IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

CHRISTOPHER LOVING and CARLA LOVING, parents of Camille Loving,	*	No. 02-469V
	*	Special Master Christian J. Moran
Petitioners,	*	
	*	Filed: July 30, 2009
v.	*	
	*	entitlement, DTaP, significant aggravation of infantile spasms, decision after remand, six-part test, natural course of infantile spasms, apportionment, six month rule
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

William Dobreff, Esq., Dobreff & Dobreff, Warren, MI., for petitioners;
Melonie J. McCall, Esq., United States Dep't of Justice, Washington, D.C., for respondent.

PUBLISHED RULING ON ENTITLEMENT[*]

A judge of the United States Court of Federal Claims vacated the undersigned's earlier decision, which denied compensation, and remanded this case to the undersigned for additional adjudication. Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135 (2009).

Christopher Loving and Carla Loving claim that a diphtheria, tetanus and acellular pertussis ("DTaP") vaccine significantly aggravated a neurological problem, known as infantile spasms, suffered by their daughter, Camille Loving. Before Camille received the third dose of

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[*] Because this published ruling contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the website for the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

All decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, the person submitting the information has 14 days to identify and to move to delete such information before the document's disclosure. If the special master agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access. 42 U.S.C. § 300aa-12(d)(4)(B); Vaccine Rule 18(b).

the DTaP vaccine on March 27, 2001, she had already experienced infantile spasms. Within minutes after this third dose of the vaccine, Camille had a seizure. Afterwards, she started experiencing infantile spasms more frequently.

The Lovings claim that the third DTaP vaccination caused the worsening of her problems, and, pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 et. seq. (2006), the Lovings seek compensation for this worsening. A preponderance of the evidence establishes that the DTaP vaccine significantly aggravated Camille's infantile spasms for a limited period of time. However, a preponderance of the evidence in the existing record suggests that the DTaP vaccine did not alter the long-term consequences of Camille's infantile spasms in general.

Additional proceedings will be necessary to resolve whether the Lovings are entitled to compensation. The Lovings have not established that the period of time in which Camille was worse due to the vaccination exceeds six months, which appears to be a prerequisite to compensation. 42 U.S.C. § 300aa–11(c)(1)(D). Assuming that the Lovings meet this threshold, they will be given an opportunity to present specific items for which they seek compensation. Respondent will be given an opportunity to respond with appropriate arguments, including an argument that the Lovings would have incurred the cost due to the pre-existing infantile spasms. The reasons for these conclusions are set forth below.

I. Factual History

The basic facts are not disputed, although the inferences drawn from those facts are contested. This section provides a skeletal chronology. A more detailed discussion of the facts and additional fact-finding are found in section III. B and III.D below.

Camille's date of birth is August 2, 2000. She was healthy until January 2001.

In January 2001, Camille began having infantile spasms. There is no dispute about the accuracy of this diagnosis. "Infantile spasms, known also as West Syndrome, are a paroxysmal disorder that most commonly manifests itself in children less than a year old. . . . The medical profession classifies infantile spasms as a form of generalized epilepsy." Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 137 (2009) (citation omitted).

Camille was hospitalized and was prescribed medication. To some degree, Camille's condition improved while on medication. The number of seizures she experienced was greatly reduced although she did not stop all seizures. The extent and permanency of Camille's improvement are disputed strenuously.

On March 6, 2001, Camille was the subject of a video electroencephalogram ("EEG") for 23 hours. This test provides important information about Camille's condition after she began having infantile spasms, but before she received the third dose of DTaP. The results are

described in detail in section III.B.1 and section III.D. below. The bottom line result is that the EEG was abnormal. Exhibit 9B at 234.

On March 27, 2001, Camille received the third dose of the DTaP vaccine. Within minutes of the vaccination, Camille had a seizure and thereafter began having seizures more frequently. Exhibits 5A, 3B, 4B at 103, 10B at 237, and exhibit 29B at 345.

After Camille's seizures returned, they did not abate for a long time. Camille's development was impaired. When a hearing was held in this case, Camille's development approximately matched that of a three-year-old child, although chronologically Camille was seven years old. She is unlikely to advance beyond her current condition.

II. Procedural History

The basic outline of the procedural history was given in the undersigned's October 6, 2008 decision denying compensation. Loving v. Sec'y of Health & Human Servs., No. 02-469V, 2008 WL 4692376, at *1-2 (Fed. Cl. Spec. Mstr. Oct. 6, 2008). A focus of the hearing before the undersigned was whether the DTaP vaccine can cause infantile spasms. Little, if any, evidence touched upon whether Camille suffered the adverse effects of the vaccination – as distinguished from the adverse effects of her pre-existing infantile spasms – for more than six months.

After this decision, the Lovings filed a motion for review with the Court of Federal Claims, which was assigned to the Honorable Charles F. Lettow. The ensuing opinion provides the procedural history before Judge Lettow. Loving, 86 Fed. Cl. at 140.

Judge Lettow vacated the undersigned's October 6, 2008 decision and remanded for additional adjudication. In doing so, Judge Lettow established a six-part test for determining whether petitioners who allege that a vaccination significantly aggravated an injury that is not listed on the Vaccine Injury Compensation Table are entitled to compensation.

> The resulting six elements of proof for significant aggravation off-table claims thus become proof by a preponderance of the evidence of (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition is a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

Judge Lettow found that the Lovings established the sixth element, an appropriate temporal relationship.[2] In doing so, Judge Lettow also ruled that the undersigned's initial decision, which had found that the Lovings did not meet their burden of proof on this element, was wrong. Therefore, Judge Lettow vacated the undersigned's decision. Judge Lettow also remanded "for proceedings to determine whether petitioners can satisfy the required elements of a significant-aggravation off-Table claim. If petitioners establish a *prima facie* case, the burden passes to respondent to show by a preponderance of evidence that Camille's illness was the result of some cause other than her DTaP vaccination." Loving, 86 Fed. Cl. at 152.

The parties filed several briefs addressing the scope of Judge Lettow's order. The undersigned also considered the briefs the parties filed after the hearing. The case is ready for adjudication.

III. Analysis

A. Scope of Remand

After remand, the parties were ordered to file briefs addressing the fourth and fifth elements of Judge Lettow's six-part test. Order, dated March 26, 2009. The parties differed in their views. Respondent maintained that Judge Lettow did not make any finding on these two elements. Resp't Resp., filed April 17, 2009, at 2-6. In contrast, the Lovings argued that Judge Lettow found that these elements were met. See Pet'r Brief, filed May 4, 2009, at 1.[3]

The Court of Federal Claims is an appellate court for decisions by special masters. 42 U.S.C. § 300aa–12(e); Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 869 (Fed. Cir. 1992) (stating an effect of 42 U.S.C. § 300aa–12(e) is "to place the [Court of Federal Claims] judge in the role of reviewing judge.") In the context of the Vaccine Program, Judge Lettow's

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[2] It is clear that Judge Lettow found that the Lovings established this element. Respondent agreed that Judge Lettow found that the Lovings established this element. Resp't Resp., filed April 17, 2009, at 2-3; Resp't Resp., filed June 12, 2009, at 2.

Nevertheless, respondent argued that "Judge Lettow appears to conclude that Camille may well have experienced a systemic reaction. However, he did not – and could not – find that she did. Certainly, if it is faulty logic to conclude that Camille did not have a systemic reaction when there is no evidence of one, it is faulty logic to conclude that she did have one when there is no evidence of it." Resp't Resp., filed April 17, 2009, at 5 (emphasis in original); accord Resp't Resp., filed June 12, 2009, at 2-3. Respondent's argument is misdirected in that special masters do not review decisions by judges of the Court of Federal Claims.

[3] The Lovings' brief would have been more helpful if it had been organized by element.

role, therefore, is analogous to the role of a circuit court of appeals in the judicial hierarchy for most federal cases.

When these principles about the judicial hierarchy are applied to this case, it appears that Judge Lettow found that the Lovings met the fourth and fifth elements of his six-part test used in cases alleging a significant aggravation of an off-Table injury. To review, the fourth, fifth and sixth elements derive from the Federal Circuit's test to determine causation in an off-Table case. Loving, 86 Fed. Cl. at 144, citing Althen, 418 F.3d at 1278.

The undersigned's decision denied compensation on the ground that the Lovings had failed to establish the appropriate temporal relationship between Camille's receipt of the third dose of the DTaP vaccine and the resumption of her infantile spasms. Loving, No. 02-469V, 2008 WL 4692376, at *9; see also Loving, 86 Fed. Cl. at 144. This finding corresponded to the sixth element in Judge Lettow's six-part test.

Judge Lettow determined that this finding was in error. Loving 86 Fed. Cl. at 137. Having reached this conclusion, Judge Lettow was authorized to "issue [his] own findings of fact." 42 U.S.C. § 300aa–12(e)(2)(B). Judge Lettow found that the Lovings had established an appropriate temporal relationship.

In doing so, Judge Lettow also reviewed evidence about the fourth and fifth elements of his six-part test. Loving, 86 Fed. Cl. at 145-51. The fourth element is "a medical theory causally connecting such a significant worsened condition to the vaccination," and the fifth element is "a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation." Id. at 144.

Judge Lettow stated that "the proofs related to the causal element are of a different character, and the issue of causation is not so close." Id. at 149. This statement indicates that Judge Lettow has found that a preponderance of evidence supports finding that the Lovings met their burden of proof on the fourth and fifth elements of his six-part test.

In an initial brief, respondent argued that Judge Lettow did not make findings with regard to the fourth and fifth elements. Essentially, respondent summarized various portions of Judge Lettow's opinion in which Judge Lettow discussed the underlying evidence. Respondent asserted that these passages show that Judge Lettow did not resolve the question whether the Lovings met their burden on these elements. Resp't Resp., filed April 17, 2009, at 3-6.

But, respondent failed to address Judge Lettow's statement that "the issue of causation is not so close." Loving, 86 Fed. Cl. at 149. Thus, respondent was given an opportunity to address this statement. Order, filed May 28, 2009.

After Judge Lettow's statement was called to the attention of respondent, respondent stated that she "is not certain how to interpret Judge Lettow's discussion regarding the closeness of the proofs related to causation." Resp't Resp., filed June 12, 2009, at 3. Respondent also

argued that "Judge Lettow's reasoning requires a leap of logic for which there is no clear evidentiary support." Id. at 4.

Even if respondent's arguments were persuasive – a point on which the undersigned cannot and does not comment – respondent's arguments are misdirected. At best, respondent offered arguments for why Judge Lettow may have made a mistake. But, these arguments do not refute the undersigned's understanding that Judge Lettow made a finding with regards to the fourth and fifth prongs.

A fair inference from Judge Lettow's statement that "the issue of causation is not so close" is that Judge Lettow found the Lovings' evidence, including the contraindications prepared by the manufacturer of the vaccine, persuasive.[4] Even if Judge Lettow did not make this finding expressly, this finding is within the spirit of his mandate. See Engel Industries, Inc. v. Lockformer Co., 166 F.3d 1379, 1383 (Fed. Cir. 1999) (lower tribunal must abide by the spirit of the mandate); Laitram Corp. v. NEC Corp., 115 F.3d 947, 951 (Fed. Cir. 1997) (same).

The mandate rule states that a lower tribunal does not have a choice about obeying the mandate of an appellate tribunal. E-Pass Technologies, Inc. v. 3Com Corp., 473 F.3d 1213, 1219 (Fed. Cir. 2007); In re Roberts, 846 F.2d 1360, 1363 (Fed. Cir. 1988); Northern Helex Co. v. United States, 634 F.2d 557, 560 (Ct. Cl. 1980); Globe Sav. Bank, F.S.B. v. United States, 74 Fed. Cl. 736, 740 (2006).

Consequently, Judge Lettow's decision contains findings of fact with regard to the fourth, fifth, and sixth elements of his six-part test. The remaining open questions concern the first, second, and third elements of his six-part test. (These elements address whether the vaccinee significantly worsened after receiving the vaccine.) Another remaining open issue is whether respondent has established that a factor unrelated to the vaccine caused the worsening of Camille's condition. Loving, 86 Fed. Cl. at 144 n.14 & at 152; see also Pet'r Brief, filed May 4, 2009, at 1.

B. Significant Worsening

To establish the legal framework for determining whether a petitioner's off-Table condition was significantly worse, Judge Lettow borrowed from Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1107 (Fed. Cir. 1996), which evaluated petitioners' claim for on-Table significant aggravation. Loving, 86 Fed. Cl. at 143. The result was that the Lovings are required to establish "proof by a preponderance of the evidence of (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), [and] (3) whether the person's current

[4] Contraindications are usually not considered evidence that a drug can cause a particular harm. See Werderitsch v. Sec'y of Health & Human Servs., No. 99-319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005).

condition constitutes a 'significant aggravation' of the person's condition prior to vaccination." Id. at 144.

Judge Lettow's remand order requires the special master to evaluate these three elements. Id. at 144 n.14.[5] These elements are addressed in the following sections.

1. Camille's Condition Before the Vaccination

Camille was born on August 2, 2000. For her first five months, she was healthy. During this time, she received two doses of the DTaP vaccine. Exhibit 3B.

On January 12, 2001, Camille was having diarrhea. Exhibit 6B at 119, 122. Around that same day, Camille started raising her arms to ears, screaming, flexing her torso, and looking fearful. These episodes lasted two to three minutes during which she could have 10 of these episodes. Exhibit 6B at 125.

On January 22, 2001, Camille was admitted to the Children's Hospital of Michigan to determine whether she was having seizures. Exhibit 6B at 119. A nurse observed Camille having a seizure.

On January 23, 2001, a neurologist (the handwriting may indicate Dr. Nigro) obtained a history of Camille's development. The doctor noted that Camille rolls over, holds her head up, and vocalizes. Camille did not sit up yet. Exhibit 6B at 143. Dr. Nigro ordered an EEG on January 23, 2001. Exhibit 100 at 1416. The doctors gave Camille vitamin B6 and Topamax to control her seizures. However, they did not work. Exhibit 8B at 219.

Camille's EEG was consistent with infantile spasms. Exhibit 6B at 131. One sign of infantile spasms is that an EEG shows a particular pattern, known as hypsarrhythmia. Camille's first EEG showed hypsarrhythmia. See tr. 143 (Dr. Shuman discussing this report).

With the information from the EEG, Camille's doctors attempted to try to stop the infantile spasms. Camille's doctors included Dr. Harry T. Chugani, a pediatric neurologist whom Dr. Shuman and Dr. Kohrman (the experts retained in this case by the parties) described as one of the best doctors to treat this condition. Tr. 252 (Dr. Kohrman), tr. 300 (Dr. Shuman), tr. 477 (Dr. Shuman), tr. 600 (Dr. Kohrman).[6] The doctors originally planned to use a medication called

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[5] In their brief, the Lovings argue that "Judge Lettow expressly or impliedly ruled or stated how [he] would rule on the significant aggravation claim." Pet'r Br., filed May 4, 2009, at 1. However, given the explicit instructions in footnote 14 of the remand order, the Lovings have read too much into Judge Lettow's order.

[6] Although Dr. Shuman generally praised Dr. Chugani, Dr. Shuman also stated that Dr. Chugani appeared not to be aware that even the acellular form of the pertussis vaccination was

ACTH. Exhibit 6B at 138. However, Camille's parents declined to use ACTH because of its possible side effects. Exhibit 7B at 207; see also tr. 460. Instead, Camille was given vigabatrin, which is also known by its brand name, Sabril.[7] Exhibit 142 at 143 (noting that Camille started taking vigabatrin before being discharged from the hospital); see also tr. 143.

Camille had another seizure / infantile spasm on January 30, 2001. Exhibit 29 at 8-9. Camille's parents believed that this was her last one before her third DTaP vaccination. Exhibit 7B at 206 (report dated Feb. 5, 2001); exhibit 8B at 219 (report dated March 6, 2001).

On February 5, 2001, a neurologist saw Camille for the first time after Camille had been discharged from the hospital. This visit was approximately ten days after Camille started taking vigabatrin. Tr. 461. Camille's mother expressed a concern that Camille had "stopped developing." The neurologist examined Camille. He determined that she could roll from back to front and could lift her head and chest while prone. On the other hand, Camille did not track objects visually, did not reach for objects, could not hold her head up when seated, and did not sit up without support. The doctor stated that Camille should have "acellular pertussis" for future vaccinations. Exhibit 7B at 206; see also tr. 460-61 (discussing this visit),[8] tr. 557 (discussing this visit).

On approximately February 20, 2001, Camille had a PET (positron emission tomography) scan.[9] Exhibit 12B at 242. A PET scan allows doctors to measure the body's abnormal molecular cell activity to detect brain disorders by using a glucose tracer to measure the brain's glucose utilization level. Tr. 253-54. The PET scan did not provide any helpful information about the cause of the infantile spasms. Instead, the PET scan showed the damage caused by the infantile spasms. Tr. 344-45.

Camille went to the hospital for another EEG on March 6, 2001. Records surrounding her hospitalization contain some information about diagnostic code. One document indicates that Camille suffered from infantile spasms without intractable epilepsy. Exhibit 8B at 218; see also tr. 160 (Dr. Shuman discussing this entry), tr. 304 (same). Intractable epilepsy means that

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contraindicated. Tr. 478-79.

[7] The witnesses used the terms "vigabratin" and "Sabril" interchangeably. For the sake of consistency, this decision uses "vigabratin."

[8] Dr. Shuman made an error in that he stated that Camille was five months old. Tr. 461. On February 5, 2001, Camille actually was six months old. She was born on August 2, 2000.

[9] The record is not exact about when Camille had the PET scan. Mrs. Loving's journal stated, on February 13, 2001, that Camille was scheduled for a PET scan next week. Exhibit 29 at 333. The exact date of Camille's PET scan is not material.

seizures are continuing despite trying to use at least two anti-epileptic medications. Tr. 552, tr. 620.

The diagnostic code is not persuasive evidence about Camille's condition as she entered the hospital on March 6, 2001, for several reasons. First, special masters are not bound by any diagnosis appearing in the record. 42 U.S.C. § 300aa–13(b). Second, the basis for the diagnostic code is not clear. Dr. Kohrman persuasively explained that doctors do not code charts. Instead, a clerk has the responsibility of entering a code. Thus, whether any doctor (as opposed to an assistant) diagnosed Camille as not having intractable epilepsy is not clear. Tr. 552-55, tr. 619. Third, and most important, the code appears to have been entered when Camille entered the hospital before she had the EEG. The EEG, as discussed in the following paragraphs, showed that Camille was having seizures. Thus, the diagnostic code appears to be in error. See tr. 623-25.

Between the February 5, 2001 visit with Dr. Chugani (exhibit 7B at 206) and Camille's admission to the hospital on March 6, 2001 for the EEG, Camille's development advanced. She could perform some new tasks, such as cooing, smiling socially, and raking for objects. Exhibit 8B at 220; see also tr. 312-14 (discussing this medical record).

Despite these advances, Camille's development before receiving the third dose of DTaP was behind the development of other seven-month-olds. Camille's development matched the development of a child approximately three- or four-months-old. Exhibit 99 (Early intervention records - Detroit Public Schools - Multidisciplinary Evaluation Team Summary) at 1323; tr. 248 (testimony of Dr. Kohrman describing Camille in March and April 2001)); see also tr. 461 (noting that Camille was developmentally delayed before the third vaccination), tr. 555 (same). Chronologically, on March 2, 2001, Camille reached seven months.

According to Mrs. Loving's journal, on March 1, 2001, Camille experienced "startles & possible head drops." Exhibit 29 at 18. The record does not suggest that a doctor saw Camille on this date and the record does not indicate that Camille was diagnosed as having a seizure. However, Camille's initial presentation, in January 2001, included "startles." Exhibit 6B at 126; exhibit 8B at 219.

When Camille was admitted to the hospital, information about her development was recorded. She could roll over, coo, sit with support, rake, and smile socially. Camille could not track visually and she could not grab for items. Camille also had a head lag. Exhibit 8B at 220; id. at 224

As just mentioned, the March 6, 2001 EEG showed Camille having a seizure. This EEG was more extensive than the previous EEG. It lasted for 23 hours and included simultaneous monitoring by video. This EEG was considered not normal. The background rhythm was "severely disorganized and consists of very high amplitude pattern of multifocal spike and wave activity." When Camille was asleep, "normal sleep architecture [was] not seen." The EEG indicated that Camille had at least one seizure. Mechanical problems with the machine interfered

with an evaluation of Camille at some times. Camille may have had more than one seizure during the video EEG. The doctors interpreted the EEG as "abnormal" and recommended a repeat EEG due to the mechanical problems. Exhibit 9B.

Dr. Kohrman interpreted the results of the EEG as possibly showing an episode of cluster spasms. Tr. 600-02. Additionally, as accurately noted by Dr. Shuman, the report does not use the term "hypsarrhythmia." Exhibit 9B; tr. 150. Additionally, Mrs. Loving's journal states that the doctor told her that Camille did not have hypsarrhythmia. Exhibit 29 at 340 (entry for March 6, 2001); tr. 153. What this EEG means for Camille's expected development will be discussed in section III.D below.

By March 26, 2001, 56 days had elapsed since Camille last had a clinical seizure that was observed. Tr. 458. The previous sentence contains two important qualifications. First, it discusses only clinical seizures. The March 6, 2001 EEG shows that Camille experienced one seizure within her brain that had a clinical manifestation. Tr. 462-63, tr. 530, tr. 535, tr. 547. Second, any discussion about the number of clinical seizures depends, in part, on the degree of observation. Camille's parents may not have observed a seizure or recognized behavior that constitutes a seizure. Tr. 614. One reason for this phenomenon is due to something like the placebo effect in that a child's parents so greatly want the child to be better, that the parents' desire shapes what they observe. Tr. 546. Another reason that the mathematical count of clinical seizures may not be accurate is that behavior may not be recognized as a seizure. Tr. 619 (explaining that nurses miss seizures in the hospital).

These concerns about the number of observed clinical seizures are not purely academic. Mrs. Loving's journal describes some behaviors, such as head drops, that a neurologist may have classified as a seizure. Exhibit 29 at 338 (March 1); tr. 530 (discussing this entry), tr. 603 (same). Mrs. Loving also noted that she was concerned about the number of seizures. Exhibit 29 at 338; tr. 538.

Overall, there is relatively little dispute that between the time of Camille's discharge from the hospital and the day before she received the third dose of the DTaP vaccine, she improved. See tr. 605, tr. 616. As discussed below, the experts dispute whether Camille would have continued to improve or would remain impaired by the infantile spasms.

On March 27, 2001, Camille received the third dose of the DTaP vaccine. Within minutes of the vaccination, Camille resumed having seizures. Exhibits 5A, 3B, 4B at 103, 10B at 237, and exhibit 29B at 345. She resumed having seizures even though she was taking vigabatrin, which is administered to prevent seizures. Tr. 430-33.

2. Camille's Condition After the Vaccination

The second element of the six-part test is to determine "the person's current condition (or the condition following the vaccination if that is also pertinent)." Loving, 86 Fed. Cl. at 144. As

discussed in the subsequent sections, the timing of when Camille is evaluated affects the outcome of the Lovings' claim for compensation.

When the evidence is considered strictly about Camille's condition in the time immediately after the vaccination (in 2001), there is minimal dispute. In contrast, there is much more dispute about whether her current condition (in 2009) is meaningfully different from her condition before the vaccination.

Following Camille's receipt of the third dose of DTaP, she started having clusters of spasms again. Exhibit 29B at 347; exhibit 29 at 28-31 (Mrs. Loving's journal).

Within 14 days of her vaccination, Camille's doctors increased her dose of vigabatrin and also added Topamax. Exhibit 11 at 239-40. The spasms decreased in intensity, as Camille stopped having full jack-knife seizures and instead had head drops. Id., exhibit 29 at 35.

Camille saw Dr. Chugani on April 10, 2001. Dr. Chugani stated:

> Camille is an eight-month-old child with a history of infantile spasms that occurred at four[10] months of age and who was subsequently initially tried on Pyridoxine which did not work and also tried on Topamax which did not work. At that point in time, a choice was made for vigabatrin over ACTH and within four days of starting the vigabatrin, her seizures stopped[11] and she also made developmental gains from a point where she had regressed. However, when she went to get her six month shots, within minutes of getting the shots, actually within five minutes, she started having clusters of infantile spasms again. Since then, she has had four to five daily clusters. At this point in time, the vigabatrin was initially increased to 750mg a day from 500mg a day and then later onto 1000mg a day. Also, Topamax was initiated and was increased to her current level of 100 mg a day. Since yesterday, the mother has not seen any jack-knife kind of spasms at all. She also actually admits that since the initiation of the Topamax and the increase of the dose of vigabatrin, the jack-knife spasms have reduced to mere head drops and sometimes Camille is teary eyed. The parents are concerned, however, that Camille sleeps approximately 20 hours a day. She eats well when awake. When awake she will also coo a little and sometimes will cry. She seems to have bouts of irritability and settling down, especially in the evening. As far as playing with toys are concerned, she may track off and on. She, however, responds completely to sounds.

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[10] Dr. Chugani made an error in that he stated that Camille was four months. She was actually five months at the time her first seizures took place on January 12, 2001. She was born on August 2, 2000.

[11] Although Dr. Chugani states that Camille's spasms "stopped," she had at least one seizure during the March 6, 2001 EEG.

PHYSICAL EXAMINATION: On physical examination, she had three cafe-au-lait spots, one on the right medial shin one on the left thigh and also around the umbilicus. Her head circumference was 45.5 cm. Anterior fontanel was fibrotic. Pupils were bilaterally equal and reactive to light. Camille did not tract to sound and intermittently exhibits poor head tone. Face was symmetrical and tongue central. As far as the motor examination was concerned, she exhibited bilateral cortical fisting. She also exhibited opistho tone intermittently. In addition, she seemed to have a mixture of hypo and hypertonicity. She moved both extremities equally. Reflexes were bilaterally brisk with down going toes. There was no clonus at the ankles.

Recently, developmental evaluation was done by Early On on March 29, 2001, and Camille was evaluated to be functioning between zero and two months. Thus, in a sense, Camille is an eight-month-old child with a relapse of infantile spasms after getting immunized recently and who has been treated with increases in her Topamax as well as vigabatrin, which seems to have helped some. Her recent video monitoring recording shows bilateral foci. Out of the five seizures that were documented by the family, only one was an actual seizure and seemed to originate from the left temporoparietoccipital region. Her electroencephalogram, however, shows independent right center temporal activity. Her PET scan shows a left temporal focus. In addition, BAERS were performed, which were thought to be normal and the VEP's were nonspecifically abnormal. Given all of the above factors, at the moment, we are not going to make any changes to the medication. However, should seizures recur in the next few days, we have advised Mr. and Mrs. Loving to increase the vigabatrin by 250 mg and decrease Topamax by 25 mg. We expect the tiredness and drowsiness, if at all related to the Topamax to go away with time. Also, if the seizures persist, we shall consider a repeat of the video monitoring recording test. Although Mr. and Mrs. Loving have shown interest in evaluation for epilepsy surgery, we have explained to them that if indeed only one seizure was actually a seizure, then on the basis of only one seizure we will not be able to make the decision as to whether she is a epilepsy surgery candidate at the present time.

Exhibit 11B at 241-43; see also tr. 296 (Dr. Shuman discussing this visit); cf. tr. 606 (Dr. Kohrman acknowledging that Camille had cluster seizures after the third DTaP). Dr. Chugani observed that Camille had bilateral cortical fisting. Exhibit 11 at 242. Fisting is a sign of damage to the central nervous system. Tr. 318. Dr. Chugani also reported opisthonous, exhibit 11 at 242; which also is a sign of neurological injury. Tr. 318-20.

Attempts were made to control the seizures using different medications, including ACTH. See exhibit 13B at 247. Camille sometimes responded to the medication but any response did not last more than a few weeks.

Camille made some progress developmentally. By June 25, 2001, she smiled and cooed. She could also sit by herself. Exhibit 16B at 259.

However, this development seems to have reached a plateau. On July 18, 2001, Camille was taking strong medications against seizures. Even so, Camille was diagnosed as having intractable epilepsy. Exhibit 18 at 254; tr. 175 (discussing this visit).

By the time Dr. Shuman examined Camille in early 2003, she was almost vegetative. She was having seizures every day with 10-20 head drops per cluster. Exhibit 32 at 451. Dr. Shuman examined Camille as part of his work for this litigation. Id. at 449-50.

Dr. Shuman also tried different approaches such as different medications (keppra and depakote). He also tried a vagus nerve stimulator. These attempts did not produce any significant, lasting improvements. Tr. 172-73.

By the time of the hearing, Camille's development was approximately the same as the development of a three-year-old child. Tr. 559. She is unlikely to advance. Tr. 178.

3. Whether Camille's Current Condition Constitutes a "Significant Aggravation" of Her Condition Prior to Vaccination

The third element is to determine "whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to the vaccination." Loving, 86 Fed. Cl. at 144. Significant aggravation means "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa–33(4).

Pursuant to the instructions given by Judge Lettow, this element requires a comparison of Camille's condition before the vaccination and her condition after the vaccination. It does not entail projecting how Camille would have been if she did not receive the third dose of the DTaP vaccine. It appears that Judge Lettow has made this part of respondent's affirmative defense. See section III.C. below.

In some respects, Camille's condition is unchanged. Her development, essentially, stopped. For example, before the vaccination, at eight months old, Camille could not walk and she could not speak. She could not care for herself.

Of course, Camille's inability to doing any of these tasks was normal on March 27, 2001, because she was only eight-months-old. A normal eight-month-old, one that is not affected by infantile spasms, is expected to mature and to develop abilities, such as walking and talking. Normal eight-month-olds have the potential to master increasingly difficult tasks, which are recognized as milestones in an infant's development, such as rolling over, pulling to stand, cruising, walking, and talking.

In other respects, Camille's condition after vaccination was worse than her condition before vaccination. For example, after being discharged from the hospital and before her third DTaP vaccination, Camille did not have any more episodes of infantile spasms. See exhibit 11 at

241-43 (Dr. Chugani's April 10, 2001 report); see also tr. 513-14. After the vaccination, she resumed having infantile spasms or clusters of seizures. Exhibit 11 at 241-43. This change from no infantile spasms to clusters of seizures is a worsening of Camille's condition. Tr. 296 (Dr. Shuman).

4. Summary Regarding First Three Elements

Pursuant to Judge Lettow's instructions, the first step is to consider three elements. These factors are (1) to establish Camille's condition before vaccination, (2) to establish Camille's condition after vaccination, and (3) to compare the conditions. Loving, 86 Fed. Cl. at 144. The Lovings have met their burden regarding these three points. The findings on these points does not end the inquiry because "the government may still prevail if it can show, to a preponderance of the evidence, that the pre-existing condition was, in fact, the cause of the individual's post-vaccination significant aggravation." Id., quoting Whitecotton, 81 F.3d at 1107. This issue is taken up in the next two sections.

C. Method of Evaluating How a Pre-existing Condition Affected a Person's Development

The remand order states: "'once a petitioner has made a *prima facie* case, the government may still prevail if it can show, to a preponderance of the evidence, that the pre-existing condition was, in fact, the cause of the individual's post-vaccination significant aggravation.'" Loving, 86 Fed. Cl. at 144, quoting Whitecotton, 81 F.3d at 1107.[12] This section explains how to evaluate the effect, if any, of a pre-existing condition on a person's development. The next section discusses the evidence presented about Camille's infantile spasms.

Preliminarily, it must be observed that Judge Lettow placed the burden of proof on the respondent. His statement, quoted in the preceding paragraph, is direct and explicit. Therefore, it is binding on remand. Hanlon v. Sec'y of Health & Human Servs., 40 Fed. Cl. 625 (1998). Respondent's arguments to the contrary, see Resp't Resp., filed April 17, 2009, at 6-8, are misplaced.

Respondent argues that the third dose of DTaP did not affect Camille's infantile spasms because her condition after vaccination is a natural progression of infantile spasms. Thus,

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[12] The conclusion of the remand order uses slightly different language: "If petitioners establish a *prima facie* case, the burden passes to the respondent to show by a preponderance of evidence that Camille's illness was the result of some cause other than her DTaP vaccination." Loving, 86 Fed. Cl. at 152.

As discussed in the text, the inquiry concerns the significant aggravation, not the cause, of the infantile spasms. Thus, the illness experienced by Camille in January 2001 before she was diagnosed with infantile spasms is not relevant. Respondent has not argued that this viral illness caused an aggravation of the infantile spasms.

Camille's current condition approximates what her condition would have been if she did not receive the vaccination. Resp't Resp. filed April 17, 2009, at 2-3. Other than the effect of Camille's pre-existing infantile spasms, respondent has not argued that anything else substantially aggravated Camille's condition. See Resp't Post-Hearing Brief., filed May 20, 2008, at 19-31.[13]

To determine how the injured person's pre-existing condition affected her (or his) development, the injured person must be imagined as not receiving the vaccine. The hypothetical person can then be compared to how the actual injured person developed to determine the difference between the "but-for" person and the actual person.

In different contexts, the Federal Circuit has discussed creating a hypothetical model to determine whether something "caused" something else.

> But for causation is a hypothetical construct. In determining whether a particular factor was a but-for cause of a given event, we begin by assuming that that factor was present at the time of the event, and then ask whether even if that factor had been absent, the event nevertheless would have transpired in the same way.

Mittal Steel Point Lisas Litd. v. United States, 542 F.3d 867, 876 (Fed. Cir. 2008) (quoting Price Waterhouse v. Hopkins, 490 U.S. 228, 240 (1989)).[14] In determining whether the International Trade Commission erred in determining whether the importation of steel rods from Trinidad and Tobago affected the domestic industry, the Federal Circuit quoted Price Waterhouse and explained that the principle from Price Waterhouse "requires the finder of fact to ask whether conditions would have been different for the domestic industry in the absence of dumping." Mittal Steel, 542 F.3d at 867.

The Federal Circuit made a similar analysis in the context of reviewing a decision by the Court of Federal Claims that awarded a bank damages caused by the enactment of legislation (FIRREA), which breached a contract between the bank and the government. The Federal Circuit stated that "To assess those claims, it is necessary to analyze how Fidelity [a bank] would have fared in the hypothetical non-breach world in which the FIRREA restrictions on the use of

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[13] In testimony, Dr. Kohrman suggested that the injection of the DTaP with a needle could have caused Camille to hyperventilate. Tr. 243. But, respondent has not pursued this argument. Even if respondent had, the cause of the significant aggravation would still be attributable to the vaccination.

[14] The Supreme Court recently declined to extend the burden-shifting framework used in mixed motive cases established in Price Waterhouse to cases involving the Age Discrimination in Employment Act. Gross v. FBL Financial Services, Inc., ___ U.S. ___, 123 S.Ct. 2343, 2349 (2009).

supervisory goodwill were not adopted." Astoria Fed. Savings & Loan Ass'n v. United States, 568 F.3d 944, 950 (Fed. Cir. 2009).

Although the Federal Circuit has not directly stated that a but-for model is required in examining off-Table significant aggravation cases, the Federal Circuit "has adopted the actual causation standard of the Restatement (Second) of Torts, which requires the petitioner to show that the vaccine is a 'but-for' cause of the illness – i.e. that the harm would not have occurred but for the vaccine." Walther v. Sec'y of Health & Human Servs., 485 Fed. Cir. 1146, 1150 (Fed. Cir. 2007).[15]

Judge Lettow has considered hypothetical, but-for models in several cases. Examples include Arkansas Game and Fish Comm'n v. United States, ___ Fed. Cl. ___, 2009 WL 1931088, at *29-40 (determining whether flooding caused by the United States, and not some other cause, killed trees owned by the plaintiff); and Boston Edison Co. v. United States, 80 Fed. Cl. 468, 490-96 (2008) (calculating costs associated with government's failure to accept spent nuclear fuel).

Several decisions from judges of the Court of Federal Claims have commented upon a need to consider how the vaccinee's underlying condition would have affected the person's health. O'Connor v. Sec'y of Health & Human Servs., 24 Cl. Ct. 428 (1991), aff'd, 975 F.2d 868 (Fed. Cir. 1992); Misasi v. Sec'y of Health & Human Servs., 23 Cl. Ct. 322, 324 (1991).

Collectively these precedents indicate that in evaluating significant aggravation claims, special masters should consider how a disease would have progressed absent the vaccination. Although there appears to be some dispute as to how the burden of proof should be allocated, and whether this allocation varies depending upon whether the injury is on-Table or off-Table, see Hennessey v. Sec'y of Health & Human Servs., No. 01-190V, 2009 WL 1709053, at *58 (Fed. Cl. Spec. Mstr. May 29, 2009), motion for review filed (June 29, 2009); these subtle points do not have to be addressed in this ruling. Judge Lettow has ruled that respondent "may show, to a preponderance of the evidence, that the pre-existing condition was, in fact, the cause of the individual's post-vaccination significant aggravation.'" Remand Order, 86 Fed. Cl. at 144, quoting Whitecotton, 81 F.3d at 1107. Consequently, Camille's pre-existing infantile spasms are discussed in the following section.

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[15] Although Walther places a burden on the petitioner to prove that a vaccine caused an illness, the remand order places the burden on respondent to establish that Camille's pre-existing infantile spasms were the cause of her worsening. Loving, 86 Fed. Cl. at 144. The respondent's burden to establish that a factor unrelated to the vaccination caused the person's condition is the same as the petitioner's burden regarding causation. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994).

D. Camille's Predicted Condition if the Vaccination Were Not Given

The crux of Camille's case is this section. Relying upon the opinion of Dr. Shuman, the Lovings maintain that Camille had a good chance of achieving something close to normal development. In contrast, respondent contends that the prognosis for anyone with infantile spasms is bleak. Thus, Camille was likely to be developmentally delayed regardless of the vaccination.

Predicting Camille's condition as of March 26, 2001 (the day before she received the third DTaP) necessarily requires some understanding about infantile spasms. In general, infantile spasms portend an impaired development. Exhibit E (M.T. Mackay et al., Practice Parameter: Medical Treatment of Infantile Spasms: Report of the American Academy of Neurology and Child Neurology Society, 62 Neurology 1668 (2004)) at 1668 ("onset of spasms is frequently associated with neurodevelopmental regression"). "Infants who suffer from infantile spasms often are developmentally challenged." Loving, 86 Fed. Cl. at 137, citing John H. Menkes et al., Child Neurology 877 (7th ed. 2006).[16]

Infantile spasms are divided into two types. The first category is symptomatic, meaning that the infantile spasms are a symptom of an underlying cause. The second category is cryptogenic, meaning that the origins of the infantile spasms are not known. Camille's infantile spasms are cryptogenic. Tr. 213 (Dr. Shuman); but see tr. 609 (Dr. Kohrman questioning whether Camille's PET scan detected something indicating that she had symptomatic infantile spasms). The likelihood of recovering from infantile spasms is greater when the infantile spasms are cryptogenic. Tr. 49-50, tr. 244, tr. 638.

A significant portion of the evidence discusses the likely outcomes for a person with infantile spasms. The evidence can be divided into two types: information reported in the medical literature and the expert's own experiences with treating children with infantile spasms.

1. Medical Articles

Several articles about the expected outcome for children with infantile spasms were introduced. Because they are part of the record, they must be considered. 42 U.S.C. § 300aa–13; Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367 (Fed. Cir. 2009).

a. Practice Parameter

One informative and reliable article was filed as exhibit E (M.T. Mackay et al., Practice Parameter: Medical Treatment of Infantile Spasms: Report of the American Academy of Neurology and Child Neurology Society, 62 Neurology 1668 (2004)). This article was written by "excellent people." Tr. 31 (Dr. Shuman); cf. tr. 245 and tr. 634-35 (Dr. Kohrman discussing

[16] It appears that the textbook by Dr. Menkes was not introduced as an exhibit.

development of practice parameter). The practice parameter analyzes different types of medicine to attempt to determine the best way to care for patients. Tr. 550-51. Due to its authoritativeness, the practice parameter is worth discussing in detail.

The authors collected various studies about infantile spasms. They classified the studies into four different tiers, depending upon the quality of the studies. The best type of study was a "prospective, randomized, controlled clinical trial with masked outcome assessment." Exhibit E at 1670 & 1679 (Appendix I); accord tr. 493-94 (Dr. Shuman discussing different classes of studies). The relative strength of the studies influenced the authors' rating of their recommendations. Exhibit E at 1679 (Appendix II).

In conjunction with the assessment of long-term outcomes, the authors did not come to any conclusion. Instead, they stated:

> The evidence is conflicting and limited to class III and IV [the two least reliable forms of evidence] that treatment of infantile spasms with agents including ACTH, oral corticosteroids, vigabatrin, valproic acid, and pyridoxine improves the long-term outcome or decreases the later incidence of epilepsy.

Exhibit E at 1679; tr. 495-97 (Dr. Shuman discussing conclusion).

This conclusion summarizes information presented in Table 5, titled "Results of treatment of infantile spasms on long-term outcome." Table 5 showed seven studies. All of the seven studies were classified as class III or class IV forms of evidence. The percentage of children who attained normal development ranged from 0 to 90.

The practice parameter also shows the results of treatment with vigabatrin, which is the drug that Camille was taking before the third dose of the vaccination. Exhibit E at 1674 (Table 4). It also shows the results of treatment with ACTH, which is a drug that Camille did not take before the vaccination. Exhibit E at 1670-73 (Table 1 & Table 2).

Given the inconsistent results, the experts, unsurprisingly, emphasized different aspects of the practice parameter. Dr. Shuman stated that the practice parameter reported that some children who were developmentally normal had an abnormal EEG. Tr. 288-89, discussing exhibit E at 1677.[17] Similarly, some studies in Table 1 show that children taking ACTH may

[17] The particular passage discussed by Dr. Shuman is unclear. This portion of the practice parameter discusses a study by Lombroso, which is reference 23 in the practice parameter. Table 3, which summarizes the Lombroso study, presents the numbers slightly differently than how Dr. Shuman explained them. However, the basic point remains accurate. The number of developmentally normal children exceeds the number of children with normal EEGs. Therefore, at least some children are developmentally normal, despite an abnormal EEG.

stop having spasms but continue to have abnormal EEGs. Tr. 290-91. Dr. Shuman also pointed out that the practice parameter showed that 72 percent of children taking vigabatrin were seizure free for one year. Tr. 306-07, discussing exhibit E at 1678.[18]

Dr. Kohrman said that the practice parameter shows that anticonvulsant medicines stop infantile spasms in approximately 50 percent of the cases, but that seizures recur in one-third of the cases in which the seizures were stopped. Tr. 245. In regard to Table 1, Dr. Kohrman noted that other studies show that the resolution of spasms occurs with the same frequency as the normalization of the EEG. Tr. 549, citing exhibit E at 1671 (Table 1).

b. Swaiman

Another text discussed by the experts was a chapter from the book Pediatric Neurology Principles & Practice (4th ed. Kenneth F. Swaiman et al., eds.). Tr. 26 (Dr. Shuman describing this work as "excellent."). This book is frequently cited as one of the leading texts on pediatric neurology. The specific chapter on Infantile Spasms was written by Tallie Z. Baram, who also contributed to the practice parameter discussed above. Respondent filed this chapter as exhibit K.

In the context of introducing infantile spasms, Dr. Baram wrote "Because the outcome with infantile spasms, in terms of cognitive function and intellect, is poor (with mental retardation in 80% to 90% of children and epilepsy in greater than 50%), the economic and emotional burdens to society associated with this disorder are enormous." Exhibit K (Baram, "Myoclonus, Myoclonic Seizures, and Infantile Spasms") at 1065. Dr. Kohrman discussed this portion in his testimony. Tr. 533-34.

Nevertheless, Dr. Baram recognized that some children develop normally: "A minority of infants (approximately 10%) have an apparently normal CNS, as defined by normal development, imaging studies, and etiologic evaluation." Exhibit K at 1067. Dr. Baram supports this statement by citing, among other studies, the work by Dr. Lombroso in 1983.

For the natural history of infantile spasms, "[i]n a majority of cases, the hypsarrhythmia disappears over weeks to months, regardless of treatment, followed by waning of the spasms themselves. Even without treatment, 89% of patients have been reported to be spasm free by age 5 years." Exhibit K at 1068.

Dr. Baram also provides information about how treatment affects a patient. "Whether early treatment of infantile spasms with rapid resolution of both spasms and the hypsarrhythmic

[18] However, a different portion of the same sentence in the practice parameter indicates that only 17 percent of the children were developmentally normal or slightly delayed. Exhibit E at 1678. Given that 72 percent were seizure-free, 55 percent of the children were seizure-free, yet delayed in development (72 percent - 17 percent = 55 percent).

EEG improves cognitive outcome is not fully resolved." "Currently recommended treatment for infantile spasms, based on information gathered over the past decade, involves adrenocorticotropic hormone [ACTH], vigabatrin, or, in selected infants with focal lesions that trigger the spasms, surgical resection." Id.

2. Experts' Own Experiences

Both experts testified about their own experiences in treating children with infantile spasms.

In Dr. Shuman's practice from 1993 to 2006, he saw 42 patients with infantile spasms. He estimated that about half suffered from the symptomatic form of infantile spasms. Of this group, either two patients or five patients died. (Dr. Shuman's testimony is somewhat ambiguous on this point.) The other half of the group of infantile spasms suffered from cryptogenic infantile spasms. From this group, two patients died. Tr. 30, tr. 198.

Of the group of patients who lived, "of course, all of them have epilepsy." Dr. Shuman stated that in most cases, the patients stopped having seizures. Tr. 30, tr. 39-40, tr. 48-50, tr. 191-92, tr. 198-99. Dr. Shuman stated that he improved the EEGs in all of the children he treated. Tr. 80. Dr. Shuman described his regimen for treating children with infantile spasms. Tr. 31-36, tr. 47, tr. 200-01.

Dr. Shuman recognized that for some patients in which the infantile spasms stopped, the spasms resumed. The percentage of his patients who had a breakthrough seizure does not appear in his testimony. However, Dr. Shuman estimated that among the patients who had a breakthrough seizure, he identified the agent that triggered the resumption of seizures in about 90 percent of the cases. Tr. 233-35; see also tr. 505-06.

On the issue of the improvement of his patients with infantile spasms, Dr. Shuman recognized that his statement "is kind of an estimate and estimates tend to be rosy. Maybe I didn't do that well. Maybe it's only 80 percent, but it's in that range." Tr. 49; accord tr. 199 (Dr. Shuman stating "I can only tell you my gut feeling."). With respect to Dr. Shuman's testimony only about his own experience with treating patients with infantile spasms, Dr. Shuman's demeanor suggested some exaggeration. Dr. Shuman appears proud of his accomplishments as a treating doctor and may have overestimated his own success. See Andrew Corp. v. Gabriel Electronics, Inc., 847 F.2d 819, 824 (Fed. Cir. 1988) (finder of fact may consider demeanor of experts when evaluating their testimony). Dr. Shuman recognized that his personal experience does not carry the weight of an epidemiologic study. Tr. 202. Dr. Shuman also acknowledged that his experience in treating patients has not been reviewed by his peers. Tr. 680.

Dr. Kohrman has also treated patients with infantile spasms who show some improvement on one drug, but then worsen. Tr. 257-58, tr. 653. Like Dr. Shuman's numbers, Dr. Kohrman's numbers are a little vague. Dr. Kohrman did not provide any estimate about the number of children who worsened while taking a second drug. However, he did testify that when

he stopped the infantile spasms, some form of seizure returned in 50 percent of the children. He explained that "even seizure control today doesn't necessarily mean I'm going to have seizure control tomorrow. And at any given day those seizures can reoccur." Tr. 660.

3. Expert's Opinions

The initial decision noted that both Dr. Shuman and Dr. Kohrman possess excellent credentials. Loving, No. 02-469V, 2008 WL 4692376, at *4; see also tr. 188-89 (Dr. Shuman describing his training in epilepsy); tr. 238-39 (Dr. Kohrman's experience with epilepsy). Upon review, Judge Lettow noted this finding and appeared to accept it. Loving, 86 Fed. Cl. at 138. Despite the similarity in credentials, Dr. Shuman and Dr. Kohrman do not have the same opinion as to how Camille would have developed if she had not received the third dose of the DTaP vaccine. Dr. Kohrman summarized the issue as "is your cup half-empty or is your cup half-full?" Tr. 547.

a. Dr. Shuman

Dr. Shuman presented an optimistic, if qualified, assessment. He stated that as of March 6, 2001, Camille's condition had improved from January 26, 2001. For her likely outcome, Dr. Shuman said "She was going to become better. I can't tell if she was going to become normal. . . . I'm secure that she was going to become better." Tr. 166. When asked to clarify whether he expected Camille to become normal, Dr. Shuman opined about Camille's abilities:

> The ability to forecast a child's development at seven months of age is very poor. A normal child still has a measurable incidence of school failure, if you look at them at six months of age. And to try to prognosticate. Given a child who's been damaged with infantile spasms, I know that their risk of failing to meet normal is much greater than the normal population. I can only assure you that she was going to be better. I can with reasonable, with reasonable certainty say that she would have been functional. . . . I think it's more probable than not, that she would have been in school in the 80, 85 IQ area. I don't think she'd have been in a wheelchair, I don't think she would have had to be fed, I don't think she would have been dependent upon an aid.

Tr. 167. Dr. Shuman stated that Camille's seizures would have remained controlled if she did not receive a third dose of DTaP. Tr. 168, tr. 184.

On cross-examination, Dr. Shuman stated that before the March 27, 2001 vaccination, Camille "had marked clinical improvement. I don't think it was really possible to call her stable but she was certainly markedly improved, clinically." Tr. 457. Dr. Shuman also testified that "I think it was early in the days of [vigabatrin]. I think the proper expectation was that she would break through those seizures soon, break through the [vigabatrin] control soon." Tr. 466.

Dr. Shuman offered various reasons for expecting Camille to improve. He stated that Camille's rapid response to vigabatrin augured an enduring response. Tr. 168; see also tr. 38; but see exhibit L (Timothy A. Pedley, et al., "Seizures and Epilepsy" Chapter 17 in Current Practice of Clinical Electroencephalography, (3d ed. John S. Ebersole and Timothy A. Pedley, eds.)) at 545. Dr. Shuman also relied on the fact that Camille's parents had refused to allow Camille to be treated with ACTH. If the vigabatrin failed, then Camille's parents could have begun ACTH. Tr. 505.[19] Dr. Shuman also testified that Camille's treatment with Dr. Chugani increased her likelihood for improvement because Dr. Chugani is an excellent doctor. Tr. 298-300.

Dr. Shuman stated that whether the March 6, 2001 EEG showed that Camille suffered from hypsarrhythmia did not affect his opinion about whether Camille would improve. To Dr. Shuman, Camille's clinical improvement and development between January 26, 2001 and March 26, 2001, meant that Camille's EEG would eventually improve as well. Tr. 81; see also tr. 292-293, tr. 515-16 (Dr. Shuman discussing Table 1 in the practice parameter, exhibit 135 at 1670).

b. Dr. Kohrman

Dr. Kohrman's projection differs from to Dr. Shuman's prediction. Dr. Kohrman stated that Camille was not likely to reach normal development. In response to a question about the normal course of infantile spasms, Dr. Kohrman stated that "Infantile spasms is probably one of the most horrible conditions I can tell a parent about in my practice. . . . 90 percent of these children will be developmentally delayed with infantile spasms." Tr. 244; accord tr. 264.[20] To Dr. Kohrman, Camille's poor development after the vaccination is the "result of her infantile spasms[,] not the result of her vaccinations." Tr. 248.

Dr. Kohrman based his prediction on Camille's March 6, 2001 EEG, which showed that she was still having seizures. Tr. 547, tr. 652, tr. 651-52. Dr. Kohrman stated that "None of these kids who have an abnormal EEG pattern go on to have normal development. That is universally known." Tr. 548.

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[19] Dr. Shuman's testimony with regard to Camille taking ACTH after vigabatrin, tr. 505, was not especially persuasive. The testimony was given in response to leading questions from the Lovings' attorney. In addition, this portion of Dr. Shuman's testimony is at least somewhat inconsistent with his earlier testimony in which he stated a "response to one drug doesn't really predict response to another. . . . It didn't mean that because she responded to [vigabatrin], she would definitely have responded to ACTH." Tr. 169-70.

[20] The Lovings' briefs state that Dr. Kohrman stated "50% of children with infantile spasms will be developmentally normal." Pet'r Post-Hearing Br., filed Feb. 1, 2008, at 69, citing tr. 244; Pet'r Post-Hearing Reply, filed June 23, 2008, at 44. This statement is not correct. Dr. Kohrman's stated that "90 percent of these children [who are diagnosed as having infantile spasms] will be developmentally disabled with infantile spasms. That means only 10 percent of them are normal." Tr. 244.

Dr. Kohrman discussed the connection between hypsarrhythmia and seizure activity. According to Dr. Kohrman's understanding of the practice parameter, the resolution of hypsarrhythmia is correlated with stopping the spasms. Tr. 548-49, see also tr. 643-44. The practice parameter, exhibit E, summarizes 18 studies. In 14 studies, the percent of patients whose spasms stopped were within ten percentage points of the percent of patients whose hypsarrhythmia resolved. Exhibit E at 1671. This correlation supports a prediction that Camille was likely to continue having spasms because her hypsarrhythmia was not resolved. Tr. 549-50; tr. 652-53 ("until you see cessation of spasms completely it's unlikely your EEG is going to normalize. And the best predictor of developmental outcome is normalization is [the] EEG."); see also tr. 155 (Dr. Shuman testifying that although the clinical state and the electrical state are "not necessarily congruent. They're inextricably linked with one another.").

Dr. Kohrman emphasized the conclusions of the practice parameter. Tr. 548-52. His interpretation of its conclusion was that doctors "may be able to in some ways modify the short-term outcome with our medications. There's no evidence that we modify the long-term outcome of this disease process with our medications." Tr. 551-52.

In regard to potential medication, Dr. Kohrman doubted the long-term effectiveness of both vigabatrin, which Camille was taking before her third vaccination, and ACTH, which Camille was not taking. Dr. Kohrman stated that vigabatrin has shown some effectiveness in treating infantile spasms only when those spasms are symptomatic of tuberous sclerosis. Tr. 630-31, discussing the practice parameter, exhibit K at 1068; see also tr. 654. Camille was not diagnosed as having tuberous sclerosis.

Dr. Kohrman recognized that Camille had fewer seizures while on vigabatrin. Tr. 626-27. Vigabatrin can reduce the number of seizures steadily. Tr. 652. But, at some point, vigabatrin ceases its effectiveness and/or the side-effects require stopping vigabatrin. For Dr. Kohrman's patients, he will usually prescribe the medication for one month or two months as a trial. If there are signs that the medication is improving the patient's condition, Dr. Kohrman would continue vigabatrin for as long as six months or until the patient evidences some toxic reaction to the vigabatrin. Tr. 654-55. Consequently, Camille would probably have been taken off the vigabatrin by the end of July 2001, because she started taking vigabatrin before being discharged from the Children's Hospital of Michigan. Exhibit 142 at 143. Dr. Shuman did not directly explain how long he would allow a patient to take vigabatrin. Tr. 672-73.

Dr. Kohrman also discounted Camille's improvement in development. Dr. Kohrman stated that development waxes and wanes depending upon the frequency of seizures. Although Camille may have made some progress, seizures - as reflected in the EEG - would have interfered with continued development. Tr. 555-57; see also tr. 652 (Dr. Kohrman stating that "it's unlikely that she's going to be normal given where she is in March [on] her video EEG.").

4. Resolution

The result of comparing the actual Camille to the hypothetical Camille who did not receive the third dose of DTaP depends upon what time the comparison is made. For a period of time immediately after the vaccination, the actual Camille differed (that is, was worse than) the but-for Camille. But, the degree of difference diminishes over time. Eventually, the actual Camille appears to match the but-for Camille.

For a period of time immediately after the third DTaP, the real Camille differed, in some respects, from the hypothetical Camille. The real Camille resumed having cluster seizures after her March 27, 2001 vaccination. These cluster seizures may have caused the Lovings to incur unreimbursed medical expenses for which they may be entitled to compensation. The cluster seizures also caused Camille some emotional distress for which an award of compensation may be appropriate.[21]

The difference between the real Camille and the hypothetical Camille diminishes as more time elapses. Respondent met her burden of establishing that Camille's current condition is predominantly due to the infantile spasms, which began in January 2001, and not due to the resumption of her infantile spasms following her third DTaP vaccination on March 27, 2001. A preponderance of the evidence supports a finding that there is a relatively small difference, if any, between Camille as she actually developed and the hypothetical Camille as she would have developed but for receiving the third dose of the DTaP vaccination.

The following graph presents a visual representation of the concept of a shrinking difference between the actual Camille and the but-for Camille. The functional level of the actual Camille is expressed graphically as the line marked with "X's". (This line happens to start a bit lower than 100% functioning solely to distinguish the line with the X's from the line with the diamonds.) The line with the X's depicts that Camille worsened after the onset of infantile spasms at age five months and then worsened after the vaccination at age eight months. After eight months, Camille's functional level declined slightly.

The graph also presents how Camille would have functioned but-for the third DTaP as the dashed line. The dashed line indicates that even without receiving the DTaP at eight months,

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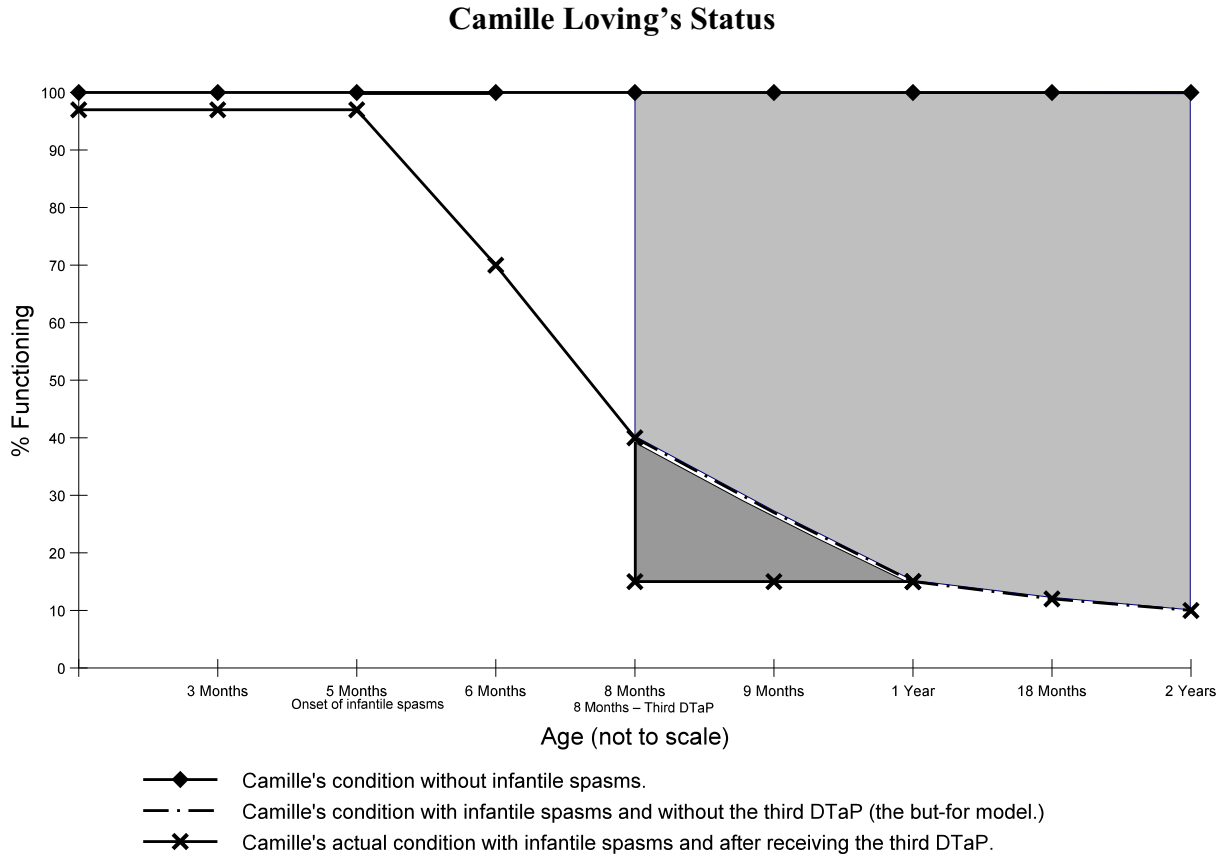
[21] The existing record does not permit a finding that the Lovings are definitely entitled to compensation. To be entitled to compensation, it appears that petitioners must establish that the vaccine "(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention." 42 U.S.C. § 300aa–11(c)(1)(D). The parties have not briefed this issue. Without the benefit of input from the parties, the undersigned is reluctant to decide a legal issue prematurely.

Camille's condition would have worsened. The difference between the actual Camille (the line with the X's) and hypothetical Camille (the dashed line) is depicted by the grey triangle.



However, the graph is limited. For example, Camille's changes are presented as straight lines. The development of Camille (regardless of whether the "Camille" is real or hypothetical) would have slight ups and downs alone a general trend line. Similarly, the line showing Camille's actual condition (the line with the X's) meets the line showing Camille's but-for condition (the dashed line) at approximately one year. This point of intersection is assumed solely for the purpose of presenting the graph. Evidence that will be evaluated in the next phase of the case may establish that the date of intersection is different from what is presented on the graph.

The graph expresses the idea that the infantile spasms, which afflicted Camille before she received the third DTaP, reduced her functioning. For the general proposition that the infantile spasms impaired Camille's development, there is an abundance of evidence. Dr. Shuman, the expert retained by the Lovings, estimated that Camille's IQ would have been approximately 85. Tr. 167.

The parties dispute the degree to which the pre-existing infantile spasms diminished Camille's potential. See Tr. 511-12. The Lovings go so far as to argue that Camille would have

had a better chance to be normal. Pet'r Post-Hearing Reply Br., filed June 23, 2008, at 33-34, citing tr. 321. An examination of all the evidence, including, but not limited to, the experts' reports, their testimony, their demeanor while testifying, and the literature submitted by the parties, supports a finding that the pre-existing infantile spasms significantly diminished Camille's development. The evidence can be broadly divided into two groups: evidence about Camille specifically and evidence about infantile spasms generally.

A preponderance of evidence supports a finding that Camille was not cured of her infantile spasms by the date she received the third dose of DTaP. Camille's March 6, 2001 EEG was not normal. Exhibit 9B. Camille was experiencing seizures between January 30, 2001 and March 27, 2001. She certainly had at least one seizure during the 23-hour EEG. Exhibit 9B. Additional evidence shows that Camille was behaving in a way consistent with having a seizure. Exhibit 29 at 338. (Mrs. Loving's journal entry for March 1). A reasonable inference is that Camille was, in fact, having seizures.[22]

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[22] Special masters may draw plausible inferences from facts. Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1527 (Fed. Cir. 1991).

Special masters find facts at any evidentiary threshhold of a "preponderance of the evidence." Althen, 418 F.3d at 1279-80; Loving, 86 Fed. Cl. at 144 n.13. In simple terms, this level of proof means that a fact is more probable than not. Id. Here, it is more likely than not that Camille experienced clinical seizures between January 30, 2001 and March 26, 2001.

Citing Capizzano, 440 F.3d at 1324-26, and Althen, 418 F.3d at 1280, the Lovings argue that "close calls go to the petitioner." Pet'r Post-Hearing reply Br., filed June 23, 2008, at 17 (capitalization eliminated without notation). It is not clear whether this statement constitutes binding holding or dicta. See Loving, 86 Fed. Cl. at 144 n. 13 (noting that Althen also references the preponderance-of-the-evidence standard).

The Lovings fairly identify some records that could support a finding that Camille was not experiencing clinical seizures. Exhibit 8B at 224, 226; see Pet'r Post-Hearing Br., filed Feb. 1, 2008, at 25-26. The Lovings also point to the absence of a notation in a medical record.

However, these arguments are not persuasive. First, Judge Lettow has already ruled that the absence of a statement in a medical record does not necessarily mean that the event did not happen. Loving, 85 Fed. Cl. at 151-52. Second, the accuracy of the record created by the doctors during Camille's hospitalization for the 23-hour EEG necessarily depends upon the accuracy of observations of the historian. See Michael H. Graham, 2 Handbook of Federal Evidence § 601.1 (6th ed. 2006); cf. Boston Edison Co. v. United States, 64 Fed. 167, 181 (2005) (discussing Rule 602 and Rule 701 of the Federal Rules of Evidence). While there is no doubt that Mrs. Loving, as an attentive and caring mother, would relate her observations as accurately and as honestly as possible, there is reason to believe that she could have either not seen the seizures or not recognized behaviors as seizures. Tr. 28 (Dr. Shuman noting that seizures in the first six months of life are subtle), tr. 546, tr. 614, tr. 619. Third, another contemporaneously created medical record, Mrs. Loving's journal, appears to contradict the statement from the hospitalization. When records created contemporaneously with the events being described are inconsistent, the presumption that such records are accurate, Cucuras v. Sec'y of Health & Human Servs., 993

The March 6, 2001 EEG also provides information about the character of Camille's brain activity. This report indicates that the "background is severely disorganized and consists of very high amplitude pattern of bilateral multi-focal spike and wave activity." Exhibit 9B.

A preponderance of evidence supports a finding that Camille's brain was hypsarrhythmic. The definition of hypsarrhythmia is that it "consists of high voltage slow waves and spikes. The spikes vary from moment to moment, both in duration and location. At times they may appear focal. A few seconds later they originate from multiple foci. Occasionally, they become generalized. It never appears as rhythmically repetitive and a highly organized pattern. The abnormality is almost continuous." Exhibit L at 540; accord tr. 539-41; tr. 157.

Dr. Kohrman opined that Camille's EEG fit this definition of hypsarrhythmia. Tr. 242, tr. 253, tr. 541-42, tr. 535. Dr. Shuman did not disagree. Dr. Shuman stated that qualified pediatric neurologists could disagree whether a particular pattern should be labeled hypsarrhythmic. With that qualification, Dr. Shuman said that he "could very well have called this [Camille's EEG] hypsarrhythmic." Tr. 158. Actually, in his initial report, Dr. Shuman said the pattern was hypsarrhythmic. Tr. 498-99.

The Lovings did not present a persuasive contrary opinion from Dr. Shuman. The Lovings do note that the report from the EEG does not include the term "hypsarrhythmia." Exhibit 9B at 234; tr. 156; Pet'r Post-Hearing Br. at 18-19, Feb. 1, 2008. The Lovings also note that Mrs. Loving's journal indicated that Dr. Chugani told Mrs. Loving that "the hypsarrhythmia is gone." Exhibit 29 at 339; accord tr. 153.

Much like the question of whether Camille suffered clinical seizures, the Lovings have identified some evidence that could support a finding that Camille's EEG was not hypsarrhythmic. But, again, the preponderance of the evidence, supports a finding that the EEG was hypsarrhythmic. Dr. Kohrman's testimony on this point was very strong. Tr. 242, tr. 252. Because Dr. Kohrman testified on the first day of the hearing, November 17, 2006, a strong response from the Lovings and/or Dr. Shuman was expected when the hearing resumed about one year later. Order, filed Nov. 15, 2007. But, this rebuttal was relatively weak. See tr. 497-99.[23]

F.2d 1525, 1528 (Fed. Cir. 1993); cannot resolve which record is more accurate.

In short, some evidence supports a finding that Camille was not experiencing clinical seizures. But, the more persuasive evidence supports a finding that she was having clinical seizures.

[23] Helpful information might have come from Dr. Chugani, Camille's pediatric neurologist. See order, filed Nov. 15, 1997. However, the Lovings did not submit additional information from him. Tr. 283. No inference is drawn from the absence of information from Dr. Chugani.

The absence of the term "hypsarrhythmia" is not dispositive. While a diagnosis from a treating doctor must be considered, any such diagnosis is not binding on the special master. 42 U.S.C. § 300aa–13(b). The report from the EEG is actually ambiguous. It neither states that Camille has hypsarrhythmia nor states that Camille does not have hypsarrhythmia. In this silence, the description of Camille's EEG is more important. Tr. 542.

The wave pattern shows hypsarrhythmia. Tr. 535-37, tr. 541-42. Dr. Shuman recognized this pattern in his initial report. Shuman Report, filed Dec. 23, 2005. This evidence is persuasive enough to constitute a preponderance of evidence that Camille's EEG showed hypsarrhythmia.

These two findings underlie a further finding that Camille's infantile spasms were not controlled on vigabatrin. The testimony of the experts agreed on this point. Although Dr. Shuman emphasized Camille's improvements, he conceded that she was not out of the woods. Tr. 458. Camille required medication to lessen her seizures. Tr. 459. Dr. Kohrman opined that despite Camille's improvements, she was still likely to have profound problems in development. See tr. 663.

The treatment provided by Dr. Chugani reflects his concern, before the third DTaP, with Camille's potential development. In February, Dr. Chugani ordered a PET scan for Camille. See exhibit 29 at 333; tr. 463. (PET scans are described at pages 253-54). Dr. Shuman stated that Dr. Chugani ordered the PET scan to determine whether Camille was a candidate for surgery because Dr. Chugani expected that Camille "would break through those seizures soon, break through the [vigabatrin] control soon." Tr. 465. Dr. Kohrman presented essentially the same interpretation of Dr. Chugani's actions. According to Dr. Kohrman, Dr. Chugani ordered a PET scan because Dr. Chugani "was concerned that she was intractable." Tr. 662. "Intractable" means that the seizures were not controlled completely. Tr. 543.

These features about Camille indicated that she had not defeated the infantile spasms by the date she received the third DTaP. Compared to a "normal" child, one who was not suffering from a disease, Camille was not well on March 26, 2001. However, Camille was relatively "better" in the sense of having fewer seizures on March 26, 2001, when compared with her condition two months earlier.

Camille's relative improvement while on vigabatrin does not mean that she would have attained the condition of a "normal" child. Camille would not have taken vigabatrin for much longer. According to Dr. Shuman, Dr. Chugani expected that Camille would break through the vigabatrin control soon after February 20, 2001. See tr. 466. Alternatively, even if vigabatrin remained relatively effective in reducing Camille's seizures, the doctors would have had to stop prescribing vigabatrin because of the side effects that worsen with continuous use. Tr. 654-55, tr. 672-73.

Camille's condition before the third DTaP fits with what is known about infantile spasms generally. A useful starting point for information about infantile spasms is the practice

parameter. Both experts recognized the authoritativeness of this article. Tr. 31 (Dr. Shuman), tr. 245 and tr. 634-35.

In conjunction with the assessment of long-term outcomes, the authors did not come to any conclusion. Instead, they stated:

> The evidence is conflicting and limited to class III and IV [the two least reliable forms of evidence] that treatment of infantile spasms with agents including ACTH, oral corticosteroids, vigabatrin, valproic acid, and pyridoxine improves the long-term outcome or decreases the later incidence of epilepsy.

Exhibit E at 1679; tr. 495-97 (Dr. Shuman discussing conclusion).

Another text, Pediatric Neurology Principles & Practice, edited by Dr. Swaiman, reaches a similar conclusion. Dr. Baram, who wrote the chapter on infantile spasms, stated that "80% to 90%" of children with infantile spasms become mentally retarded. Exhibit K at 1065.

To the extent that the practice parameter opens the door for some optimistic outlook for children suffering from infantile spasms, it relies upon a study by Lombroso. See exhibit E at 1677, citing, as reference 23, CT Lombroso, A prospective study of infantile spasms: clinical and therapeutic correlations, 24 Epilepsia 135 (1983). This article was not filed into the record. However, the practice parameter classified Lombroso as a "Class III" study, meaning it was ranked third (out of four categories). Exhibit E at 1677 and 1679.

The Swaiman textbook presents additional context for the Lombroso study. Relying upon Lombroso among other articles, Dr. Baram stated that infants with "an apparently normal CNS, as defined by normal development, imaging studies, and etiologic evaluation" are "the infants with potentially excellent outcomes." Exhibit K at 1067.

Camille's imaging study was not normal. It was improved but showed that she was having seizures. Exhibit 9B. This evidence removes Camille from the relatively small percentage of children with infantile spasms who develop normally. Tr. 547-48.

Even if Camille's EEG showed that she did not suffer from hypsarrhythmia, Camille's future remained dark. "There is, unfortunately, little evidence that early resolution of spasms and hypsarrhythmia results in lasting, long-term neurological improvement. It is therefore important to emphasize that normalization of EEG activity is not necessarily correlated with neurologic status and that nearly 90% of patients remain disabled by epilepsy and other neurologic abnormalities, including severe mental retardation." Exhibit L (Pedley,"Seizures and Epilepsy") at 545.

The consensus view of these books is that children with infantile spasms do not develop normally. Judge Lettow recognized this in his earlier determination. Loving, 86 Fed. Cl. at 137 (stating "[i]nfants who suffer from infantile spasms are often developmentally challenged.").

Of course, a few children with infantile spasms attain normal development. The percentage appears to be between 10 and 20 percent. Tr. 638. Thus, there is a chance that Camille could have been one of those children. But, a preponderance of the evidence does not support a finding that she would have developed normally. The evidence about Camille especially her video EEG, supports a finding that the infantile spasms, which began in January 2001, impaired her long-term development. Tr. 652.

Dr. Shuman did not predict that Camille would have become normal. In the hearing on November 17, 2006, Dr. Shuman stated that children with infantile spasms may improve but "may not normalize." Tr. 49. Within his experiences some children with cryptogenic infantile spasms might become normal, but a normal outcome is not guaranteed even when Dr. Shuman has stopped the seizures. Tr. 49-50. When asked directly whether he believed that Camille would become normal, Dr. Shuman testified that "she was going to become better. I can't tell if she was going to become normal." Tr. 166. In the second hearing, Dr. Shuman stated, in passing, that without the third DTaP the outcome for Camille was "possibly normal or near normal." Tr. 305.

The record contains little, if any, persuasive evidence that Camille would have achieved normal status but for the third DTaP. In addition to all the evidence discussed above, Dr. Kohrman testified that Camille would not have been normal. Tr. 244-48, tr. 548-49, tr. 663.

Virtually all the evidence, certainly a preponderance of the evidence, supports a finding that the course of infantile spasms devastates those afflicted with the disease. Camille was not different from the vast majority of people with infantile spasms. Treatment regimens can improve a person's condition, but such improvements are usually temporary. If Camille had not received the third dose of the DTaP vaccine, she probably would have remained in a state of less-frequent seizures past March 27, 2001, but this honeymoon period was almost certainly bound to end. This distinction will need to be addressed when the parties present their cases about Camille's damages.

E. Entitlement to Compensation and Apportionment

The findings made in the previous section will affect the process for determining whether the Lovings are entitled to compensation. This process will probably involve more detailed factual analysis and expert testimony. The briefs of both parties have not captured the subtle distinctions that need to be drawn.

The Lovings appear to assume that by establishing that Camille was worse the day after she received the vaccine than she was the day before she received the vaccine, they are entitled to

compensation. While showing a worsening is one part of their case, it appears that the Lovings must establish additional elements.

For a period of time after the March 27, 2001 vaccination, Camille was worse because she experienced spasms and seizures that she would not have had but for the third DTaP vaccination. The Lovings may be entitled to compensation for this difference if Camille's worsening resulted in "markedly greater disability, pain or illness accompanied by substantial deterioration in health." 42 U.S.C. § 300aa–33(4) (defining "significant aggravation). Further, it appears that the Lovings are also required to establish that Camille's substantial deterioration in health lasted more than six months. 42 U.S.C. § 300aa–11(c)(1)(D); Gruber v. Sec'y of Health & Human Servs., 61 Fed. Cl. 674, 683 (2004); Jordan v. Sec'y of Health & Human Servs., 38 Fed. 148, 151 (1993); Musarra v. Sec'y of Health & Human Servs., No. 99-677V, 2007 WL 5185476, at *9 (Fed. Cl. Spec. Mstr. Oct. 16, 2007).[24]

The evidentiary record on this point is not adequate to resolve whether Camille's worsened condition lasted more than six months. The evidence focused primarily on whether DTaP can cause infantile spasms and Camille's condition from January 2001, when she began experiencing infantile spasms, to April 10, 2001, when Camille saw Dr. Chugani after receiving the third dose of DTaP. The parties did not develop much, if any, evidence on whether Camille's worsened condition lasted more than six months. The post-trial briefs also do not discuss this issue. See Pet'r Post-Appeal Br., filed May 4, 2009, at 24-25 (comparing Camille for two months before DTaP with Camille for two months after DTaP).

It should be noted that the six-month requirement is a prerequisite to an award of any compensation. If a petitioner established that a vaccine caused an injury that lasted only five months, then that petitioner would fail to establish all the elements required for compensation. See 42 U.S.C. § 300aa–11(c)(1) (listing petition content) & 13(a)(1) (authorizing special masters to award compensation when items in section 11(c)(1) are established).

Even if the Lovings establish that they are entitled to some compensation, they are not necessarily entitled to all the harm that Camille has suffered. Here, "harm" is used to mean the damage caused by the infantile spasms and the damage caused by the third DTaP. The Lovings suggest that the harm cannot be apportioned between the two different causes. In essence, the Lovings argued that (a) respondent bears the burden of proving apportionment, (b) respondent has failed to meet this burden, and (c), therefore, the amount of compensation to which they are entitled should not be diminished. See Pet'r Brief, filed May 4, 2009, at 16-17, citing Schumacher v. Sec'y of Health & Human Servs., 26 Ct. Cl. 1033, 1043 (1992); Pet'r Reply, filed June 23, 2008, at 23-24, citing Deribeaux v. Sec'y of Health & Human Servs., No. 05-306V, 2007 WL 4623461, at *34-36 (Fed. Cl. Spec. Mstr. Dec. 17, 2007) and Schumacher; Pet'r Br.,

[24] The parties' briefs do not address the interplay between the six-month rule and significant aggravation. The parties will have an opportunity to present legal arguments in the next phase of the case.

filed Feb. 1, 2008, at 11, citing the same cases. In effect, the Lovings argue that they are entitled to not only the damages represented by the grey triangle in the graph on page 25, but they are also entitled to the damages represented by the hatched area.

These arguments are misplaced in the sense that they concern the quantification of damages. Unlike the way most cases are typically litigated, cases in the Vaccine Program are bifurcated between a determination of entitlement and a determination of damages. Office of Special Masters, Guidelines for Practice under the National Vaccine Injury Compensation Program § XI (Rev. Ed. 2004); Order dated May 16, 2002. Special masters routinely separate the two phases because, in most cases, the analysis requires different evidence. In the entitlement phase, the predominant evidence is the opinion of a medical doctor. In contrast, evidence about quantifying damages usually is presented by life care planners and vocational experts. Further, because information about the quantification of damages is relevant only after a petitioner is determined to be entitled to damages, the parties do not incur the expense of retaining life care planners or vocational experts until they are needed.

Consistent with this practice, the Lovings have not developed their case regarding damages. There is little evidence about the medical treatment Camille requires or the cost of this treatment. The Lovings's approach in waiting to see the outcome of the entitlement phase of the case is sensible.

Although the Lovings have not presented any evidence about damages, they argued that respondent has not met her burden of establishing apportionment. But, the Lovings overlook that the respondent's burden arises only after they have presented their case. See Rio Mar Associates, LP, SE v. UHS of Puerto Rico, Inc., 522 F.3d 159, 167 (1st Cir. 2008) (holding that after trial court bifurcated claim and cross-claim, defendant / cross-claiming plaintiff was entitled to a second hearing to apportion damages). It would be difficult for respondent to argue that damages should be apportioned when the Lovings have not proposed what the "damages" are.

Respondent presents an argument that is like the flip side of the coin offered by the Lovings. Respondent suggests that because Camille's outcome appears to be unaffected by the third dose of the DTaP in the sense that the infantile spasms already portended a bleak outcome before Camille was vaccinated on March 27, 2001, the Lovings are not entitled to any compensation. See Resp't Post-Hearing Br., filed May 20, 2008, at 32 n.10 (stating "even if the court accepts that the vaccination triggered the reoccurrence of Camille's spasms, petitioner cannot show that the vaccination was a substantial factor in bringing about her severe developmental delay."); Resp't Resp., filed April 17, 2009, at 2 (stating "petitioners' claim fails because petitioners cannot demonstrate that the DTaP vaccine Camille received on March 27, 2001, changed her pre-existing infantile spasms for the worse or resulted in a markedly different disability.").

By focusing on the current outcome, respondent overlooks the time between the March 27, 2001 vaccination and the present. For some time – the amount of which has not been

determined, Camille was worse due to the vaccination. As explained above, if this period of time exceeds six months, then the Lovings are entitled to some compensation.

In a significant aggravation case, such as Camille's case, the distinction between determining whether a vaccine caused a worsening of the underlying condition and determining the extent to which the person is worse due to a natural progression of the underlying disorder is oblique. Both parties will have an opportunity to present evidence related to this point in the next phase of the case. For example, the Lovings may show that Camille requires an aide to come to her house for three hours per day. Respondent might counter that Camille's pre-existing infantile spasms would have required two hours of assistance, and, thus, the vaccination is responsible for only one hour per day. Another example is lost wages. The Lovings may claim that the current Camille cannot be employed. But, respondent could argue that Camille's could not have earned income after the infantile spasms began in January 2001. These examples are purely hypothetical, but they are intended to illustrate that determinations about apportionment should be made based upon concrete issues. The parties' contrary approach – in which apportionment is either "all or nothing" – is rejected.[25]

Distinguishing how the pre-existing infantile spasms affected Camille from the effects of the third DTaP comports with the general law regarding apportionment. See Restatement (Second) of Torts § 433A.[26] When Congress did not give specific guidance to special masters, special masters may look to general law. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999) (citing the Restatement (Second) of Torts); cf. Commonwealth Edison Co. v. United States, 271 F.3d 1327, 1356-57 (Fed. Cir. 2001) (en banc) (citing Restatement (Second) of Torts § 433A).

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[25] The parties are also expected not to follow the model of tenacious litigation described in Spence v. Sec'y of Health & Human Servs., No. 95-57V, 2001 WL 99893 (Fed. Cl. Spec. Mstr. Jan. 3, 2001).

[26] After Congress enacted the National Childhood Vaccine Injury Act, Pub. L. No. 99-660, tit. III, 100 Stat. 3755; the American Law Institute issued the Restatement (Third) of Torts: Apportionment of Liability (2000). Section 26 of that volume updates § 433A of the Second Restatement.

With regard to apportionment, whether section 433A of the Second Restatement differs from section 26 of the Third Restatement is not clear. If there is a difference between the two editions, the Second Restatement appears controlling. See Burlington Northern and Santa Fe Ry Co. v. United States, __ U.S. __, 129 S.Ct. 1870, 1881 (2009) (citing section 433A); In re Kelvin Manbodh Asbestos Litigation Series, No. 324/1997, 2006 WL 1084317 (D.V.I. 2006) (discussing contribution and indemnification under the first, second and third restatements); Whirlpool Corp. V. CIT Group/ Business Credit, Inc., 293 F. Supp. 2d 1144, 1149 (D. Ha. 2003) ("[a]bsent a statute, most jurisdictions continue to look to the Second Restatement for guidance.").

Section 433A of the Restatement (Second) of Torts offers the general rule. It provides:

> (1) Damages for harm are to be apportioned among two or more causes where
>
> (a) there are distinct harms, or
>
> (b) there is a reasonable basis for determining the contribution of each cause to a single harm.
>
> (2) Damages for any other harm cannot be apportioned among two or more causes.

Restatement (Second) of Torts § 433A (1965). Comment a to that section states, in relevant part, that "The rules stated in this Section apply whenever two or more causes have combined to bring about harm to the plaintiff, and each has been a substantial factor in producing the harm, as stated in §§ 431 and 433. . . . The rules stated apply also where one or more of the contributing causes is an innocent one, as . . . with a pre-existing condition which the defendant has not caused, to bring about the harm to the plaintiff." (emphasis added).

Here, a preponderance of the evidence indicates that Camille suffered two harms. In January 2001, Camille started to experience infantile spasms. The infantile spasms meant that, it was more probable than not that, Camille's development was impaired. On March 27, 2001, Camille received the third DTaP. This vaccine worsened Camille's condition temporarily.

When Camille's problems stopped being caused predominantly by her reaction to the third DTaP and when Camille's problems started being caused predominantly by the pre-existing infantile spasms may be difficult to determine with precision. However, exactness is not required. See Indiana Michigan Power Co. v. United States, 422 F.3d 1369, 1373 (Fed. Cir. 2005); see also John G. Danielson, Inc. v. Winchester-Conant Properties, Inc., 322 F.3d 26, 49 (1st Cir. 2003) (stating that the trial court's jury "instructions required mathematical exactness and complete separability to allow apportionment, but the law imposes no such requirements."); Systems Fuels, Inc. v. United States, 79 Fed. Cl. 37, 71 (2007) (stating "any 'benefits' the government seeks to offset must be shown to a reasonable certainty.").

The extent to which Camille's situation worsened after the third DTaP has not been developed. The Lovings have not presented any evidence quantifying Camille's damages. The respondent has not argued that an item of requested compensation should be apportioned to the pre-existing infantile spasms. Both parties will have an opportunity to present evidence in the next phase of the case. Consequently, because the evidence has not been completed, this ruling expresses certain findings using tentative language, such as the "Lovings may be entitled to compensation." Any statements relating to the extent of compensation are subject to revision after the introduction of additional evidence in the next phase of the case.

Evaluating apportionment in the damages phase of the case also complies with a stipulation offered by respondent on the first day of trial. The attorney representing respondent on the first day of the hearing, who is not respondent's current counsel, stipulated that "whatever

is responsible for [Camille's] seizure activity is also responsible for her delayed development." Tr. 137-38. A preponderance of the evidence supports a finding that respondent has met her burden of establishing that the pre-existing infantile spasms caused the problems in Camille's development. But, if the Lovings truncated their case or shortened their presentation of evidence due to their understanding of respondent's stipulation, the Lovings will be afforded a reasonable opportunity to present evidence during the next phase.

IV. Conclusion

Judge Lettow found that the Lovings met the fourth, fifth and sixth elements of the six-part test to determine whether petitioners prevail upon a theory that a vaccine significantly aggravated an underlying condition. Moreover, the Lovings have also established that Camille's condition was worse after receiving the third dose of DTaP. On the other hand, respondent has established that, at least in some respects, Camille's current status does not differ from the condition in which she would have been but for the third dose of DTaP.

The parties will be given an opportunity to develop evidence to distinguish problems that the DTaP caused from problems that Camille would have experienced due to her pre-existing infantile spasms. When this process concludes, another decision will issue.

A status conference will be held on **Wednesday, August 26, 2009 at 2:00 P.M.** to discuss this ruling. Finally, the Clerk's Office is instructed to deliver a copy of this ruling to Judge Lettow. See Vaccine Rule 28A.

IT IS SO ORDERED.

s/ Christian J. Moran
Christian J. Moran
Special Master