (quoting 42 U.S.C. § 300aa-12(e)(2)(B) and citing *Althen v. Sec'y of*

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[23]/ The court presumes that the special master is relying on this statement in *de Bazan*, a decision cited on the same page of the special master's opinion, which defines *Althen* prong three:

> Thus, the proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact.

de Bazan, 539 F.3d at 1352.

Health & Human Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005)) (alteration in original). This court uses three distinct standards of review in Vaccine Act cases, depending upon which aspect of a special master's judgment is under scrutiny:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard.

Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

The arbitrary and capricious standard of review is used to consider factual findings by the special master. *Id.* The scope of this review is limited, and highly deferential. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000); *Burns by Burns v. Sec'y of Dep't of Health & Human Servs.*, 3 F.3d 415, 416 (Fed. Cir. 1993). "If 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 ex rel. Sevier v. Sec'y of Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). This court's arbitrary and capricious review of the fact findings of a special master is "well understood to be the most deferential possible." *Munn*, 970 F.2d at 870 (citations omitted). When the court's review of a special master's decision involves statutory construction or other legal issues, the "not in accordance with law" standard is applied. *Hines*, 940 F.2d at 1527. The third standard of review, abuse of discretion, is applicable when the special master excludes evidence or otherwise limits the record upon which he relies. *See Munn*, 970 F.2d at 870 n.10.

II. Burden of Proof in a Causation-in Fact Vaccine Injury Case

For the type of Vaccine Act case presented here, a petitioner may make out a prima facie case of entitlement to compensation by showing, by a preponderance of the evidence, that vaccinations actually caused the petitioner to sustain an illness, disability, injury or condition. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citing 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii)(I), 300aa-13(a)(1)). To establish causation-in-fact requires "preponderant evidence

both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Id.* (citing *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)). The vaccinations "must be a 'substantial factor'" in bringing about the injury, but "need not be the sole factor or even the predominant factor." *Id.* at 1357 (citing *Shyface*, 165 F.3d at 1352-53).

The United States Court of Appeals for the Federal Circuit has further explained the evidentiary burden associated with causation-in-fact Vaccine Act cases. That court explained that a petitioner who wishes to demonstrate that a vaccination brought about his or her injury should present:

> (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, 418 F.3d at 1278. These three elements of proof are often referred to as the three *Althen* prongs.

As to the evidence related to the three factors, "these prongs must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford*, 451 F.3d at 1355. Further, "[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278 (citing *Grant v. Sec'y of Dep't of Health & Human Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992)). It is likewise critical to recognize that the special master may not make a finding of causation that is based on the claims of a petitioner alone, which are not substantiated by medical records or by medical opinion. *See* 42 U.S.C. § 300aa-13(a)(1). Thus, the presentation of medical records or medical opinion supporting a claim is a prerequisite to recovery. *Id.*

Only if a petitioner presents adequate evidence on the three essential aspects of causation, and thus makes a prima facie case for liability, does the burden shift to the Secretary to prove, also by a preponderance of the evidence, an alternative cause

of the alleged injury. *Althen*, 418 F.3d at 1278 (citations omitted). As a general rule, when a petitioner seeks to demonstrate causation-in-fact by meeting the three *Althen* requirements, each of those requirements must be established by a preponderance of the evidence.[24] *See Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010); *de Bazan*, 539 F.3d at 1351-52; *Caves v. Sec'y of Dep't of Health & Human Servs.*, 100 Fed. Cl. 119, 132, 144 & n.18 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012). There are instances, however, where preponderance of the evidence on all three *Althen* prongs may not be required:

> As we explained in *Walther*, we have held that a petitioner may . . . rule out possible alternative causes to prove causation-in-fact when evidence as to the *Althen* requirements is insufficient.

de Bazan, 539 F.3d at 1352 n.3 (citing *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1149-50 (Fed. Cir. 2007); *Pafford*, 451 F.3d at 1357-59). Finally, it has also been said that "close calls" as to the causal link between a vaccine and the petitioner's injury should be resolved in favor of the petitioner.[25] *Althen*, 418 F.3d at 1280 (stating that in the system provided for deciding vaccine injury claims, "close calls regarding causation are resolved in favor of injured claimants") (citing *Knudsen by Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)).

III. Analysis

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[24]/ Although it is clear that a preponderance standard applies to a petitioner's prima facie case, some decisions of this court hold that a petitioner is not required to prove each of the three *Althen* prongs, separately, by a preponderance. *See Doe 93 v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 553, 566-68 (2011); *see also Graves v. Sec'y of Dep't of Health & Human Servs.*, 101 Fed. Cl. 310, 324 (2011) (approving of the approach taken in *Doe 93*).

[25]/ There is a potential ambiguity as to the proper balancing of this principle of "close calls" being decided in favor of petitioners, and petitioners' burden to establish causation-in-fact by a preponderance of the evidence. *Compare Althen*, 418 F.3d at 1280, *with id.* at 1278. The court does not believe these statements in *Althen* are irreconcilable. At a minimum, the special masters must not heighten the standard required to satisfy any of the three *Althen* prongs. Unfortunately, that is exactly what happened here, as discussed *infra*.

Petitioner raises a variety of arguments in his challenge to the special master's decision denying Jessie compensation for his alleged vaccine injury. Several of these arguments suggest that the special master erred in weighing certain evidence in the record. The court refrains from re-weighing the evidence, because the standard of review for the special master's fact finding is highly deferential. *E.g.*, *Hines*, 940 F.2d at 1528.

More importantly, petitioner raises a variety of challenges to the special master's interpretation and application of the law, and the court exercises *de novo* review of such questions. *See, e.g.*, *Althen*, 418 F.3d at 1278-79. Many of petitioner's arguments give examples of how the special master utilized the wrong standard for evaluating petitioner's prima facie case. *See* P's Mot. at 1-2. The court shares petitioner's view that the special master: (1) improperly chose to diagnose Jessie's illness; (2) inappropriately dismissed the opinions of two treating physicians; and, (3) incorrectly heightened the standard of proof on *Althen* prong three. *See* P's Mot. at 39, 41, 48.

Thus, the court agrees with petitioner that several errors of law occurred, but views some of the errors from a different perspective than that espoused by petitioner. The court also discusses in this opinion an error that was raised by petitioner in a more indirect fashion – the failure of the special master to rule on petitioner's assertion that no other cause had been identified for Jessie's illness. P's Mot. at 49. The court must reject, however, petitioner's arguments that focus on the special master's "failure" to rule on *Althen* prongs one and two, *id*. at 40, because a special master may indeed deny compensation based on a failure to meet just one of the three *Althen* prongs, although this approach may frustrate judicial economy. *See infra*.

Respondent ably argues that petitioner proposes a more relaxed standard of proof for causation-in-fact than precedent permits. R's Resp. at 9 n.6. To the extent that some of petitioner's statements regarding Jessie's burden of proof may contradict precedent binding on this court, the court agrees with respondent. Respondent is also persuasive when urging this court to reject petitioner's invitation to re-weigh the evidence of causation in this case. *Id.* at 13-14. The court does not agree with respondent, however, that the special master applied the correct standard to the testimony of Jessie's treating physicians. *Id.* at 21-23. Finally, the court cannot agree that the special master utilized the correct standard for *Althen* prong three. *Id.* at 23-24.

A. May a Special Master Diagnose a Petitioner's Illness Before Applying the *Althen* Prongs?

The special master diagnosed Jessie as suffering from TM, although petitioner contended that Jessie suffered from TM and GBS. Despite ample evidence that TM and GBS are similar diseases with similar pathologies, and despite the parties' unified position that an exact diagnosis of Jessie's illness was not required to rule on causation, the special master chose to diagnose Jessie as the first step in his causation analysis. The court cannot justify this choice of the special master.

First, the special master did not correctly assess the parties' litigation positions on this issue. The special master stated that the parties disputed Jessie's diagnosis. *See* Opin. at 11 (noting that the first of "three points of dispute between the two sides . . . concerns the disease that afflicted Mr. Contreras"). Respondent did not, as a matter of fact, dispute Jessie's diagnosis. *See generally* R's Post-Trial Br.; R's Post-Trial Supp. Br. Thus, the special master misread the record to evidence a dispute that in fact was not there.

It is also impossible to justify the special master's *sua sponte* diagnosis of Jessie's illness under the precedent of the Federal Circuit. The general scheme of Vaccine Act cases is such that a level of precision is not required of a petitioner as to the specific biological mechanism which caused his or her alleged vaccine injury, just as the government is not obliged to identify the particular virus it puts forth as an alternative cause of that injury. *See, e.g.*, *Knudsen*, 35 F.3d at 549. This general scheme for awarding compensation for vaccine injuries also does not assign to a special master the task of diagnosing a petitioner's injury. *See, e.g.*, *id.* ("The special masters are not 'diagnosing' vaccine-related injuries."). This particular principle has been so often repeated that this court must conclude that the general rule is that a special master should not conduct a differential diagnosis, at the outset of the causation analysis, to choose one diagnosis over another, or over a combination of diagnoses. *See, e.g.*, *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249-50 (Fed. Cir. 2011); *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1351 (Fed. Cir. 2011); *Broekelschen*, 618 F.3d at 1345; *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009); *Althen*, 418 F.3d at 1277 n.4, 1280-81.

There are, however, to the court's knowledge, two permitted exceptions to

the general rule. In *Broekelschen*, for example, the petitioner suffered from symptoms which could have been attributed to either TM or anterior spinal artery syndrome, and the correct diagnosis was disputed by the parties. 618 F.3d at 1343-44. In the Federal Circuit's opinion, it was noted that

> the instant action is atypical because the injury itself is in dispute, the proposed injuries differ significantly in their pathology, and the question of causation turns on which injury Dr. Broekelschen suffered. Therefore, it was appropriate in this case for the special master to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test so that the special master could subsequently determine causation relative to the injury.

Id. at 1346. Further, the *Broekelschen* court distinguished two cases where the varying diagnoses of the alleged vaccine injury were along a continuum of related conditions; in those cases, a precise diagnosis would be unnecessary for the causation analysis. *See* 618 F.3d at 1346 (distinguishing *Andreu*, 569 F.3d at 1378, 1381 and *Kelley v. Sec'y of Health & Human Servs.*, 68 Fed. Cl. 84, 100-01 (2005)). Thus, in an atypical case, where "the question of causation turns on which injury [the petitioner] suffered," the special master is permitted to choose between two competing diagnoses of dissimilar diseases as a first step in the causation analysis.[26] *See id.*

It is interesting to note that each of the reasons given in *Broekelschen* to support an exception to the general rule that special masters should not diagnose alleged vaccine injuries is absent in this case: the parties did not dispute Jessie's diagnosis, TM and GBS do not differ significantly in their pathologies, and the experts specifically testified that their opinions as to causation would not change if TM, GBS, or a combination of both, were determined to be the correct diagnosis for Jessie. *See* Tr. at 191, 294, 438. Thus, the *Broekelschen* exception to the general rule is inapplicable in this case. Here, the special master's decision to diagnose

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[26]/ The dissenting judge in *Broekelschen* disagreed, and stated that "[t]his approach, of first assigning a diagnosis to Broekelschen's symptoms before applying the *Althen* test, is not supported by statute, caselaw, or logic, and its effect was to impermissibly heighten Broekelschen's burden." 618 F.3d at 1352 (Mayer, J., dissenting).

Jessie's illness as a first step in the causation analysis was not in accordance with law.

There are isolated statements in *Broekelschen* which might have misled the special master in this regard. For example, the court stated that "identifying the injury is a prerequisite to the [causation] analysis." 618 F.3d at 1346. The court also stated that "[m]edical recognition of the injury claimed is critical and by definition a 'vaccine-related injury,' i.e., illness, disability, injury or condition, has to be more than just a symptom or manifestation of an unknown injury. Thus, it was appropriate for the special master to initially determine which injury Dr. Broekelschen suffered before applying the *Althen* test." *Id.* at 1349. These statements should not, however, be taken out of the context of the particular circumstances of the *Broekelschen* case,[27] and should not be considered to reject the general rule, first stated in *Knudsen*, that special masters should not diagnose alleged vaccine injuries. A later panel of the Federal Circuit must follow precedent set by an earlier panel, and any perceived inconsistencies in Federal Circuit precedent must be reconciled, if at all possible. *See, e.g., Sacco v. Dep't of Justice*, 317 F.3d 1384, 1386 (Fed. Cir. 2003) ("A panel of [the Federal Circuit] is bound by prior precedential decisions unless and until overturned *en banc*.") (citation omitted); *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1579 (Fed. Cir. 1989) ("Where conflicting statements such as these appear in our precedent, the panel is obligated to review the cases and reconcile or explain the statements, if possible."). To reconcile *Knudsen* and *Broekelschen*, this court holds that a special master must not diagnose a petitioner's alleged vaccine injury except in the limited circumstances outlined in the *Broekelschen* case, or in the *Lombardi* case, to which the court now turns. *See Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 n.3 (Fed. Cir. 2012) ("This court has previously discussed *instances* where it is appropriate for the Special Master to first determine an injury before applying the *Althen* test." (citing *Broekelschen*, 618 F.3d at 1349)) (emphasis added).

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[27]/ There are, for example, many statements in *Broekelschen* which appear to discourage an overbroad reading of that case. *See, e.g.*, 618 F.3d at 1346 (noting that "the instant action is atypcial"); *id.* (stating that "it was appropriate *in this case* for the special master to first determine which injury was best supported by the evidence") (emphasis added); *id.* (distinguishing a case where the varying diagnoses were "'variants of the same disorder'"); *id.* at 1349 (suggesting that the dissent was "ignoring the atypical nature of this case"); *id.* (stating that "this case is unusual").

The other exception this court has found in Federal Circuit precedent which permits a special master to *attempt* to choose among the competing diagnoses for an alleged vaccine injury, before proceeding to the *Althen* analysis, is found in *Lombardi*. In that "unusual" case, petitioner's experts disagreed as to her injury: one posited that she suffered from TM; the other testified that she suffered from either chronic fatigue syndrome or systemic lupus erythematosus. *Lombardi*, 656 F.3d at 1346, 1352. Of particular note is the fact that the petitioner in that case had not argued that her three diagnoses were all "conditions along a spectrum of diseases." *Id.* at 1352 (internal quotations and citation omitted). The Secretary's experts disputed those diagnoses, and proposed five other possible diagnoses. *Id.* The Federal Circuit stated that "[i]n the face of such extreme disagreement among well-qualified medical experts, each of whom had evaluated the petitioner, it was appropriate for the special master to first determine what injury, if any, was supported by the evidence presented in the record before applying the *Althen* test to determine causation." *Id.* at 1352-53 (citing *Broekelschen*, 618 F.3d at 1346). The *Lombardi* court concluded that "[i]n the absence of a showing of the very existence of *any* specific injury of which the petitioner complains, the question of causation is not reached." *Id.* at 1353 (emphasis added).

Thus, *Lombardi* permits a special master to attempt to diagnose the petitioner's illness in an unusual case where: (1) the petitioner presents conflicting diagnoses of her alleged vaccine injury; (2) the experts have "extreme disagreement" as to the malady suffered; and, (3) the diagnoses are not along a continuum of similar conditions. This is another limited exception to the general rule that special masters should not diagnose alleged vaccine injuries.[28] It is also an exception that does not apply here. Petitioner's experts were consistent in the diagnosis assigned to Jessie (TM and GBS), TM and GBS are similar demyelinating diseases of the nervous system, and there was not extreme disagreement among the experts as to Jessie's diagnosis – indeed, one of respondent's experts agreed, at least at one point in time, that Jessie had both TM and GBS. Ex. L at 2-3. Because the *Lombardi* exception does not apply here, the special master's decision to diagnose Jessie's illness as a first step in his causation analysis was not in accordance with law.

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[28]/ The concurring judge in *Lombardi* stated that *Broekelschen* had been wrongly decided, and that although the *Lombardi* panel was bound by *Broekelschen*, *Althen* did not permit a special master to diagnose an alleged vaccine injury before proceeding with the three prongs of the *Althen* analysis. *Lombardi*, 656 F.3d at 1356-58 (O'Malley, J., concurring).

As a final note on this topic, the court considers an overbroad reading of *Broekelschen* to conflict with the general analytical scheme set forth in *Knudsen* and *Althen*. If, in a case unlike *Broekelschen* in significant respects, the petitioner's array of symptoms is diagnosed, perhaps wrongly, by the special master, as an initial step in the causation-in-fact analysis, that petitioner's case could be drastically compromised. The testimony mustered by the petitioner might focus on a causation mechanism that could persuasively link a vaccine to petitioner's proffered diagnosis, but that same testimony might be unpersuasive as to causation of the diagnosis assigned by the special master. The special master's fact findings as to the diagnosis of the petitioner's illness, under an overbroad reading of *Broekelschen*, would be virtually unassailable upon review. The petitioner, in essence, would be forced to prove causation-in-fact of an illness diagnosed by the special master based on his reading of the evidence. That burden is impermissibly greater than the burden placed on a petitioner by *Knudsen*, 35 F.3d at 549, and *Althen*, 418 F.3d at 1280, where a diagnosis is not to be made by the special master, and close calls are resolved in favor of the petitioner. For all of these reasons, the court finds that the special master's decision to diagnose Jessie's illness before proceeding to the *Althen* analysis was not in accordance with law.

B. May a Special Master Deny Compensation after Making a Finding on Only One of the *Althen* Prongs?

The short answer to this question is yes, at least in general. The court has found one example where the Federal Circuit has affirmed a denial of compensation after the special master made a finding on only one of the *Althen* prongs. *Broekelschen*, 618 F.3d at 1350-51. The court concludes, therefore, that there is no *per se* rule forbidding a special master to deny compensation upon a finding that a petitioner has failed to meet one of the *Althen* prongs by a preponderance of the evidence.

The court notes, however, that there is logical overlap between the three *Althen* prongs, *Caves*, 100 Fed. Cl. at 145, and that evidence that goes to one prong may also be probative for another prong, *Capizzano*, 440 F.3d at 1326. When a special master focuses on only one *Althen* prong, he or she may fail to consider relevant evidence that was presented primarily in support of another *Althen* prong. In this case, there is a massive evidentiary record. If the special master restricted his review of the record to testimony, portions of reports, and exhibits that exclusively address the timing of onset issue, he ran the risk of ignoring other

relevant evidence that might also tend to support petitioner's burden on *Althen* prong three. *See* 42 U.S.C. § 300aa-13(b)(1) (requiring a special master to consider "all . . . relevant medical and scientific evidence"); *Hines*, 940 F.2d at 1528 (noting the expectation that a special master "consider[] the relevant evidence of record").

It is difficult to tell from the special master's opinion whether the special master considered all evidence in the record relevant to *Althen* prong three. Petitioner, for example, alleges that when the special master omitted any discussion of *Althen* prongs one and two, inconsistencies in respondent's position were hidden. P's Mot. at 40; *see also* P's Reply at 4 (discussing Dr. Sladky's "minority" view as to *Althen* prong one). To the extent that petitioner is arguing that the special master's opinion does not discuss all of the relevant evidence in this case, the court agrees, because the omission of any discussion of *Althen* prongs one and two truncates or avoids large bodies of evidence in record. To cite just one example, in the entire opinion Dr. Poser's views are accorded a few sentences, Opin. at 7, 16 n.12, and are omitted from further discussion because "Dr. Poser's opinions [on the timing issue] overlap with Dr. Steinman's opinions," *id.* at 16 n.12. The special master's opinion does not convince the court that the special master considered all of the relevant evidence in the record that bears upon *Althen* prong three.

Based on the court's review of the evidentiary record, this case appears to be a much closer call if evidence pertinent to all three *Althen* prongs is considered. For this reason, the court will require the special master, on remand, to make findings on all three *Althen* prongs in this case.

Finally, the court notes that judicial economy is not always well-served if a special master denies entitlement after making a finding on only one *Althen* prong. When a petitioner files a motion for review of a special master's decision denying entitlement, this court, and eventually the Federal Circuit, may need to determine whether that petitioner has met his or her burden to establish a prima facie case for causation. *See, e.g.*, *Andreu*, 569 F.3d at 1382 (reversing this court after making findings on all three *Althen* prongs). The review of a denial of entitlement is, therefore, often more efficient if the special master has made findings on all disputed *Althen* prongs.[29] *See, e.g.*, *Isaac v. Sec'y of Health & Human Servs.*, No.

[29]/ In many cases, one or two *Althen* prongs will not be disputed by respondent; findings of fact on these prongs are not required. *See, e.g., de Bazan*, 539 F.3d at 1352 (noting in that

continue...

08-601V, 2012 WL 3609993, at *2 & n.5 (Fed. Cl. Spec. Mstr. July 30, 2012) (finding, in a case where *Althen* prong three was conceded by respondent, that *Althen* prong one required denial of entitlement, but nonetheless proceeding to "review the evidence under Prong 2 of the *Althen* test for the sake of judicial economy and to provide additional context for [the special master's] ultimate conclusion"). In the circumstances of this case, the special master must make findings on all three *Althen* prongs to provide an adequate record for this court's review.

C. May a Special Master Ignore a Petitioner's Assertion that He Has Ruled Out Alternative Causes for His Illness?

In this case, petitioner repeatedly alerted the special master that no other alternative cause has been identified to explain Jessie's illness. P's Pre-Trial Br. at 23; P's Post-Trial Br. at 5, 12, 55; *cf.* P's Mot. at 49 (arguing to this court that Jessie's physical on June 16, 2003 "ruled out gastrointestinal and respiratory illness as potential causes for the TM/GBS"). Although these statements vary somewhat in their tone, petitioner asserted that Jessie's treating physicians had "eliminated" alternative causes or diseases. P's Post-Trial Br. at 12. Petitioner also cited appropriate precedent for the proposition that a petitioner may, as a practical matter, address the absence of alternative causes as part of the proof for petitioner's prima facie case. *Id.* at 54 (citing *Walther*, 485 F.3d at 1151). The special master focused his analysis exclusively on the timing of disease onset issue, and did not address whether petitioner had ruled out alternative causes for his alleged vaccine injury.

The special master did not apply the law correctly in this instance. The binding precedent of *de Bazan*, 539 F.3d at 1352 n.3, *Walther*, 485 F.3d at 1151, and *Pafford*, 451 F.3d at 1357-59, permits a petitioner to rule out alternative causes as a supplement to other evidence that goes to the three *Althen* prongs. Here, the court has no finding of the special master as to whether or not petitioner successfully ruled out alternative causes for Jessie's illness, and it cannot determine whether such a finding would have aided petitioner in meeting his burden to establish a prima facie case. Because the special master's legal analysis was deficient in this respect, remand is required. *See Walther*, 485 F.3d at 1151

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[29]/ ...continue
case that the first two *Althen* prongs were undisputed).

(holding that a "petitioner is certainly permitted to use evidence eliminating other potential causes to help carry the burden on causation and may find it necessary to do so when the other evidence on causation is insufficient to make out a prima facie case, [and in] such instances, clearly the special master must evaluate what evidence a claimant presents as part of determining whether the claimant makes a prima facie case.") (citation and footnote omitted).

The court will not attempt to make its own finding on this issue, but observes that there is some limited guidance for the special master in the Vaccine Act and precedent. First, no guidelines for a petitioner's attempt to rule out alternative causes are clearly stated in the Vaccine Act. On the other hand, the provisions governing respondent's burden in proving alternative causes, which apply only if a petitioner has established a prima facie case, clearly do not permit an unexplained, idiopathic origin of the injury to deny the petitioner compensation. 42 U.S.C. § 300aa-13(a)(2)(A). It is important to understand that the restrictions on respondent's rebuttal evidence regarding an alternative cause do not apply to petitioner's burden to establish its prima facie case, including, as in this case, the attempt to rule out alternative causes. *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1357-58 (Fed. Cir. 2010).

Does this mean that a petitioner suffering from a type of illness which often occurs as a result of unknown causes is foreclosed from ruling out alternative causes for his or her injury? The court believes that the answer to this question is no. Such a *per se* rule is not supported by precedent binding on the special masters and this court.

First, in *Pafford*, the Federal Circuit clearly believed that the petitioner in that case could have, with more persuasive testimony from her experts, ruled out alternative causes for her Still's disease. *See* 451 F.3d at 1359 (discussing the failure of one of Pafford's experts to "discuss in detail the other contemporaneous events unrelated to the vaccinations," as well as the special master's "proper[] introduc[tion] [of] the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations"). Still's disease, according to the underlying special master opinion affirmed by the Federal Circuit, has a variety of suspected causes but no known cause: "A dispositive etiology is unknown, but like many other types of arthritis, abnormal immune response, genetic predisposition and environmental triggers, and infectious agents are all being considered." *Pafford v. Sec'y of Dept. of Health & Human Servs.*, No. 01-165V,

2004 WL 1717359, at *3 (Fed. Cl. Spec. Mstr. 2004) (*Pafford I*) (footnote omitted). Thus, *Pafford* supports the view that a petitioner who suffers from an illness that has some idiopathic expressions may nonetheless rule out alternative causes. To do so, the focus must be on the contemporaneous events unrelated to the vaccinations in question, *see Pafford*, 451 F.3d at 1357-59; *Pafford I*, 2004 WL 1717359, at *8-*9 (considering whether contemporaneous incidents such as sinus infections or tonsillitis might have triggered Still's disease in that petitioner), not on the perplexing nature of the illness suffered by the petitioner.

The court now turns to *Doe*, where the Federal Circuit also discussed alternative causes in the context of the petitioner's prima facie case. At issue was whether an infant's death was caused by a vaccination. Among the competing explanations for the death were acute encephalopathy or edema, as proposed by the petitioner, or sudden infant death syndrome (SIDS), an alternative cause that petitioner attempted to rule out. *Doe*, 601 F.3d at 1353, 1358. SIDS is often described as an idiopathic or unexplained death. *Hossack v. Sec'y of Dep't of Health & Human Servs.*, 32 Fed. Cl. 769, 771 n.4 (1995). *Doe* thus might be read to support the view that unknown causes for an alleged vaccine injury should be considered by a special master when a petitioner attempts to rule out alternative causes for an illness or death. This, however, would be an overbroad reading of *Doe*.

The chief special master in *Doe* did not rely on the idiopathic characteristics of an illness to determine that a petitioner had failed to rule out an alternative cause for the alleged vaccine injury. She looked, instead, at the contemporaneous record of the alleged vaccine injury, in that case, an infant death. She identified a specific potential mechanism of causation for the SIDS death (asphyxiation), and credited expert testimony which indicated that asphyxiation might have caused the infant's death. *Doe*, 601 F.3d at 1356-57. The chief special master also compared facts in the record with facts common to SIDS deaths. *Id.* at 1357. Finally, the chief special master considered all of the evidence in the record which might explain the infant's death as a SIDS death, and concluded that this evidence weighed against finding that the vaccination had caused the death, under *Althen* prong two. *Id.* In *Doe*, the chief special master evaluated a specific alternative cause, weighed specific evidence, and cannot be said to have rejected a petitioner's attempt to rule out alternative causes by mere reference to the idiopathic nature of a particular illness.

Thus, the approach taken by the chief special master in *Doe* is perfectly consistent with the approach taken in *Pafford*. When a special master rules on whether a petitioner has eliminated alternative causes of an alleged vaccine injury, the focus should be on the contemporaneous circumstances of the injury that are unrelated to the vaccination. It is by presenting these contemporaneous facts, and by eliminating the specific alternative causes that can be identified within these facts, that petitioners may meet their burden to rule out alternative causes of their alleged vaccine injury.

This court has found no support in Federal Circuit precedent for holding petitioners to a higher burden. None of the binding precedent discussing a petitioner's attempt to rule out alternative causes, at least none that this court has found, defines that task as ruling out every known and unknown cause of an illness.[30] It is unreasonable to assume that the Federal Circuit in *de Bazan*, *Walther* and *Pafford* expected a petitioner's expert to conduct years of research to identify all previously unknown causes of the illness at issue in a case in order to rule out alternative causes of a petitioner's illness. Petitioners need address only those alternative causes that can be identified in the evidentiary record before the special master:

> This requirement [to address alternative causes] does not saddle petitioner with the unfair burden of disproving the role of the entire spectrum of alternative causes or "every possible ground of causation," but rather limits the petitioner's burden to proving, by a preponderance of the evidence, why the vaccine at issue and *not those other factors evidenced in the record* was the substantial factor in the alleged injury.

Pafford v. Sec'y of Dep't of Health & Human Servs., 64 Fed. Cl. 19, 36 (2005) (*Pafford II*) (citing *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991); *Wagner v. Sec'y of Dep't of Health & Human Servs.*, 37 Fed. Cl.

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[30]/ This court in *Caves* discussed this issue in *dicta*. Noting that "the majority of cases of TM" are idiopathic, the court opined that ruling out identified alternative causes for a petitioner's TM would not, in itself, satisfy *Althen* prong two. *Caves*, 100 Fed. Cl. at 141. This court considered a petitioner's task in ruling out alternative causes, however, to only include "the elimination of other identified causes." *Id.*

134, 139 (1997)) (emphasis in original); *cf. Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012) ("Indeed, in some cases a sensible assessment of causation cannot be made while ignoring the elephant in the room – the presence of *compelling evidence of a different cause* for the injury in question.") (citing *Walther*, 485 F.3d at 1151 n.4) (emphasis added).

While a special master may consider the fact that the illness in question is idiopathic in some or many cases, as part of the causation analysis, that fact does not frustrate a petitioner's ability to rule out alternative causes of his or her illness. In the court's view, unexplained occurrences of the illness in question are largely irrelevant to the question of whether alternative causes have been ruled out by a petitioner. Upon remand, the special master shall follow the precedent of *Pafford* and *Doe*, as discussed in this opinion, to determine whether or not petitioner has eliminated alternative causes for Jessie's illness as part of petitioner's effort to meet his burden to establish a prima facie case.

D. May a Special Master Assign Little Weight to the Opinions of Treating Physicians for *Althen* Prong Three?

Two of Jessie's treating physicians asserted that twenty-four hours was not too short a time for the onset of Jessie's illness to have occurred as the result of the vaccinations Jessie received on June 16, 2003. This was the opinion of Dr. Mark S. Wagner, M.D., who treated Jessie for approximately five hours in an emergency room on June 17, 2003. Ex. 12 ¶¶ 3, 6; Tr. at 89-91, 96, 99. The same opinion was expressed by Dr. Garrett, who treated Jessie at Miller's Children's Hospital for a number of weeks that summer. Ex. 13 ¶ 16. In other words, these two treating physicians opined that twenty-four hours was a medically-acceptable time-frame separating the vaccinations and Jessie's illness, opinions bearing directly on *Althen* prong three and petitioner's burden to establish a prima facie case of causation-in-fact.

The special master rejected Dr. Wagner's and Dr. Garrett's opinions as not persuasive. Opin. at 32-33. Several errors of law invalidate the special master's rejection of the opinions of these two treating physicians. Some of these errors, when viewed in isolation, might be excusable, but the cumulative effect of these errors is a significant departure from a proper application of the law.

First, the court examines the special master's opening paragraph of the

"Treating Doctors" section of his opinion, where he discusses the Federal Circuit's instruction to special masters as to the weight to be given to the opinions of treating physicians. According to the special master,

> [t]he Federal Circuit has instructed special masters to consider carefully the views of treating doctors about whether a petitioner has presented "'a logical sequence of cause and effect show[ing] that the vaccination was the reason for the injury.'" *Capizzano*, 440 F.3d at 1326, quoting *Althen*, 418 F.3d at 1280. Although this portion of *Capizzano* refers specifically to the second factor in *Althen*, in an effort to weigh all evidence potentially helpful to Mr. Contreras, the undersigned will review the statements of Mr. Contreras's treating physicians to see whether they provide information relevant to the third prong of *Althen*.

Opin. at 31.[31]

If the special master believes that *Capizzano*'s instruction, which assigns probative value to the opinions of treating physicians, should apply only to *Althen* prong two, the court finds little support in that decision for this view. In the same paragraph as the sentence fragment quoted by the special master, *Capizzano* clearly instructs that "evidence used to satisfy one of the *Althen* . . . prongs [may] overlap to satisfy another prong." *Capizzano*, 440 F.3d at 1326. The "evidence" in *Capizzano* was an appropriate temporal relationship between the vaccine cause and the illness effect, along with a reliable causation theory, which the treating physicians could logically rely upon to opine that the vaccine in that case had caused the petitioner's illness. *Id.* The discussion of the overlap of the three *Althen* prongs in *Capizzano* does not suggest that treating physicians' opinions are only probative as to *Althen* prong two.

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[31]/ The court believes that the special master's assertion that, in *Capizzano*, "[t]he Federal Circuit has instructed special masters to *consider carefully* the views of treating doctors about whether a petitioner has" satisfied *Althen* prong two is an inaccurate weakening of the instruction given by this precedent. Opin. at 31 (emphasis added). A more accurate reading of *Capizzano* shows that "medical opinion testimony [of treating physicians is] *favored*" for the *Althen* prong two analysis, not merely carefully considered. 440 F.3d at 1326 (emphasis added).

Indeed, it is difficult to conceive of a treating physician who would conclude that a vaccine caused the petitioner's illness without also concluding that the onset of the illness was within a medically-acceptable time-frame. In the court's view, the special master does not appear to have understood *Capizzano*'s instruction as to the weight that should be accorded to the opinions of treating physicians, for *any* of the three *Althen* prongs.[32] *See id.* (stating that treating physician testimony is "favored"); *Campbell v. Sec'y of Health & Human Servs.*, 90 Fed. Cl. 369, 386-87 (2009) (finding that the statements of treating physicians should be accorded more than just "'some consideration'" when weighing *Althen* prong three evidence (citing *Capizzano*, 440 F.3d at 1326)); *see also Andreu*, 569 F.3d at 1375-76 (citing *Capizzano* for the proposition that treating physician testimony is quite probative as to *Althen* prong two, but also discussing the statements of two treating physicians in that case which tended to show that the vaccine injury in *Andreu* had occurred in a medically-acceptable time-frame). For this reason, the special master committed legal error in failing to give the opinions of Dr. Wagner and Dr. Garrett significant weight in his analysis of the evidence relevant to *Althen* prong three.

There are other obvious legal errors in the special master's discussion of the opinions of Dr. Wagner and Dr. Garrett. First, he decided that Dr. Wagner "falls short of being persuasive," relying, in part, on a citation to the Federal Circuit's decision in *Moberly*. Opin. at 32 (citing *Moberly*, 592 F.3d at 1323). Apparently, the special master considered Dr. Wagner's opinion, that Jessie's injury fell within a medically-acceptable time-frame, to be based "essentially" on Dr. Wagner's ruling out of alternative causes for the illness, and that *Moberly* required such an opinion to be discounted:

> [Dr. Wagner's] affidavit essentially reasons that he ruled out other potential causes of Mr. Contreras's condition, leaving only the vaccines as the potential cause. The

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[32]/ It is certainly true that treating physicians' opinions are usually discussed in the context of *Althen* prong two. *See, e.g.*, *Andreu*, 569 F.3d at 1375 (noting that "the second [*Althen*] prong can be met though medical opinion testimony"); *Isaac*, 2012 WL 3609993, at *22 n.36 ("Normally, the review of treating physicians' statements would occur under the analysis of *Althen* Prong 2."). But treating physicians' opinions on prongs one and three have also been credited. *E.g.*, *Myer v. Sec'y of Health & Human Servs.*, No. 06-148V, 2011 WL 3664358, at *12 (Fed. Cl. Spec. Mstr. July 28, 2011).

> Federal Circuit, however, has rejected such reasoning. *Moberly*, 592 F.3d at 1323.

Opin. at 32. The problem with the special master's analysis is that *Moberly*'s rejection of "such reasoning" refers to a petitioner's prima facie case, not to the opinion of a treating physician.

The statement in *Moberly* upon which the special master apparently relies is: "the problem with [the petitioner's] evidence is that it amounts at most to a showing of temporal association between a vaccination and a seizure, together with the absence of any other identified cause for the ultimate neurological injury." 592 F.3d at 1323. This phrase in *Moberly* simply means that a temporal relationship between the vaccine and an injury, along with an absence of any other identified cause of the injury, is not sufficient to meet the three *Althen* prongs. This statement has no relevance as to the weight or persuasiveness of a treating physician's opinion for *Althen* prong three. To the contrary, the only pertinent statement in *Moberly* as to the persuasiveness of a treating physician's opinion is this:

> Had any of [the petitioner's] treating physicians provided . . . an opinion [that the vaccine caused the injury], it could have been probative with respect to causation.

592 F.3d at 1323 (citing *Capizzano*, 440 F.3d at 1326).[33] Thus, the special master has incorrectly relied on *Moberly* to reject a treating physician's opinion on the timing of disease onset issue.

In a somewhat similar fashion, the special master inappropriately relies on *Perreira v. Sec'y of Dep't of Health & Human Servs.*, 33 F.3d 1375 (Fed. Cir. 1994), to reject Dr. Garrett's opinion on *Althen* prong three as "not overcom[ing] the persuasive testimony of Dr. Sladky and Dr. Whitton." Opin. at 33. The particular statement in *Perreira* relied upon by the special master is: "An expert opinion is no better than the soundness of the reasons supporting it." 33 F.3d at

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[33]/ Indeed, as the Federal Circuit in *Capizzano* pointed out, treating physicians' opinions as to causation often rely, in part, on a temporal relationship between the vaccine and the injury, and that this is not a reason to discount a treating physician's opinion. 440 F.3d at 1326 ("The fact that these physicians' diagnoses may have relied in part on the temporal proximity of [the petitioner's] injuries to the administration of the vaccine is not disqualifying.") (citation omitted).

1377 n.6. *Perreira* is a decision which focuses on attorneys fees, and which discusses the lack of a reasonable basis for litigating a Vaccine Act case once the expert retained by the petitioner has filed a report which does not adequately support the petition. *Id.* at 1376. There is no discussion in *Perreira* of the opinions of treating physicians. While it would have been appropriate for the special master to have relied on *Andreu*, *Capizzano*, *Althen*, or the relevant portion of *Moberly* to determine the weight he should accord Dr. Garrett's opinion, the footnote in *Perreira* cited by the special master has no relevance to the favored status of treating physician opinions in Vaccine Act cases. Because the special master has not applied the appropriate standard to the opinion of Dr. Garrett, the court finds that the special master erred as a matter of law.

The court's concerns are not limited to the special master's disregard of the appropriate standard to apply to the opinions of Dr. Wagner and Dr. Garrett. The special master's analysis, in the court's view, does not reflect a careful consideration of the probative weight of those opinions. Although the special master discusses the doctors' opinions given by affidavit or in live testimony in one section of his published decision, he omits any further mention of their opinions in his "Synopsis on Timing" section providing his overall ruling on *Althen* prong three. *See* Opin. at 34. This omission suggests that the opinions of Dr. Wagner and Dr. Garrett were ultimately given little or no weight in the special master's overall conclusion as to *Althen* prong three.

To give an example of the minimal weight accorded to the opinions of treating physicians, the special master characterizes Dr. Wagner's opinion, which agrees with Dr. Steinman's opinion, as being "only as strong as Dr. Steinman's opinion is probative." *Id.* at 32. Apparently, the special master finds no additional probative value in the fact that a treating physician, based, at least in part, on his hands-on experience treating Jessie, came to the same conclusion as Dr. Steinman – that Jessie's illness occurred within a medically-acceptable time-frame so as to satisfy *Althen* prong three.[34] This appears to the court to be yet another error of law.

As for Dr. Garrett's opinion on *Althen* prong three, the special master appears to have rejected the opinion of Dr. Garrett primarily because his affidavit did not fully rebut the expert testimony of Dr. Sladky and Dr. Whitton. Opin. at 33 ("A

[34]/ The special master, as discussed *supra*, appears to have similarly found no additional probative value in Dr. Poser's opinion on *Althen* prong three, for the reason that Dr. Poser's opinion, too, overlapped with Dr. Steinman's opinion.

weakness in Dr. Garrett's affidavit is the absence of any meaningful explanation of why a one-day interval is medically appropriate."); *id.* ("Dr. Garrett's opinion, which was clearly presented in good faith, does not overcome the persuasive testimony of Dr. Sladky and Dr. Whitton."). An article cited by Dr. Garrett in support of his affidavit was criticized by the special master for various perceived flaws, such as its early date of publication, its "very general" statement on post-vaccine injury onset, and the lack of citation, in the article, to studies that support onset within twenty-four hours. *Id.* Dr. Garrett's opinion was further criticized for not addressing the blood brain barrier. *Id.* The special master appears to have appropriated petitioner's overall burden to prove his prima facie case and used that as a persuasiveness test for a treating physician's opinion.[35]

To the extent that the special master required Dr. Garrett's opinion, along with its supporting exhibits, to overcome all of the testimony and exhibits submitted by respondent's experts, this was a clear error of law. Dr. Garrett's opinion is just one "quite probative" piece of evidence to be weighed by the special master. *Capizzano*, 440 F.3d at 1326; *see also Althen*, 418 F.3d at 1280 (emphasizing that medical opinion is, in itself, acceptable proof in Vaccine Act cases). Dr. Garrett's opinion is not required to do all of the "'heavy lifting'" for petitioner's prima facie case. *Althen*, 418 F.3d at 1280. It is all of petitioner's evidence, together, that may establish, by a preponderance of the evidence, that Jessie's injury occurred within a medically-acceptable time-frame. The special master's opinion does not show that he considered the opinions of Jessie's treating physicians as quite probative components of the totality of the evidence put forth by petitioner in this case, and this too appears to be an error of law.

Finally, the special master appears to have consistently favored the opinions of experts over those of Jessie's treating physicians. *See* Tr. at 4 ("We[']re primarily here to hear the expert testimony of Dr. Steinman, Dr. Whitton, and Dr. Sladky."). In his post-hearing order requesting briefing from the parties, the special master raised the issue of Dr. Wagner's selective preparation for his testimony, whereas none of the experts retained by the parties were similarly identified as

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[35]/ Respondent appears to share the special master's erroneous view: "The special master had ample reasons for finding that the statements of petitioner's treating physicians were insufficient to satisfy petitioner's burden." R's Resp. at 22-23. There is no requirement that each component of petitioner's evidence – the testimony of treating physicians, medical literature, expert reports and testimony – must separately meet petitioner's burden to prove his prima facie case.

possibly being less than impartial:

> The parties are encouraged to discuss the weight to be given to Dr. Wagner's testimony. Dr. Wagner's opinion was informed by reading the reports of Dr. Steinman, but Dr. Wagner did not read reports from Dr. Whitton and Dr. Sladky.

Order of April 22, 2010 at 4. This criticism of Dr. Wagner was again levied in the special master's opinion, where he found that "Dr. Wagner did not undertake a dispassionate consideration of the material in this case." Opin. at 32. Thus, rather than favoring the opinions of treating physicians, as instructed by *Capizzano*, 440 F.3d at 1326, the special master appears to have disfavored the opinions of treating physicians. For all of these reasons, the court finds that the special master's weighing of the opinions of treating physicians as to *Althen* prong three was not in accordance with law.

E. May a Special Master Heighten the Burden of Proof for a Proximate Temporal Relationship, *Althen* Prong Three?

1. *Althen*, *Pafford* and *de Bazan*

The court begins with a brief review of *Althen* prong three. Petitioner may satisfy this prong if he has shown by a preponderance of the evidence "a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. The phrase "proximate temporal relationship" in *Althen* prong three has taken on a special sense in Vaccine Act cases. The evidentiary burden has been referred to as evidence of a "medically-acceptable temporal relationship," *id.* at 1281, or "[e]vidence demonstrating [that] petitioner's injury occurred within a medically acceptable time frame," *Pafford*, 451 F.3d at 1358. Thus, a petitioner must show that the alleged vaccine injury occurred within a medically-acceptable time-frame to satisfy *Althen* prong three.

In the Federal Circuit decision that is most on point, a more elaborate rephrasing of *Althen* prong three was provided:

> Thus, the proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical

> understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact.

de Bazan, 539 F.3d at 1352. The court notes that this is the same burden identified in *Althen* and *Pafford*. Indeed, *Pafford* includes a similar statement that *Althen* prong three "requir[es] specific evidence about a medically acceptable time frame linking the onset of [the alleged vaccine injury] to the vaccinations at issue." 451 F.3d at 1360. The *de Bazan* phrasing of the standard, and the *de Bazan* opinion in general, give no indication that petitioners are, post-*de Bazan*, subject to a heightened burden of proof on *Althen* prong three. *See de Bazan*, 539 F.3d at 1352 (citing *Althen* and *Pafford* in support of the standard of proof used in that case).

2. The Special Master's Heightened Standard

The special master erred when he crafted a higher standard of proof than that required in *de Bazan*. The first indication of this higher standard is given in his order requesting post-hearing briefs after the 2010 hearing:

> The first part of [*Althen* prong three] is the time within which medical science expects an injury to appear after a vaccination, assuming that the vaccination caused the injury.

Order of April 22, 2010 at 5. The second indication is found in the special master's order requesting briefing after the second hearing in 2011: "It would be helpful if the . . . briefs focused on whether approximately 26 hours is a medically acceptable time from which to infer causation." Order of Sept. 19, 2011.

In these orders, the court notes the subtle shift from the *de Bazan* phrasing of the standard. Phrases such as "medical science expects," "a medically acceptable time," and "from which to infer causation" all subtly alter and increase the burden on petitioner. In the court's view, the special master in these orders strayed from the correct standard in *de Bazan* and implied that Jessie must prove that twenty-six hours is within a time-frame that "medical science expects" to separate an injury from the vaccine that caused the injury. The correct question for *Althen* prong three is whether Jessie established by a preponderance of the evidence that his onset of symptoms occurred within a time-frame for which it is medically acceptable to infer causation-in-fact.

Turning now to the special master's opinion, a heightened standard is again used to evaluate *Althen* prong three in this case:

> Mr. Contreras must establish that his transverse myelitis arose within an interval after the vaccination that is "medically appropriate." *Althen*, 418 F.3d at 1278. Here, significant evidence was presented regarding whether the medical community would accept one day as being a basis for inferring that the hepatitis B vaccine caused the transverse myelitis.

Opin. at 34. First, as a minor point, *Althen* uses the term "medically-acceptable," not medically appropriate.[36] 418 F.3d at 1281. Second, and much more importantly, the special master required petitioner to present evidence that the "medical community would accept" one day as "a basis for inferring" that the HepB vaccine caused Jessie's illness. This is not the standard for *Althen* prong three.

Evidence of medical community acceptance is not the same as evidence of a medically-acceptable time-frame. The former requires Jessie to muster favorable, preponderant evidence of a majority or consensus view as to when a vaccine injury could occur at the earliest; the latter requires Jessie to show that a medically-acceptable time-frame for the onset of his type of illness includes a twenty-four hour post-vaccination occurrence. That medically-acceptable time-frame may be established by reliable opinion that does not perfectly match the dominant or consensus view in the medical community. *See Althen*, 418 F.3d at 1279 (rejecting as too stringent a requirement of "confirmation of medical plausibility from the medical community and literature"); *see also Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368, 1384 (Fed. Cir. 2012) (holding that the petitioner's expert in that case had created a material issue of fact as to whether an earlier onset of the disease than that generally accepted in the medical literature was "'medically acceptable'" (quoting *de Bazan*, 539 F.3d at 1352)). By crafting a heightened standard for *Althen* prong three, the special master erred as a matter of law.

3. Case Reports Dismissed as Virtually Valueless

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[36]/ The court notes that *de Bazan* does employ the term "medically appropriate" when discussing the proximate temporal relationship requirement of *Althen* prong three, but only to describe one of the petitioner's arguments in that case. *See de Bazan*, 539 F.3d at 1353.

The court turns now to case reports, one type of proof offered by petitioner in this case, and the weight assigned to case reports by the special master. The special master appears to believe that case reports, which discuss possible links between disease occurrences and vaccinations, have no evidentiary value. *See* Opin. at 26 (stating that "[e]ven if a case report could carry some evidentiary weight in the Vaccine Program . . . , this particular case report holds relatively little value") (citation omitted). The special master relies on *Porter* for his view of the evidentiary value of case reports. *Id.* at 25. The special master's reliance on *Porter* is misplaced.

The Federal Circuit in *Porter* specifically stated that it does not "reweigh the factual evidence or assess whether the special master correctly evaluated the evidence, nor does it examine the probative value of the evidence," which in that case included case reports. 663 F.3d at 1253-54. Better authority for the probative value of case reports is the statement in *Althen* that circumstantial evidence is permitted in Vaccine Act cases, where "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." 418 F.3d at 1280. Better yet are similar statements in *Capizzano*, 440 F.3d at 1325-26, and *Andreu*, 569 F.3d at 1378-79, which note that epidemiological studies are not required, and that circumstantial evidence is sometimes enough to prove causation in a Vaccine Act case. The special master's disregard for this precedent is another example of how the special master impermissibly heightened the standard of proof for *Althen* prong three in this case. *See, e.g.*, *Paluck v. Sec'y of Health & Human Servs.*, 104 Fed. Cl. 457, 475-76 (2012) (vacating a special master's denial of compensation in part because of his failure to accord sufficient weight to case reports cited by the petitioners).

4. Preponderance or Scientific Certainty?

Finally, petitioner argues that the special master required scientific certainty rather than preponderance of the evidence for *Althen* prong three. P's Mot. at 34; P's Reply at 7. This is a close question, and one which almost invites the court to re-weigh the evidence upon which the special master relied. The court will attempt to discern the standard of proof employed by the special master by reviewing the overall approach taken by the special master, but will not examine the evidentiary record in detail to re-weigh the evidence. The court notes, first, that the special master does reference the preponderance standard in the introduction to the "Analysis" section of his opinion. *See* Opin. at 12 (stating that "Mr. Contreras has

failed to present preponderant proof that a vaccination caused his demyelinating disease").

a. The "Priming" Argument

In the "Priming" section of the opinion, which examined whether previous HepB vaccinations could have made Jessie more vulnerable to an autoimmune response to his third HepB shot on June 16, 2003, the special master references *Moberly* and *Althen*, apparently for the preponderance standard set forth in those opinions, and gives his assessment of the relevant evidence:

> In effect, the record contains the opinion of two extremely qualified doctors presenting opposite opinions regarding the effect, if any, of prior doses. Neither party has cited any studies about priming. Thus, the undersigned must weigh the relative value of the experts' testimony and accept Mr. Contreras's evidence when it weighs even slightly in his favor.

Opin. at 30 (citing *Moberly*, 592 F.3d at 1325-26; *Althen*, 418 F.3d at 1280-81). The special master, as to the priming issue, appears to have been guided by the preponderance standard in deciding whether or not petitioner's "priming" evidence should be "accepted" for the special master's analysis of *Althen* prong three evidence. *Id.* Whether the special master was permitted to use a preponderance standard to "accept" petitioner's evidence is an interesting question.

The court observes that the preponderance standard in Vaccine Cases poses some challenges in its application. As noted *supra*, there is little uniformity in this court's decisions as to whether the preponderance standard should be applied to each of the three *Althen* prongs, or simply to a petitioner's overall prima facie case. *See supra* note 24 and accompanying text. There is also some debate as to how "plausibility" factors into the preponderance standard in Vaccine Act cases. *See Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 352 (2011) (suggesting that plausibility is valid as a test for *Althen* prong one, but not for *Althen* prong two), *aff'd*, 475 F. App'x 765 (Fed. Cir. Aug. 20, 2012) (table). Another complication, as noted *supra*, is that the preponderance requirement co-exists with the admonition that close calls will be resolved in favor of petitioners. *See supra* note 25 and accompanying text. Finally, there is some potential for conflating petitioner's burden to provide a *reliable* or reputable theory of causation,

to satisfy *Althen* prong one, *Andreu*, 569 F.3d 1379-80, with the general requirement that a special master consider "all relevant and *reliable* evidence," Vaccine Rule 8(b)(1) (emphasis added).

Despite these difficulties in applying the preponderance standard, it is clear that if the special master meant that he could not *consider* the "priming" argument of Dr. Steinman (and Dr. Poser, *see* Ex. 23 ¶ 5), because that argument was not preponderant proof that priming could hasten an autoimmune response to a vaccine, such an exclusion from consideration of petitioner's priming argument would have been a clear error of law. The test for the reliability of scientific evidence is not a preponderance test – it is the *Daubert* test, as that test has been applied in Vaccine Act cases. *See, e.g.*, *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) ("By inclusion of the terms 'relevant and reliable,' Vaccine Rule 8(b)(1) necessarily contemplates an inquiry into the soundness of scientific evidence to be considered by special masters.") (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593-94 (1993)).

It is more likely, however, that the special master meant that he did not find the "priming" theory advanced by Dr. Steinman and Dr. Poser to be persuasive.[37] In what is sometimes described as a battle of the experts, one side typically wins by being more persuasive. *See, e.g.*, *Broekelschen*, 618 F.3d at 1347. The weighing of evidence to determine the persuasiveness of a single scientific argument advanced by a petitioner, however, is not typically characterized as a preponderance inquiry, which more appropriately describes petitioner's overall burden as to one or all of the *Althen* prongs.[38] To the extent that the special master mistakenly characterized

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[37]/ Because the special master did not discuss, in any detail, Dr. Poser's opinion and support for the priming argument, on remand he must explain whether or not Dr. Poser's opinion, and Dr. Steinman's opinion, are together more persuasive than the opinions of respondent's experts on the priming issue. *See infra*.

[38]/ The court has found no instance in Federal Circuit precedent where the fact findings of a special master were described as weighing the preponderance of the evidence regarding each scientific contention advanced by an expert. Rather, the preponderance standard is consistently described as the measure for all of the petitioner's evidence on causation, or all of the petitioner's evidence as to one of the *Althen* prongs. *See, e.g.*, *de Bazan*, 539 F.3d at 1353-54 (noting that the special master in that case had found certain evidence presented by the parties to be more credible, reliable or probative, and affirming the special master's overall holding that the petitioner's evidence had not met the preponderance of the evidence standard for *Althen* prong three); *Hodges v. Sec'y of Dep't of Health & Human Servs.*, 9 F.3d 958, 962 & n.4 (Fed.

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his inquiry into "priming" as a determination of the preponderance of the evidence on this issue, but actually ruled on the persuasiveness of petitioner's argument, this was harmless error.[39]

b. The Tuberculin Test Analogy

Turning now to a different ruling, the special master examined the parties' dispute over the tuberculin (TB) test analogy. Dr. Steinman argued that because a TB test in some cases shows a significant immune response in twenty-four hours, an autoimmune response to the HepB vaccine could also occur in twenty-four hours. The special master weighed a large body of conflicting testimony and relevant literature, and concluded that Dr. Steinman's argument lacked persuasiveness. Opin. at 28. This, too, is an example of weighing record evidence for persuasiveness, which is the special master's function.[40]

c. Analogies to Experiments on Rodents

Some of the special master's inquiry, however, appears to have strayed into a highly technical subject area – *i.e.*, the amount of time required for "nine steps" of molecular mimicry to occur so as to cause the symptoms of TM. Opin. at 15. To this end, the special master thoroughly examined the expert's interpretations of Exhibit 118, a rodent study by Odoardi titled: "Blood-borne soluble protein antigen intensifies T cell activation in autoimmune CNS lesions and exacerbates clinical disease." *Id.* at 18-22. The special master concluded that "Odoardi strongly

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[38]/ ...continue
Cir. 1993) (noting the special master's consideration of all of the petitioner's evidence, and affirming his finding that the evidence fell short of meeting the preponderance of the evidence burden for the petitioner to establish causation).

[39]/ The court notes, however, that a balance must be struck between the *Daubert* analysis, as it used in Vaccine Act cases, and the guiding principle that petitioners' "experts' ultimate conclusions [are not required to] be generally accepted in the scientific community." *Cedillo*, 617 F.3d at 1339; *see also Capizzano*, 440 F.3d at 1325 (holding that "requiring . . . general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in *Althen*").

[40]/ The special master's finding was "most importantly" based on the blood brain barrier, which would need to be breached for TM to occur, whereas the reaction in a TB skin test does not involve a breach of the blood brain barrier. Opin. at 28. This finding must be re-examined by the special master on remand. *See supra* notes 21-22.

supports the view that molecular mimicry cannot happen within one day." *Id.* at 22.

Five other rodent studies, and expert testimony regarding these articles, were discussed by the special master. Opin. at 22-24. The special master stated that in these articles, "the rodents did not manifest a neurologic problem for many days after the introduction of the antigen." *Id.* at 22. The special master found that these articles were "relevant to determining whether one day is a sufficient period [for an immune-mediated neurologic response]." *Id.* When summarizing these five articles and the Odoardi article, the special master concluded that "this material supports a finding that the minimum amount of time for an autoimmune reaction to cause neurological damage via molecular mimicry exceeds one day." *Id.* at 26.

If this review of medical literature, as explained by expert testimony, provided the sole support for the special master's decision in this case, the court would be troubled. The burden of proof for *Althen* prong three is for petitioner to show that his injury, by a preponderance of the evidence, occurred within a medically-acceptable time-frame after the vaccinations. The special master appears to have embarked on a quest to quantify the amount of time required for molecular mimicry to cause neurological diseases such as TM. Opin. at 15.

The Federal Circuit has discouraged special masters from taking on elusive questions that science has not yet answered. *See, e.g.*, *Knudsen*, 35 F.3d at 549 (stating that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program"); *see also Andreu*, 569 F.3d at 1380 ("Medical literature and epidemiological evidence must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." (citing *Bunting*, 931 F.2d at 873)). The court notes that there is not a single scientific article submitted by the parties that attempts to prove a medically-acceptable time-frame for the onset of TM or GBS after a HepB vaccination. The special master, with the help of expert testimony, must necessarily reason from analogy as to whether twenty-four hours is within a medically-acceptable time-frame for Jessie to have suffered a vaccine injury. *See, e.g.*, *Paluck*, 104 Fed. Cl. at 475 (stating that "[i]t is axiomatic that animal studies are only 'indirect evidence that may establish biologic plausibility [in humans].'" (quoting *Kelley*, 68 Fed. Cl. at 93)). It would have been clear error for the special master to require Jessie to satisfy *Althen* prong three by means of medical literature alone, *see Althen*, 418 F.3d at 1279-80, and it would have been clear error for the special master to demand scientific certainty as to the timing of disease onset issue,

see, e.g., *Bunting*, 931 F.2d at 873 ("The standard of proof required by the Vaccine Act is simple preponderance of evidence; not scientific certainty.").

The special master's opinion, however, does not clearly show that he required scientific certainty as to *Althen* prong three. Although there is a heavy reliance on laboratory studies on rodents, the special master also relied on the opinions of Dr. Whitton and Dr. Sladky. When discussing the evidence regarding *Althen* prong three in the "Synopsis on Timing" section of his opinion, the special master presents this rationale for his finding against petitioner:

> The administration of the hepatitis B vaccine only one day before the onset of Mr. Contreras's transverse myelitis makes suspecting the vaccination as a potential cause relatively easy. However, the science does not support this quick conclusion. The Secretary's position is that one day is "simply not plausible," Resp't Br. at 25, and the evidence supports this conclusion. The testimony of Dr. Sladky and Dr. Whitton was consistent with medical literature that shows that, at a minimum, the blood brain barrier would prevent an immune-mediated reaction in the spinal cord in one day. Dr. Whitton did not see this case as being one that falls within a shade of grey. For Dr. Whitton, "24 hours is well into the black." Tr. 478. His opinion is that "there is no credible hypothesis that would explain a 24-hour timeframe, which would tie a vaccine causally to the induction of such a profound central nervous system disease." Tr. 451. Dr. Sladky shared this perspective. He stated that the shortest amount of time would be seven to ten days. Tr. 329. Despite able assistance from counsel and Dr. Steinman, Mr. Contreras did not counter this evidence persuasively.

Opin. at 34. To the extent that the special master relied on more than just the medical literature as support for his opinion on *Althen* prong three, the court finds that he did not hold petitioner to a standard of scientific certainty. The court leaves it to the special master, on remand, to determine whether the evidence for *Althen*

prong three is as black and white as Dr. Whitton asserted.[41]

The court observes that the special master may have been induced by Dr. Steinman, and Dr. Whitton in particular, to over-rely on literature describing animal studies that may have only limited relevance to Jessie's situation. The preponderance standard in Vaccine Act cases, as discussed *supra*, is focused on the proof of causation-in-fact of each petitioner's illness, which may include medical literature, but which may also simply rely on the opinions of treating physicians and expert testimony. The great unknowns of medical science are not to be resolved in Vaccine Act cases, as this passage from *Knudsen* instructs:

> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why . . . vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies.

35 F.3d at 549. The special master zealously attempted to quantify what might be unquantifiable, "given the medical understanding of the . . . etiology" of TM and GBS, through what could have been strained analyses of dense technical articles. *See de Bazan*, 539 F.3d at 1352. The court therefore suggests that the special master be wary of, on remand, any over-reliance on what the scientific literature submitted as exhibits in this case "shows." Opin. at 34.

5. Fact Finding in Other Vaccine Cases

Finally, the special master noted two instances in Vaccine Act cases where

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[41]/ The court observes, without intruding on the special master's fact-finding on remand, that different time-frames were proposed by respondent's experts as medically acceptable for the onset of Jessie's type of illness. *See* Tr. at 329 (Dr. Sladky) (testifying that "two weeks" or "seven to ten days" were acceptable times for the onset of TM); *id.* at 462 (Dr. Whitton) (testifying that five to seven days were acceptable times for the onset of TM). The court also observes that each of the time estimates cited here was given as evidence as to the medically-acceptable time-frame for the onset of TM. The medically acceptable time-frame for the onset of a combination of GBS and TM, where the blood brain barrier might not factor into the occurrence of earlier symptoms, is a different question, and one for which this testimony of respondent's experts is less probative.

disease onset within a few hours of vaccination was found to not satisfy *Althen* prong three. *See* Opin. at 34 & n.24 (citing *de Bazan*, 539 F.3d at 1353-54; *Veryzer*, 100 Fed. Cl. at 356). As a general rule, a special master should not base his findings on causation-in-fact in one case on other Vaccine Act cases. *Isaac*, 2012 WL 3609993, at *18 (stating that each Vaccine Act "case must be considered on the record in that case") (citations omitted). Thus, reliance on the fact findings in *de Bazan* and *Veryzer* to determine causation in this case is inappropriate. *See, e.g.*, *Moberly*, 592 F.3d at 1325 (noting that different evidentiary records in similar cases may not lead to the same result); *Caves*, 100 Fed. Cl. at 129 n.11 (stating that a special master is "not bound by" other Vaccine Act decisions) (citing *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998), *aff'd*, 191 F.3d 1344 (Fed. Cir. 1999)); *see also* R's Pre-Trial Br. at 10 n.4 (citing 42 U.S.C. § 300aa-13(b)(1) for the proposition that a "Special Master is required to examine each case and make an independent evaluation of the evidence").

6. Summary of the Special Master's Application of *Althen* Prong Three

The court finds, for the foregoing reasons, that although the special master did not clearly require Jessie to prove *Althen* prong three to a scientific certainty, he nonetheless applied, by misinterpreting *de Bazan* and *Porter*, an impermissibly heightened burden of proof on the timing of disease onset issue. The special master also appears to have placed an excessive emphasis on medical literature which has only limited probative value as to *Althen* prong three in the particular circumstances of this case. Furthermore, to the extent the special master relied on fact-finding in other vaccine cases to support his decision in this case, this approach is generally disfavored. Because the special master's heightened standard for *Althen* prong three was wrong as a matter of law, this case must be remanded for a re-weighing of the evidence using the appropriate standard.

IV. Instructions for Proceedings on Remand

On remand, the special master must avoid the errors of law pointed out in this opinion. As previously noted, this case has been in protracted litigation for some time. In an effort to expedite the special master's consideration of this matter on remand, the court offers here a succinct outline of the legal framework for utilization by the special master. Reference to this outline, however, is not a substitute for a thorough consideration and application of the legal analyses presented in this opinion. The outline follows the general order of topics discussed

in the analysis section of this opinion, with additional commentary where appropriate.

(A) The special master may not diagnose Jessie's illness, but shall examine whether petitioner has established a prima facie case that he suffered a vaccine-related combination of TM and GBS.

(B) The special master shall make findings on all three *Althen* prongs.

(C) The special master shall make a finding as to whether petitioner has ruled out alternative causes for his illness. In doing so, the special master's primary focus should be on the contemporaneous record of Jessie's circumstances and the specific alternative causes that petitioner has ruled out, if any. Idiopathic cases of TM or GBS are largely irrelevant in this analysis.

(D) The special master shall accord the proper weight to the opinions of Jessie's treating physicians, as to all three *Althen* prongs. Generally, the opinions of treating physicians shall be favored and shall be considered to be probative. The special master may not find these opinions to be unpersuasive merely because they do not, as one part of petitioner's evidence, satisfy all three *Althen* prongs, or do not, as one part of petitioner's evidence, outweigh the opinions of respondent's experts.

(E) The special master shall employ the correct standard for *Althen* prong three, as stated in *de Bazan*, *Pafford* and *Althen*. The special master may not disregard case reports as evidence.[42] In addition, the special

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[42]/ There are at least three case reports in the record which are relevant to the timing of disease onset issue. Only one of them, Exhibit 72, was discussed by the special master in his opinion. Exhibit 71 discusses a case of GBS in an adolescent which occurred three days after a first HepB vaccination. Ex. 71; P's Post-Trial Br. App. ¶ 53; P's Pre-Trial Br. App. ¶ 15. Exhibit 45, a letter published in a medical journal, discusses a case of "peripheral neurological symptoms" which occurred in an adult one day after a second HepB vaccination. Ex. 45; P's Post-Trial Br. App. ¶ 29. All three of these case reports have some bearing on petitioner's burden for *Althen* prong three. There are other case reports and studies which may be relevant to *Althen* prong three as well. Exhibit 38 discusses same-day hearing loss following HepB vaccinations. Ex. 38; P's Post-Trial Br. App. ¶ 22. Exhibit 34 references a patient whose central

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master, in the court's opinion, must not over-rely on research involving the immune systems of rodents to establish a medically-acceptable time-frame for a vaccine-related onset of a combination of TM and GBS in petitioner.

(F) Certain evidence omitted from detailed discussion by the special master must be addressed on remand. The court is particularly concerned that Dr. Poser's opinions as to the three *Althen* prongs have been largely ignored. In the court's view, Dr. Poser's opinions appear to complement and strengthen the persuasiveness of Dr. Steinman's opinions, and make points that do not merely "overlap" with the points made by Dr. Steinman. Opin. at 16 n.12.

To cite just one example, Dr. Poser questioned the probative value, in this case, of epidemiological studies which show that HepB vaccine is generally safe. The court notes that the Federal Circuit does not require petitioners to show, through epidemiological studies, that there is a link between the vaccine and their type of injury. *See, e.g.*, *Andreu*, 569 F.3d at 1378; *Capizzano*, 440 F.3d at 1325. In Dr. Poser's view, epidemiological studies overlook the unique circumstances of the individual. *See* Ex. 23 ¶¶ 4-6.

Dr. Steinman, agreeing with Dr. Poser, proffered a study which tends to show that among healthy urban adolescents, Hispanics respond differently to the HepB vaccine. *See* Ex. 132 at 3. Petitioner's experts thus both argued that Jessie's unique circumstances explain an unusual and rare response to the HepB vaccine. Those unique circumstances, piecing together all of petitioner's arguments, include his Hispanic ethnicity, his repeated exposure to the HepB vaccine, the administration of two vaccines at once, the adjuvant added to the vaccine, and his prior exposure to the Epstein-Barr virus and mycoplasma pneumonia.

Omitting almost all of Dr. Poser's contributions to this argument, which have relevance to *Althen* prongs one and two as well as to

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[42]/ ...continue
nervous system inflammation appeared four days after a HepB vaccination. Ex. 34 at 2-3; P's Post-Trial Br. App. ¶ 18.

Althen prong three, *see* Ex. 23 ¶ 5, does not provide an adequate record for this court's review. On remand, the special master shall consider Dr. Poser's arguments and evidence in his analysis of the three *Althen* prongs.

CONCLUSION

For all of the above reasons, the court holds that the special master's decision in this case was not in accordance with law.

Accordingly, it is hereby **ORDERED** that

(1) Petitioner's Motion for Review, filed May 4, 2012, is **GRANTED**;

(2) The decision of the special master, filed April 5, 2012, is **SET ASIDE** and **VACATED**;

(3) This case is **REMANDED** to the special master, pursuant to Vaccine Rule 27(c), for proceedings in accordance with the principles of law and the instructions set forth in this opinion; and

(4) The parties shall separately **FILE** any proposed redactions to this opinion, with the text to be redacted clearly marked out or otherwise indicated in brackets, on or before **October 19, 2012**.

LYNN J. BUSH
Judge